

Summary of Investigation Results

Dexamethasone preparations (oral dosage form and injections) and betamethasone preparations (oral dosage form, injections, suppositories and enemas)

May 13, 2022

Non-proprietary name

- a. Dexamethasone (oral dosage form) (preparations indicated for pituitary suppression tests)
- b. Dexamethasone (oral dosage form) (preparations not indicated for pituitary suppression tests)
- c. Dexamethasone sodium phosphate (injections)
- d. Dexamethasone palmitate
- e. Betamethasone (oral dosage form)
- f. Betamethasone (suppositories)
- g. Betamethasone sodium phosphate (injections)
- h. Betamethasone sodium phosphate (enemas)
- i. Betamethasone acetate/betamethasone sodium phosphate
- j. Betamethasone/d-chlorpheniramine maleate

Brand name (Marketing authorization holder)

- a. Decadron Tablets 0.5 mg, 4 mg, Decadron Elixir 0.01% (Nichi-Iko Pharmaceutical Co., Ltd.), and the others
- b. LenaDex Tablets 2 mg, 4 mg (Bristol-Myers Squibb K.K.)
- c. Decadron Phosphate Injection 1.65 mg, 3.3 mg, 6.6 mg (Sandoz Pharma K.K.), and the others
- d. Limethason Intravenous Injection 2.5 mg (Mitsubishi Tanabe Pharma Corporation)
- e. Rinderon Tablets 0.5 mg, Rinderon Powder 0.1%, Rinderon Syrup 0.01% (Shionogi Pharma Co., Ltd.), and the others
- f. Rinderon Suppositories 0.5 mg, 1.0 mg (Shionogi Pharma Co., Ltd.)

- g. Rinderon Injection 2 mg (0.4%), 4 mg (0.4%), 20 mg (0.4%), 20 mg (2%), 100 mg (2%) (Shionogi Pharma Co., Ltd.), and the others
- h. Steronema Enema 3 mg, 1.5 mg (Nichi-Iko Pharmaceutical Co., Ltd.)
- i. Rinderon Suspension (Shionogi Pharma Co., Ltd.)
- j. Celestamine Combination Tablets, Celestamine Combination Syrup (TAKATA Pharmaceutical Co., Ltd.), and the others

Indications

See Attachment

Summary of revisions

1. A statement should be added to the PRECAUTIONS CONCERNING INDICATIONS section or the Precautions concerning Indications section that the presence or absence of concurrent pheochromocytoma or paraganglioma should be confirmed before conducting pituitary suppression tests and that treatment of pheochromocytoma or paraganglioma should be prioritized if such complications are present. (a. and e.)
2. A statement should be added to the IMPORTANT PRECAUTIONS section that appropriate measures should be taken with consideration given to the possible occurrence of pheochromocytoma crisis if a marked elevation in blood pressure, etc. are observed following administration of this drug. (common to a. –j.)
3. “Patients with pheochromocytoma or paraganglioma and those with suspected pheochromocytoma or paraganglioma” should be added in the PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS section or the Careful Administration section. (common to a. –j.)

Investigation results and background of the revision

Cases of pheochromocytoma crisis for dexamethasone (oral dosage form and injections) or betamethasone (injections) reported in Japan and overseas were evaluated, and several cases for which a causal relationship between the drug and event was reasonably possible were identified in Japan and overseas. As a result of consultation with expert advisors, MHLW/PMDA concluded that revision of the IMPORTANT PRECAUTIONS section and the PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS or Careful Administration section in the package inserts of these drugs was necessary. Regarding betamethasone (oral dosage form, suppositories, enemas), although no cases of pheochromocytoma crisis have been observed following administration of these drugs, as a

result of consultation with expert advisors, MHLW/PMDA concluded that revision to the same content as the package insert of betamethasone (injections) was also necessary. In addition, as a result of consultation with expert advisors, MHLW/PMDA concluded that a cautionary statement concerning pituitary suppression tests should be added to the PRECAUTIONS CONCERNING INDICATIONS section or the Precautions concerning Indications section for the preparations indicated for pituitary suppression tests, among dexamethasone preparations and betamethasone preparations.

Number of cases involving pheochromocytoma crisis during the previous 3 fiscal years among the evaluated cases is as follows:

a.

- 1 case has been reported in Japan to date. (A causal relationship between the drug and event could not be established for this case.)

No patient mortalities have been reported to date.

- 1 case has been reported overseas to date. (A causal relationship between the drug and event could not be established for this case.)

No patient mortalities have been reported to date.

g.

- 1 case has been reported in Japan to date. (A causal relationship between the drug and event was reasonably possible for this case.)

No patient mortalities have been reported to date.

- 1 case has been reported overseas to date. (A causal relationship between the drug and event was reasonably possible for this case.)

No patient mortalities have been reported to date.

b. –f., h. –j.

- No cases have been reported in Japan and overseas to date.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

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Attachment

No.	Non-proprietary name	Brand name	Indications
a.	Dexamethasone (oral dosage form) (preparations indicated for pituitary suppression tests)	Decadron Tablets 0.5 mg, 4 mg	<ul style="list-style-type: none"> • Chronic adrenocortical insufficiency (primary, secondary, pituitary, iatrogenic), acute adrenocortical insufficiency (adrenal crisis), adrenogenital syndrome, subacute thyroiditis, thyrotoxicosis [thyroid (toxic) crisis], malignant exophthalmos accompanied by thyroid disease, isolated ACTH deficiency, pituitary suppression tests • Rheumatoid arthritis, juvenile rheumatoid arthritis (including Still's disease), rheumatic fever (including rheumatic carditis), polymyalgia rheumatica • Lupus erythematosus (systemic and chronic discoid), systemic vasculitis (including Takayasu's arteritis, polyarteritis nodosa, microscopic polyangiitis, granulomatosis with polyangiitis), polymyositis (dermatomyositis), scleroderma • Nephrosis and nephrotic syndrome • Congestive cardiac failure • Bronchial asthma, asthmatic bronchitis (including pediatric asthmatic bronchitis), allergy/poisoning caused by drugs and other chemical substances (including drug eruption, toxicoderma), serum sickness • Severe infection (in combination with chemotherapy) • Haemolytic anaemia (immunological or suspected immunological mechanism), leukaemia (acute leukaemia, blast phase chronic myelogenous leukaemia, chronic lymphocytic leukaemia) (including leukaemia cutis), granulocytopenia (essential, secondary), peliosis

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			<p>(thrombocytopenic and non-thrombocytopenic), aplastic anaemia</p> <ul style="list-style-type: none"> • Regional enteritis, ulcerative colitis • Improvement of the general condition of severely debilitating illness (including end stage cancer, sprue) • Fulminant hepatitis (including those cases considered clinically severe), cholestasis-type acute hepatitis, chronic hepatitis (active type, acute flare type, cholestasis type) (limited to refractory chronic hepatitis with persistent and markedly abnormal liver function that does not respond to conventional treatment), hepatic cirrhosis (active type, accompanied by refractory ascites, accompanied by cholestasis) • Sarcoidosis (excluding cases with bilateral hilar lymphadenopathy only), diffuse interstitial pneumonia (pulmonary fibrosis) (including radiation pneumonitis) • Pulmonary tuberculosis (limited to miliary tuberculosis, severe tuberculosis) (in combination with anti-tuberculosis drugs), tuberculous meningitis (in combination with anti-tuberculosis drugs), tuberculous pleurisy (in combination with anti-tuberculosis drugs), peritoneal tuberculosis (in combination with anti-tuberculosis drugs), tuberculous pericarditis (in combination with anti-tuberculosis drugs) • Encephalomyelitis (including encephalitis, myelitis) (In the case of primary encephalitis, it should be used for a short period when symptoms of increased intracranial pressure are observed and patients do not sufficiently respond to other treatments.), peripheral neuritis (including Guillain-Barré syndrome), myotonia, myasthenia gravis, multiple sclerosis (including neuromyelitis optica), Sydenham's chorea, facial palsy, spinal arachnoiditis
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			<ul style="list-style-type: none"> • Malignant lymphoma (lymphosarcoma, reticulosarcoma, Hodgkin's disease, cutaneous reticulosis, mycosis fungoides) and similar diseases (closely related diseases), eosinophilic granuloma, recurrent metastatic breast cancer • Digestive symptoms (nausea/vomiting) associated with administration of antineoplastic drugs (cisplatin, etc.) • Idiopathic hypoglycaemia • Fever of unknown origin • Adrenalectomy, organ/tissue transplantation, pulmonary oedema after invasion, surgical invasion for patients with adrenal cortical insufficiency • Snake/insect venom (including severe insect bite and sting) • Ankylosing spondylitis (rheumatoid spondylitis) • Prevention of adhesion after salpingoplasty • Prostate cancer (when other treatments are ineffective), penile induration • Eczema/dermatitis group[†] (acute eczema, subacute eczema, chronic eczema, contact dermatitis, nummular eczema, autosensitization dermatitis, atopic dermatitis, infancy and childhood eczema, lichen simplex chronicus Vidal, other neurodermatitises, seborrhoeic dermatitis, keratoderma tylodes palmaris progressiva, other hand dermatitises, genital or anal eczema, eczema/dermatitis of auricle and ear canal, eczema/dermatitis around nasal vestibule and alar, etc.) (not recommended in non-severe cases unless absolutely necessary), prurigo group[†] (including strophulus infantum, urticaria-like lichen, urticaria perstans (limited to severe cases and local injection is preferable for urticaria perstans), urticaria (excluding chronic cases)
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			<p>(limited to severe cases), psoriasis and similar symptoms[†] [psoriasis vulgaris (severe cases), psoriatic arthritis, erythrodermic psoriasis, pustular psoriasis, acrodermatitis continua, impetigo herpetiformis, Reiter's syndrome], palmoplantar pustulosis[†] (limited to severe cases), lichen planus[†] (limited to severe cases), scleredema adultorum, erythema (erythema exudativum multiforme[†], erythema nodosum) (limited to severe cases in case of erythema exudativum multiforme), IgA vasculitis (limited to severe cases), Weber-Christian disease, oculomucocutaneous syndrome [ectodermosis erosiva pluriorificialis, Stevens-Johnson syndrome, cutaneous stomatitis, Fuchs' syndrome, Behcet's disease (in the absence of ocular symptoms), Lipschutz' acute vulva ulcer], Raynaud's disease, alopecia areata[†] (limited to malignant type), pemphigus group (pemphigus vulgaris, pemphigus foliaceus, Senear-Usher syndrome, pemphigus vegetans), Dühring dermatitis herpetiformis (including pemphigoid, herpes gestationis), congenital epidermolysis bullosa, herpes zoster (limited to severe cases), erythroderma[†] (including Hebra pityriasis rubra), lupus miliaris disseminatus faciei (limited to severe cases), allergic vasculitis and similar symptoms (including pityriasis lichenoides et variiformis acuta), ulcerative chronic pyoderma, sclerema neonatorum</p> <ul style="list-style-type: none"> • Symptomatic treatment of inflammatory diseases of the inner eye/optic nerve/orbit/ocular muscles (uveitis, chorioretinitis, retinal vasculitis, optic neuritis, orbital pseudotumour, orbital apex syndrome, ophthalmoplegia), cases where ophthalmic administration using eye drops is inappropriate or ineffective for symptomatic treatment of inflammatory diseases of the external and anterior segment of the eye (blepharitis, conjunctivitis, keratitis, scleritis, iridocyclitis), post-operative inflammation of ophthalmologic field
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		<ul style="list-style-type: none"> • Acute/chronic otitis media, serous otitis media/eustachian tube stenosis, Meniere's disease and Meniere's syndrome, acute sensorineural hearing loss, vasomotor (nervous) rhinitis, allergic rhinitis, pollinosis (hay fever), progressive gangrenous rhinitis, laryngitis/laryngeal oedema, post-therapy of otorhinolaryngological field surgery • Refractory stomatitis and glossitis (cases that cannot be cured with local therapy) • Dysosmia, acute/chronic (repetitive) sialoadenitis • Systemic AL amyloidosis <p>†: It should be used only when topical drugs are ineffective or when it is assumed that effectiveness cannot be expected.</p>
	Decadron Elixir 0.01%	<ul style="list-style-type: none"> • Chronic adrenocortical insufficiency (primary, secondary, pituitary, iatrogenic), acute adrenocortical insufficiency (adrenal crisis), adrenogenital syndrome, subacute thyroiditis, thyrotoxicosis [thyroid (toxic) crisis], malignant exophthalmos accompanied by thyroid disease, isolated ACTH deficiency, pituitary suppression tests • Rheumatoid arthritis, juvenile rheumatoid arthritis (including Still's disease), rheumatic fever (including rheumatic carditis), polymyalgia rheumatica • Lupus erythematosus (systemic and chronic discoid), systemic vasculitis (including Takayasu's arteritis, polyarteritis nodosa, microscopic polyangiitis, granulomatosis with polyangiitis), polymyositis (dermatomyositis), scleroderma • Nephrosis and nephrotic syndrome • Congestive cardiac failure • Bronchial asthma, asthmatic bronchitis (including pediatric asthmatic bronchitis),

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			<p>allergy/poisoning caused by drugs and other chemical substances (including drug eruption, toxicoderma), serum sickness</p> <ul style="list-style-type: none"> • Severe infection (in combination with chemotherapy) • Haemolytic anaemia (immunological or suspected immunological mechanism), leukaemia (acute leukaemia, blast phase chronic myelogenous leukaemia, chronic lymphocytic leukaemia) (including leukaemia cutis), granulocytopenia (essential, secondary), peliosis (thrombocytopenic and non-thrombocytopenic), aplastic anaemia • Regional enteritis, ulcerative colitis • Improvement of the general condition of severely debilitating illness (including end stage cancer, sprue) • Fulminant hepatitis (including those cases considered clinically severe), cholestasis-type acute hepatitis, chronic hepatitis (active type, acute flare type, cholestasis type) (limited to refractory chronic hepatitis with persistent and markedly abnormal liver function that does not respond to conventional treatment), hepatic cirrhosis (active type, accompanied by refractory ascites, accompanied by cholestasis) • Sarcoidosis (excluding cases with bilateral hilar lymphadenopathy only), diffuse interstitial pneumonia (pulmonary fibrosis) (including radiation pneumonitis) • Pulmonary tuberculosis (limited to miliary tuberculosis, severe tuberculosis) (in combination with anti-tuberculosis drugs), tuberculous meningitis (in combination with anti-tuberculosis drugs), tuberculous pleurisy (in combination with anti-tuberculosis drugs), peritoneal tuberculosis (in combination with anti-tuberculosis drugs), tuberculous pericarditis (in
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			<p>combination with anti-tuberculosis drugs)</p> <ul style="list-style-type: none"> • Encephalomyelitis (including encephalitis, myelitis) (In the case of primary encephalitis, it should be used for a short period when symptoms of increased intracranial pressure are observed and patients do not sufficiently respond to other treatments.), peripheral neuritis (including Guillain-Barré syndrome), myotonia, myasthenia gravis, multiple sclerosis (including neuromyelitis optica), Sydenham's chorea, facial palsy, spinal arachnoiditis • Malignant lymphoma (lymphosarcoma, reticulosarcoma, Hodgkin's disease, cutaneous reticulosis, mycosis fungoides) and similar diseases (closely related diseases), eosinophilic granuloma, recurrent metastatic breast cancer • Idiopathic hypoglycaemia • Fever of unknown origin • Adrenalectomy, organ/tissue transplantation, pulmonary oedema after invasion, surgical invasion for patients with adrenal cortical insufficiency • Snake/insect venom (including severe insect bite and sting) • Ankylosing spondylitis (rheumatoid spondylitis) • Prevention of adhesion after salpingoplasty • Prostate cancer (when other treatments are ineffective), penile induration • Eczema/dermatitis group[†] (acute eczema, subacute eczema, chronic eczema, contact dermatitis, nummular eczema, autosensitization dermatitis, atopic dermatitis, infancy and childhood eczema, lichen simplex chronicus Vidal, other neurodermatitises, seborrhoeic dermatitis, keratoderma tylodes palmaris progressiva, other hand dermatitises, genital or anal
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			<p>eczema, eczema/dermatitis of auricle and ear canal, eczema/dermatitis around nasal vestibule and alar, etc.) (not recommended in non-severe cases unless absolutely necessary), prurigo group[†] (including strophulus infantum, urticaria-like lichen, urticaria perstans (limited to severe cases and local injection is preferable for urticaria perstans), urticaria (excluding chronic case) (limited to severe cases), psoriasis and similar symptoms[†] [psoriasis vulgaris (severe cases), psoriatic arthritis, erythrodermic psoriasis, pustular psoriasis, acrodermatitis continua, impetigo herpetiformis, Reiter's syndrome], palmoplantar pustulosis[†] (limited to severe cases), lichen planus[†] (limited to severe cases), scleredema adultorum, erythema (erythema exudativum multiforme[†], erythema nodosum) (limited to severe cases in case of erythema exudativum multiforme), IgA vasculitis (limited to severe cases), Weber-Christian disease, oculomucocutaneous syndrome [ectodermosis erosiva pluriorificialis, Stevens-Johnson syndrome, cutaneous stomatitis, Fuchs' syndrome, Behcet's disease (in the absence of ocular symptoms), Lipschutz' acute vulva ulcer], Raynaud's disease, alopecia areata[†] (limited to malignant type), pemphigus group (pemphigus vulgaris, pemphigus foliaceus, Senear-Usher syndrome, pemphigus vegetans), Duhring dermatitis herpetiformis (including pemphigoid, herpes gestationis), congenital epidermolysis bullosa, herpes zoster (limited to severe cases), erythroderma[†] (including Hebra pityriasis rubra), lupus miliaris disseminatus faciei (limited to severe cases), allergic vasculitis and similar symptoms (including pityriasis lichenoides et varioriformis acuta), ulcerative chronic pyoderma, sclerema neonatorum</p> <ul style="list-style-type: none"> • Symptomatic treatment of inflammatory diseases of the inner eye/optic nerve/orbit/ocular muscles (uveitis, chorioretinitis, retinal vasculitis, optic neuritis, orbital pseudotumour, orbital
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			<p>apex syndrome, ophthalmoplegia), cases where ophthalmic administration using eye drops is inappropriate or ineffective for symptomatic treatment of inflammatory diseases of the external and anterior segment of the eye (blepharitis, conjunctivitis, keratitis, scleritis, iridocyclitis), post-operative inflammation of ophthalmologic field</p> <ul style="list-style-type: none"> • Acute/chronic otitis media, serous otitis media/eustachian tube stenosis, Meniere's disease and Meniere's syndrome, acute sensorineural hearing loss, vasomotor (nervous) rhinitis, allergic rhinitis, pollinosis (hay fever), progressive gangrenous rhinitis, laryngitis/laryngeal oedema, post-therapy of otorhinolaryngological field surgery • Refractory stomatitis and glossitis (cases that cannot be cured with local therapy) • Dysosmia, acute/chronic (repetitive) sialoadenitis <p>†: It should be used only when topical drugs are ineffective or when it is assumed that effectiveness cannot be expected.</p>
b.	Dexamethasone (oral dosage form) (preparations not indicated for pituitary suppression tests)	LenaDex Tablets 2 mg, 4 mg	Multiple myeloma
c.	Dexamethasone sodium phosphate (injections)	Decadron Phosphate Injection 1.65 mg, 3.3 mg, and 6.6	<ul style="list-style-type: none"> • Endocrine disease <p>Chronic adrenocortical insufficiency (primary, secondary, pituitary, iatrogenic) [intramuscular injection]</p> <p>Acute adrenocortical insufficiency (adrenal crisis) [intravenous injection, intravenous infusion,</p>

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		mg	<p>intramuscular injection]</p> <p>Adrenogenital syndrome [intramuscular injection*]</p> <p>Subacute thyroiditis [intramuscular injection*]</p> <p>Thyrotoxicosis [thyroid (toxic) crisis] [intravenous injection, intravenous infusion, intramuscular injection*]</p> <p>Malignant exophthalmos accompanied by thyroid disease [intramuscular injection*]</p> <p>Idiopathic hypoglycaemia [intravenous injection, intravenous infusion, intramuscular injection*]</p> <ul style="list-style-type: none"> • Rheumatic diseases, fibrositis, and arthritis <p>Rheumatoid arthritis [intramuscular injection, intraarticular injection]</p> <p>Juvenile rheumatoid arthritis (including Still's disease) [intramuscular injection, intraarticular injection]</p> <p>Rheumatic fever (including rheumatic carditis) [intravenous injection*, intravenous infusion*, intramuscular injection]</p> <p>Polymyalgia rheumatica [intramuscular injection]</p> <p>Ankylosing spondylitis (rheumatoid spondylitis) [intramuscular injection]</p> <p>Limb arthritis accompanied by ankylosing spondylitis (rheumatoid spondylitis) [intraarticular injection]</p> <p>Periarthritis (limited to non-infectious) [injection into soft tissues, injection into tendon sheaths, injection into synovial sac]</p> <p>Tendonitis (limited to non-infectious) [injection into soft tissues, injection into tendon sheaths]</p> <p>Tenosynovitis (limited to non-infectious) [injection into tendon sheaths]</p>
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			<p>Peritendinitis (limited to non-infectious) [injection into soft tissues, injection into tendon sheaths, injection into synovial sac]</p> <p>Bursitis (limited to non-infectious) [injection into synovial sac]</p> <p>Osteoarthritis (if symptoms of inflammation are clearly noted) [intraarticular injection]</p> <p>Non-infectious chronic arthritis [intraarticular injection]</p> <p>Gouty arthritis [intraarticular injection]</p> <ul style="list-style-type: none"> • Collagen disease <p>Lupus erythematosus (systemic and chronic discoid) [intravenous injection*, intravenous infusion*, intramuscular injection]</p> <p>Systemic vasculitis (including aortitis syndrome, periarteritis nodosa, polyarteritis, and Wegener's granulomatosis) [intravenous injection*, intravenous infusion*, intramuscular injection]</p> <p>Polymyositis (dermatomyositis) [intravenous injection*, intravenous infusion*, intramuscular injection]</p> <p>Scleroderma [intramuscular injection*]</p> <ul style="list-style-type: none"> • Renal disease <p>Nephrosis and nephrotic syndrome [intravenous injection*, intravenous infusion*, intramuscular injection*]</p> <ul style="list-style-type: none"> • Heart disease <p>Congestive cardiac failure [intravenous injection*, intravenous infusion*, intramuscular injection*]</p>
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			<ul style="list-style-type: none"> • Allergic disease Bronchial asthma [intravenous injection, intravenous infusion, intramuscular injection (to be used only when routes of administration other than intramuscular injection are inappropriate), nebulizer] Asthmatic bronchitis (including pediatric asthmatic bronchitis) [intramuscular injection*, nebulizer] Status asthmaticus [intravenous injection, intravenous infusion] Allergy/poisoning caused by drugs and other chemical substances (including drug eruption, toxicoderma) [intravenous injection*, intravenous infusion*, intramuscular injection*] Serum sickness [intravenous injection, intravenous infusion, intramuscular injection*] Anaphylactic shock [intravenous injection, intravenous infusion] • Haematological disorder Peliosis (thrombocytopenic and non-thrombocytopenic) [intravenous injection, intravenous infusion, intramuscular injection*] Haemolytic anaemia (immunological or suspected immunological mechanism) [intravenous injection, intravenous infusion, intramuscular injection*] Leukaemia (acute leukaemia, blast phase chronic myelogenous leukaemia, chronic lymphocytic leukaemia) (including leukaemia cutis) [intravenous injection, intravenous infusion, intramuscular injection*] Meningeal leukaemia among the above mentioned diseases [intrathecal injection] Aplastic anaemia [intravenous injection, intravenous infusion, intramuscular injection*]
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			<p>Haemorrhagic diatheses due to coagulation factor disorder [intravenous injection, intravenous infusion, intramuscular injection*]</p> <p>Granulocytopenia (essential, secondary) [intravenous injection, intravenous infusion, intramuscular injection*]</p> <ul style="list-style-type: none"> • Digestive disease <p>Ulcerative colitis [intravenous injection*, intravenous infusion*, intramuscular injection*]</p> <p>Regional enteritis [intravenous injection*, intravenous infusion*, intramuscular injection*]</p> <p>Improvement of the general condition of severely debilitating illness (including end stage cancer, sprue) [intravenous injection*, intravenous infusion*, intramuscular injection*]</p> <ul style="list-style-type: none"> • Hepatic disease <p>Fulminant hepatitis (including those cases considered clinically severe) [intravenous injection*, intravenous infusion*, intramuscular injection*]</p> <p>Hepatic cirrhosis (active type, accompanied by refractory ascites, accompanied by cholestasis) [intramuscular injection*]</p> <ul style="list-style-type: none"> • Lung disease <p>Diffuse interstitial pneumonia (pulmonary fibrosis) (including radiation pneumonitis) [intravenous injection*, intravenous infusion, nebulizer]</p> <ul style="list-style-type: none"> • Severe infection <p>Severe infection (in combination with chemotherapy) [intravenous injection, intravenous infusion, intramuscular injection*]</p> <ul style="list-style-type: none"> • Tuberculous disease
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			<p>Tuberculous meningitis (in combination with anti-tuberculosis drugs) [intrathecal injection]</p> <p>Tuberculous pleurisy (in combination with anti-tuberculosis drugs) [intrathoracic injection]</p> <ul style="list-style-type: none"> • Neurological disease <p>Encephalomyelitis (including encephalitis, myelitis) (In the case of primary encephalitis, it should be used for a short period when symptoms of increased intracranial pressure are observed and patients do not sufficiently respond to other treatments.) [intravenous injection, intravenous infusion, intramuscular injection*, intrathecal injection]</p> <p>Peripheral neuritis (including Guillain-Barré syndrome) [intravenous injection*, intravenous infusion*, intramuscular injection*, intrathecal injection]</p> <p>Myasthenia gravis [intravenous injection, intravenous infusion, intramuscular injection*, intrathecal injection]</p> <p>Multiple sclerosis (including neuromyelitis optica) [intravenous injection, intravenous infusion, intramuscular injection*, intrathecal injection]</p> <p>Sydenham's chorea [intramuscular injection*]</p> <p>Facial palsy [intramuscular injection*]</p> <p>Spinal arachnoiditis [intramuscular injection*]</p> <ul style="list-style-type: none"> • Malignant tumors, malignant lymphoma (lymphosarcoma, reticulosarcoma, Hodgkin's disease, cutaneous reticulosis, mycosis fungoides) and similar diseases (closely related diseases) [intravenous injection, intravenous infusion, intramuscular injection*, intrathecal injection] <p>Eosinophilic granuloma [intravenous injection, intravenous infusion, intramuscular injection*]</p>
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			<p>Recurrent metastatic breast cancer [intramuscular injection*] • Concomitant therapy with other antineoplastic drugs for the following malignant tumors: Multiple myeloma [intravenous infusion] • Digestive symptoms (nausea/vomiting) associated with administration of antineoplastic drugs (cisplatin, etc.) [intravenous injection, intravenous infusion] • Surgical diseases Adrenalectomy [intravenous injection, intravenous infusion, intramuscular injection] Organ/tissue transplantation [intramuscular injection*] Pulmonary oedema after invasion [intravenous injection, nebulizer] Surgical invasion for patients with adrenal cortical insufficiency [intramuscular injection*] Surgical shock or shock-like state [intravenous injection] Brain oedema [intravenous injection] Adverse reactions due to transfusion [intravenous injection] Bronchospasm (intraoperative) [intravenous injection] Snake/insect venom (including severe insect bite and sting) [intramuscular injection*] Prevention of peritoneal adhesions after surgery [intra-abdominal injection] • Orthopedic diseases Radiculitis (including radicular sciatica) in intervertebral disc herniation [epidural injection] Cerebrospinal oedema [intravenous injection, epidural injection] • Obstetrics and gynecology diseases</p>
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			<p>Prevention of adhesion after salpingoplasty [intramuscular injection*] • Urological diseases</p> <p>Prostate cancer (when other treatments are ineffective) [intramuscular injection*]</p> <p>Penile induration [intramuscular injection*, local intradermal injection] • Dermatological disease</p> <p>Eczema/dermatitis group† (acute eczema, subacute eczema, chronic eczema, contact dermatitis, nummular eczema, autosensitization dermatitis, atopic dermatitis, infancy and childhood eczema, lichen simplex chronicus Vidal, other neurodermatitises, seborrhoeic dermatitis, keratoderma tylodes palmaris progressiva, other hand dermatitises, genital or anal eczema, eczema/dermatitis of auricle and ear canal, eczema/dermatitis around nasal vestibule and alar, etc.) (not recommended in non-severe cases unless absolutely necessary. Local administration should be limited to significant invasion, lichenification.) [intramuscular injection*, local intradermal injection]</p> <p>Prurigo group† (including strophulus infantum, urticaria-like lichen, urticaria perstans (limited to severe cases and local injection is preferable for urticaria perstans) [intramuscular injection*, local intradermal injection]</p> <p>Urticaria (excluding chronic cases) (limited to severe cases) [intravenous infusion*, intramuscular injection*]</p> <p>Psoriasis and similar symptoms† [psoriasis vulgaris (severe cases), psoriatic arthritis, erythrodermic psoriasis, pustular psoriasis, acrodermatitis continua, impetigo herpetiformis, Reiter's syndrome] [intravenous infusion*, intramuscular injection*]</p>
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			<p>Of the above mentioned diseases, psoriasis vulgaris[†] [local intradermal injection] Palmoplantar pustulosis[†] (limited to severe case) [intramuscular injection*] Lichen planus[†] (limited to severe case) [intramuscular injection*, local intradermal injection] Scleredema adultorum [intramuscular injection*] Erythema (erythema exudativum multiforme[†], erythema nodosum) (limited to severe cases in case of erythema exudativum multiforme) [intramuscular injection*] Oculomucocutaneous syndrome [ectodermosis erosiva pluriorificialis, Stevens-Johnson syndrome, cutaneous stomatitis, Fuchs' syndrome, Behcet's disease (in the absence of ocular symptoms), Lipschutz' acute vulva ulcer [intravenous injection*, intramuscular injection*] Alopecia areata[†] (limited to malignant type) [local intradermal injection] Pemphigus group (pemphigus vulgaris, pemphigus foliaceus, Senear-Usher syndrome, pemphigus vegetans) [intravenous infusion*, intramuscular injection*] Dühring dermatitis herpetiformis (including pemphigoid, herpes gestationis) [intravenous infusion*, intramuscular injection*] Herpes zoster (limited to severe cases) [intramuscular injection*] Erythroderma[†] (including Hebra pityriasis rubra) [intravenous infusion*, intramuscular injection*] Early keloid and prevention of keloid[†] [local intradermal injection] Sclerema neonatorum [intramuscular injection*] • Ophthalmologic disease Symptomatic treatment of inflammatory diseases of the inner eye/optic nerve/orbit/ocular muscles (uveitis, chorioretinitis, retinal vasculitis, optic neuritis, orbital pseudotumour, orbital</p>
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			<p>apex syndrome, ophthalmoplegia) [intravenous injection*, intramuscular injection*, subconjunctival injection, retrobulbar injection, ophthalmic administration using eye drops]</p> <p>Cases where ophthalmic administration using eye drops is inappropriate or ineffective for symptomatic treatment of inflammatory diseases of the external and anterior segment of the eye (blepharitis, conjunctivitis, keratitis, scleritis, iridocyclitis) [intravenous injection*, intramuscular injection*, subconjunctival injection, retrobulbar injection]</p> <p>Post-operative inflammation of ophthalmologic field [intravenous injection*, intramuscular injection*, subconjunctival injection, ophthalmic administration using eye drops]</p> <ul style="list-style-type: none"> • Otorhinolaryngological disease <p>Acute/chronic otitis media [intravenous injection*, intravenous infusion*, intramuscular injection*, injection into middle ear cavity]</p> <p>Serous otitis media/eustachian tube stenosis [intravenous injection*, intravenous infusion*, intramuscular injection*, injection into middle ear cavity, injection into auditory tube]</p> <p>Meniere's disease and Meniere's syndrome [intravenous injection, intravenous infusion, intramuscular injection]</p> <p>Acute sensorineural hearing loss [intravenous injection, intravenous infusion, intramuscular injection]</p> <p>Vasomotor (nervous) rhinitis [intramuscular injection, nebulizer, injection into nasal cavity, injection into nasal turbinate]</p> <p>Allergic rhinitis [intramuscular injection, nebulizer, injection into nasal cavity, injection into nasal turbinate]</p>
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			<p>Pollinosis (hay fever) [intramuscular injection, nebulizer, injection into nasal cavity, injection into nasal turbinate]</p> <p>Sinusitis/nasal polyps [intramuscular injection, nebulizer, injection into nasal cavity, injection into sinus, injection into nasal polyp]</p> <p>Progressive gangrenous rhinitis [intravenous injection, intravenous infusion, intramuscular injection, nebulizer, injection into nasal cavity, injection into sinus, injection into larynx/trachea]</p> <p>Laryngitis/laryngeal oedema [intravenous injection, intravenous infusion, intramuscular injection, nebulizer, injection into larynx/trachea]</p> <p>Pharyngeal polyp/nodule [intravenous injection*, intravenous infusion*, intramuscular injection*, nebulizer, injection into larynx/trachea]</p> <p>Oesophageal inflammation (corrosive oesophagitis, after directoscope use) and after oesophageal dilation procedure [intravenous injection, intravenous infusion, intramuscular injection, nebulizer, injection into esophagus]</p> <p>Post-therapy of otorhinolaryngological field surgery [intravenous injection, intravenous infusion, intramuscular injection, injection into soft tissues, local intradermal injection, nebulizer, injection into nasal cavity, injection into sinus, injection into nasal turbinate, injection into larynx/trachea, injection into middle ear cavity, injection into esophagus]</p> <ul style="list-style-type: none"> • Dental/oral surgery disease <p>Refractory stomatitis and glossitis (cases that cannot be cured with local therapy) [injection into soft tissues]</p> <p>*: It should be used only in the following situations:</p>
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			<p>1) Intravenous injection and intravenous infusion When oral administration is impossible, and when intramuscular injection is inappropriate</p> <p>2) Intramuscular injection When oral administration is impossible</p> <p>†: It should be used only when the effects of topical drugs are ineffective or when it is assumed that effectiveness cannot be expected.</p>
d.	Dexamethasone palmitate	Limethason Intravenous Injection 2.5 mg	Rheumatoid arthritis
e.	Betamethasone (oral dosage form)	Rinderon Tablets 0.5 mg, Rinderon Powder 0.1%, Rinderon Syrup 0.01%	<ul style="list-style-type: none"> • Internal medicine and pediatrics field (1) Endocrine disease: Chronic adrenocortical insufficiency (primary, secondary, pituitary, iatrogenic), acute adrenocortical insufficiency (adrenal crisis), adrenogenital syndrome, subacute thyroiditis, thyrotoxicosis [thyroid (toxic) crisis], malignant exophthalmos accompanied by thyroid disease, isolated ACTH deficiency, pituitary suppression tests (2) Rheumatic disease: Rheumatoid arthritis, juvenile rheumatoid arthritis (including Still's disease), rheumatic fever (including rheumatic carditis), polymyalgia rheumatica (3) Collagen disease: Lupus erythematosus (systemic and chronic discoid), systemic vasculitis (including Takayasu's arteritis, polyarteritis nodosa, microscopic polyangiitis, granulomatosis with polyangiitis), polymyositis (dermatomyositis), scleroderma (4) Renal disease: Nephrosis and nephrotic syndrome (5) Heart disease: Congestive cardiac failure

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			<p>(6) Allergic disease: Bronchial asthma, asthmatic bronchitis (including pediatric asthmatic bronchitis), allergy/poisoning caused by drugs and other chemical substances (including drug eruption, toxicoderma), serum sickness</p> <p>(7) Severe infection: Severe infection (in combination with chemotherapy)</p> <p>(8) Blood disease: Haemolytic anaemia (immunological or suspected immunological mechanism), leukaemia (acute leukaemia, blast phase chronic myelogenic leukaemia, chronic lymphocytic leukaemia) (including leukaemia cutis), granulocytopenia (essential, secondary), peliosis (thrombocytopenic and non-thrombocytopenic), aplastic anaemia, haemorrhagic diatheses due to coagulation factor disorder</p> <p>(9) Digestive disease: Regional enteritis, ulcerative colitis</p> <p>(10) Severely debilitating illness: Improvement of the general condition of severely debilitating illness (including end stage cancer, sprue)</p> <p>(11) Hepatic disease: Fulminant hepatitis (including those cases considered clinically severe), cholestasis-type acute hepatitis, chronic hepatitis (active type, acute flare type, cholestasis type) (limited to refractory chronic hepatitis with persistent and markedly abnormal liver function that does not respond to conventional treatment), hepatic cirrhosis (active type, accompanied by refractory ascites, accompanied by cholestasis)</p> <p>(12) Lung disease: Sarcoidosis (excluding cases with bilateral hilar lymphadenopathy only), diffuse interstitial pneumonia (pulmonary fibrosis) (including radiation pneumonitis)</p> <p>(13) Tuberculosis disease (in combination with anti-tuberculosis drugs): Pulmonary tuberculosis (limited to miliary tuberculosis, severe tuberculosis), tuberculous meningitis, tuberculous</p>
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			<p>pleurisy, peritoneal tuberculosis, tuberculous pericarditis</p> <p>(14) Neurological disease: Encephalomyelitis (including encephalitis, myelitis) (In the case of primary encephalitis, it should be used for a short period when symptoms of increased intracranial pressure are observed and patients do not sufficiently respond to other treatments.), peripheral neuritis (including Guillain-Barré syndrome), myotonia, myasthenia gravis, multiple sclerosis (including neuromyelitis optica), Sydenham's chorea, facial palsy, spinal arachnoiditis</p> <p>(15) Malignant tumors: Malignant lymphoma (lymphosarcoma, reticulosarcoma, Hodgkin's disease, cutaneous reticulosis, mycosis fungoides) and similar diseases (closely related diseases), eosinophilic granuloma, recurrent metastatic breast cancer</p> <p>(16) Other internal medical diseases: Idiopathic hypoglycaemia, fever of unknown origin</p> <ul style="list-style-type: none"> • Surgical field <p>Adrenalectomy, organ/tissue transplantation, pulmonary oedema after invasion, surgical invasion for patients with adrenal cortical insufficiency, snake/insect venom (including severe insect bite and sting)</p> <ul style="list-style-type: none"> • Orthopedic field <p>Ankylosing spondylitis (rheumatoid spondylitis)</p> <ul style="list-style-type: none"> • Obstetrical and gynecologic field <p>Prevention of adhesion after salpingoplasty, ovulation disorder due to adrenal cortex dysfunction</p> <ul style="list-style-type: none"> • Urological field
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			<p>Prostate cancer (when other treatments are ineffective), penile induration</p> <ul style="list-style-type: none"> • Dermatological field <p>For the indications marked with †, it should be used only when the effects of topical drugs are ineffective or when it is assumed that effectiveness cannot be expected.</p> <p>Eczema/dermatitis group[†] (acute eczema, subacute eczema, chronic eczema, contact dermatitis, nummular eczema, autosensitization dermatitis, atopic dermatitis, infancy and childhood eczema, lichen simplex chronicus Vidal, other neurodermatitises, seborrhoeic dermatitis, keratoderma tylodes palmaris progressiva, other hand dermatitises, genital or anal eczema, eczema/dermatitis of auricle and ear canal, eczema/dermatitis around nasal vestibule and alar, etc.) (not recommended in non-severe cases unless absolutely necessary), prurigo group[†] (including strophulus infantum, urticaria-like lichen, urticaria perstans) (limited to severe cases and local injection is preferable for urticaria perstans), urticaria (excluding chronic case) (limited to severe case), psoriasis and similar symptoms[†] [psoriasis vulgaris (severe cases), psoriatic arthritis, erythrodermic psoriasis, pustular psoriasis, acrodermatitis continua, impetigo herpetiformis, Reiter's syndrome], parapsoriasis[†] (limited to severe case), palmoplantar pustulosis[†] (limited to severe case), pityriasis rubra pilaris[†] (limited to severe case), Lichen planus[†] (limited to severe case), scleredema adultorum, erythema [erythema exudativum multiforme[†] (limited to severe case), erythema nodosum], IgA vasculitis (limited to severe case), Weber-Christian disease, oculomucocutaneous syndrome [ectodermosis erosiva pluriorificialis, Stevens-Johnson syndrome, cutaneous stomatitis, Fuchs' syndrome, Behcet's disease (in the absence of ocular symptoms), Lipschutz' acute vulva ulcer], Raynaud's disease,</p>
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			<p>alopecia areata[‡] (limited to malignant type), pemphigus group (pemphigus vulgaris, pemphigus foliaceus, Senear-Usher syndrome, pemphigus vegetans), Duhring dermatitis herpetiformis (including pemphigoid, herpes gestationis), congenital epidermolysis bullosa, herpes zoster (limited to severe cases), erythroderma[‡] (including Hebra pityriasis rubra), lupus miliaris disseminatus faciei (limited to severe cases), allergic vasculitis and similar symptoms (including pityriasis lichenoides et varioriformis acuta), ulcerative chronic pyoderma, sclerema neonatorum</p> <ul style="list-style-type: none"> • Ophthalmologic field <p>Symptomatic treatment of inflammatory diseases of the inner eye/optic nerve/orbit/ocular muscles (uveitis, chorioretinitis, retinal vasculitis, optic neuritis, orbital pseudotumour, orbital apex syndrome, ophthalmoplegia), cases where ophthalmic administration using eye drops is inappropriate or ineffective for symptomatic treatment of inflammatory diseases of the external and anterior segment of the eye (blepharitis, conjunctivitis, keratitis, scleritis, iridocyclitis), post-operative inflammation of ophthalmologic field</p> <ul style="list-style-type: none"> • Otorhinolaryngological field <p>Acute/chronic otitis media, serous otitis media/eustachian tube stenosis, Meniere's disease and Meniere's syndrome, acute sensorineural hearing loss, vasomotor (nervous) rhinitis, allergic rhinitis, pollinosis (hay fever), sinusitis/nasal polyps, progressive gangrenous rhinitis, laryngitis/laryngeal oedema, pharyngeal polyp/nodule, oesophageal inflammation (corrosive oesophagitis, after directoscope use) and after oesophageal dilation procedure, post-therapy of otorhinolaryngological field surgery, refractory stomatitis and glossitis (cases that cannot be</p>
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			cured with local therapy), dysosmia, acute/chronic (repetitive) sialoadenitis																														
f.	Betamethasone (suppositories)	Rinderon suppositories 0.5 mg, 1.0 mg	Ulcerative colitis (proctitis type)																														
g.	Betamethasone sodium phosphate (injections)	Rinderon injection 2 mg (0.4%), 4 mg (0.4%)	<p>The routes of administration marked with § can be used only under the conditions shown below. (If these conditions become inapplicable, switch to the other routes of administration promptly.)</p> <p>(1) Intravenous injection and intravenous infusion: When oral administration is impossible, in case of emergency, and when intramuscular injections are inappropriate</p> <p>(2) Intramuscular injection: When oral administration is impossible</p> <table border="1" data-bbox="824 810 1995 1358"> <thead> <tr> <th colspan="2">Indications</th> <th>Intravenous injection</th> <th>Intravenous infusion</th> <th>Intramuscular injection</th> <th>Other administrations</th> </tr> </thead> <tbody> <tr> <td colspan="6">1. Internal medicine and pediatrics field</td> </tr> <tr> <td colspan="6">(1) Endocrine disease</td> </tr> <tr> <td></td> <td>Chronic adrenocortical insufficiency (primary, secondary, pituitary, iatrogenic)</td> <td></td> <td></td> <td>Yes</td> <td></td> </tr> <tr> <td></td> <td>Acute adrenocortical insufficiency (adrenal crisis)</td> <td>Yes</td> <td>Yes</td> <td>Yes</td> <td></td> </tr> </tbody> </table>	Indications		Intravenous injection	Intravenous infusion	Intramuscular injection	Other administrations	1. Internal medicine and pediatrics field						(1) Endocrine disease							Chronic adrenocortical insufficiency (primary, secondary, pituitary, iatrogenic)			Yes			Acute adrenocortical insufficiency (adrenal crisis)	Yes	Yes	Yes	
Indications		Intravenous injection	Intravenous infusion	Intramuscular injection	Other administrations																												
1. Internal medicine and pediatrics field																																	
(1) Endocrine disease																																	
	Chronic adrenocortical insufficiency (primary, secondary, pituitary, iatrogenic)			Yes																													
	Acute adrenocortical insufficiency (adrenal crisis)	Yes	Yes	Yes																													

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				Adrenogenital syndrome, subacute thyroiditis, malignant exophthalmos accompanied by thyroid disease			Yes [§]	
				Thyrotoxicosis [thyroid (toxic) crisis]	Yes	Yes	Yes [§]	
			(2) Rheumatic disease					
				Rheumatoid arthritis, juvenile rheumatoid arthritis (including Still's disease)			Yes	Intraarticular injection
				rheumatic fever (including rheumatic carditis)	Yes [§]	Yes [§]	Yes	
				Polymyalgia rheumatica			Yes	
			(3) Collagen disease					
				Lupus erythematosus	Yes [§]	Yes [§]	Yes	

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			(systemic and chronic discoid), systemic vasculitis (including Takayasu's arteritis, polyarteritis nodosa, microscopic polyangiitis, granulomatosis with polyangiitis), polymyositis (dermatomyositis)				
			Scleroderma			Yes [§]	
			(4) Renal disease				
			Nephrosis and nephrotic syndrome	Yes [§]	Yes [§]	Yes [§]	
			(5) Heart disease				
			Congestive cardiac failure	Yes [§]	Yes [§]	Yes [§]	
			(6) Allergic disease				
			Bronchial asthma	Yes	Yes	Yes	Nebulizer

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			(Intramuscular injections are to be used only when the other routes of administration are inappropriate)				
			Asthmatic bronchitis (including pediatric asthmatic bronchitis)			Yes [§]	Nebulizer
			Status Asthmaticus, anaphylactic shock	Yes	Yes		
			allergy/poisoning caused by drugs and other chemical substances (including drug eruption, toxicoderma)	Yes [§]	Yes [§]	Yes [§]	
			Serum sickness	Yes	Yes	Yes [§]	
			(7) Severe infection				
			Severe infection (in combination with	Yes	Yes	Yes [§]	

Pharmaceuticals and Medical Devices Agency

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				chemotherapy)				
			(8) Blood disease					
				Haemolytic anaemia (immunological or suspected immunological mechanism), leukaemia (acute leukaemia, blast phase chronic myelogenous leukaemia, chronic lymphocytic leukaemia) (including leukaemia cutis), granulocytopenia (essential, secondary), peliosis (thrombocytopenic and non-thrombocytopenic), aplastic anaemia, haemorrhagic diatheses	Yes	Yes	Yes ^s	

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			due to coagulation factor disorder				
			Meningeal leukaemia				Intrathecal injection
			(9) Digestive disease				
			Regional enteritis, ulcerative colitis	Yes [§]	Yes [§]	Yes [§]	Enemas
			(10) Severely debilitating illness				
			Improvement of the general condition of severely debilitating illness (including end stage cancer, sprue)	Yes [§]	Yes [§]	Yes [§]	
			(11) Hepatic disease				
			Fulminant hepatitis (including those cases considered clinically severe)	Yes	Yes	Yes [§]	
			Cholestasis-type acute		Yes [§]	Yes [§]	

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			hepatitis				
			Hepatic cirrhosis (active type, accompanied by refractory ascites, accompanied by cholestasis)			Yes [§]	
			(12) Lung disease				
			Diffuse interstitial pneumonia (pulmonary fibrosis) (including radiation pneumonitis)	Yes [§]	Yes [§]		Nebulizer
			(13) Tuberculosis disease (in combination with anti-tuberculosis drugs)				
			Tuberculous meningitis				Intrathecal injection
			Tuberculosis pleuritis				Intrathoracic injection
			(14) Neurological disease				

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				Encephalomyelitis (including encephalitis, myelitis) (In the case of primary encephalitis, it should be used for a short period when symptoms of increased intracranial pressure are observed and patients do not sufficiently respond to other treatments.), myasthenia gravis, multiple sclerosis (including neuromyelitis optica)	Yes	Yes	Yes [§]	Intrathecal injection
				Peripheral neuritis (including Guillain-Barré syndrome)	Yes [§]	Yes [§]	Yes [§]	Intrathecal injection
				Sydenham's chorea,			Yes [§]	

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			facial palsy, spinal arachnoiditis				
			(15) Malignant tumors				
			Malignant lymphoma (lymphosarcoma, reticulosarcoma, Hodgkin's disease, cutaneous reticulosis, mycosis fungoides) and similar diseases (closely related diseases)	Yes	Yes	Yes [§]	Intrathecal injection
			Eosinophilic granuloma	Yes	Yes	Yes [§]	
			Recurrent metastatic breast cancer			Yes [§]	
			(16) Other internal medical diseases				
			Idiopathic hypoglycaemia	Yes	Yes	Yes [§]	
			Fever of unknown origin			Yes [§]	
			2. Surgical field				

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				Adrenalectomy	Yes	Yes	Yes		
				Organ/tissue transplantation, surgical invasion for patients with adrenal cortical insufficiency, snake/insect venom (including severe insect bite and sting)			Yes [§]		
				Pulmonary oedema after invasion	Yes			Nebulizer	
				Surgical shock and surgical shock-like state, brain oedema, side effect due to transfusion, bronchospasm (intraoperative)	Yes				
			3. Orthopedic field						
				Ankylosing spondylitis			Yes		

Pharmaceuticals and Medical Devices Agency

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			(rheumatoid spondylitis)				
			Limb arthritis accompanied by ankylosing spondylitis (rheumatoid spondylitis), osteoarthritis (if symptoms of inflammation are clearly noted), post-traumatic arthritis, non-infectious chronic arthritis, gouty arthritis				Intraarticular injection
			Periarthritis (limited to non-infectious), peritendinitis (limited to non-infectious)				Injection into soft tissues Injection into tendon sheaths Injection into synovial sac
			Tendonitis (limited to				Injection into soft

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			non-infectious)				tissues Injection into tendon sheaths	
			Tenosynovitis (limited to non-infectious)				Injection into tendon sheaths	
			Bursitis (limited to non- infectious)				Injection into synovial sac	
			4. Obstetrical and gynecologic field					
			Hydrotubation for fallopian tube obstruction (infertility)				Injection into fallopian tube	
			Prevention of adhesion after salpingoplasty			Yes [§]	Injection into fallopian tube	
			Ovulation disorder due to adrenal cortex dysfunction			Yes [§]		
			Prevention of neonatal respiratory distress syndrome by maternal			Yes		

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				therapy to enhance foetal lung maturity in cases where premature delivery is expected				
			5. Urological field					
				Prostate cancer (when other treatments are ineffective), penile induration			Yes [§]	
			6. Dermatological field					
				For indications marked with ‡, it should be used only when the effects of topical drugs are ineffective or when it is assumed that effectiveness cannot be expected. Eczema/dermatitis group [‡] (acute eczema,			Yes [§]	

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				subacute eczema, chronic eczema, contact dermatitis, nummular eczema, autosensitization dermatitis, atopic dermatitis, infancy and childhood eczema, lichen simplex chronicus Vidal, other neurodermatitises, seborrhoeic dermatitis, keratoderma tylodes palmaris progressiva, other hand dermatitises, genital or anal eczema, eczema/dermatitis of auricle and ear canal, eczema/dermatitis around nasal vestibule and alar, etc.) (not				
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				<p>recommended in non-severe cases unless absolutely necessary), prurigo group[‡] (including strophulus infantum, urticaria-like lichen, urticaria perstans) (limited to severe cases and local injection is preferable for urticaria perstans), parapsoriasis[‡] (limited to severe cases), palmoplantar pustulosis[‡] (limited to severe case), pityriasis rubra pilaris[‡] (limited to severe cases), scleredema adultorum, erythema [erythema exudativum multiforme[‡] (limited to</p>				
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				severe case), erythema nodosum], Raynaud's disease, congenital epidermolysis bullosa, herpes zoster (limited to severe cases), lupus miliaris disseminatus faciei (limited to severe cases), ulcerative chronic pyoderma, sclerema neonatorum				
				Urticaria (excluding chronic case) (limited to severe case), psoriasis and similar symptoms [†] [psoriasis vulgaris (severe cases), psoriatic arthritis, erythrodermic psoriasis, pustular psoriasis, acrodermatitis continua, impetigo		Yes [§]	Yes [§]	

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				herpetiformis, Reiter's syndrome], IgA vasculitis (limited to severe case), Weber-Christian disease, oculomucocutaneous syndrome [ectodermosis erosiva pluriorificialis, Stevens-Johnson syndrome, cutaneous stomatitis, Fuchs' syndrome, Behcet's disease (in the absence of ocular symptoms), Lipschutz' acute vulva ulcer], pemphigus group (pemphigus vulgaris, pemphigus foliaceus, Senear-Usher syndrome, pemphigus				
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			vegetans), Duhring dermatitis herpetiformis (including pemphigoid, herpes gestations), erythroderma [‡] (including Hebra pityriasis rubra)				
			7. Ophthalmologic field				
			Symptomatic treatment of inflammatory diseases of the inner eye/optic nerve/orbit/ocular muscles (uveitis, chorioretinitis, retinal vasculitis, optic neuritis, orbital pseudotumour, orbital apex syndrome, ophthalmoplegia)	Yes [§]		Yes [§]	Subconjunctival injection Retrobulbar injection Ophthalmic administration using eye drops
			Cases where ophthalmic	Yes [§]		Yes [§]	Subconjunctival injection

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				administration using eye drops is inappropriate or ineffective for symptomatic treatment of inflammatory diseases of the external and anterior segment of the eye (blepharitis, conjunctivitis, keratitis, scleritis, iridocyclitis)				Retrobulbar injection
				Post-operative inflammation of ophthalmologic field	Yes [§]		Yes [§]	Subconjunctival injection Ophthalmic administration using eye drops
			8. Otorhinolaryngological field					
				Acute/chronic otitis media	Yes [§]	Yes [§]	Yes [§]	Injection into middle ear cavity
				Serous otitis media/eustachian tube	Yes [§]	Yes [§]	Yes [§]	Injection into middle ear cavity

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				stenosis				Injection into auditory tube
				Meniere's disease and Meniere's syndrome, acute sensorineural hearing loss, post-therapy after oral surgery field surgery	Yes	Yes	Yes	
				Vasomotor (nervous) rhinitis, allergic rhinitis, pollinosis (hay fever)			Yes	Nebulizer Injection into nasal cavity Injection into nasal turbinate
				Sinusitis/nasal polyps			Yes	Nebulizer Injection into nasal cavity Injection into sinus Injection into nasal polyp

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				Progressive gangrenous rhinitis	Yes	Yes	Yes	Nebulizer Injection into nasal cavity Injection into sinus Injection into larynx/trachea
				Laryngitis/laryngeal oedema	Yes	Yes	Yes	Nebulizer Injection into larynx/trachea
				Pharyngeal polyp/nodule	Yes [§]	Yes [§]	Yes [§]	Nebulizer Injection into larynx/trachea
				Oesophageal inflammation (corrosive oesophagitis, after directoscope use) and after oesophageal dilation procedure	Yes	Yes	Yes	Nebulizer Injection into esophagus
				Post-therapy of	Yes	Yes	Yes	Injection into soft

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				otorhinolaryngological field surgery				tissues Nebulizer Injection into nasal cavity Injection into sinus Injection into nasal turbinate Injection into larynx/trachea Injection into middle ear cavity Injection into esophagus
				Refractory stomatitis and glossitis (cases that cannot be cured with local therapy)				Injection into soft tissues
				Dysosmia	Yes [§]	Yes [§]	Yes [§]	Nebulizer Injection into

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							nasal cavity	
			Acute/chronic (repetitive) sialoadenitis	Yes [§]	Yes [§]	Yes [§]	Injection into salivary gland duct	
		Rinderon injection 20 mg (0.4%)	The routes of administration marked with [§] can be used only under the conditions shown below. (If these conditions become inapplicable, switch to the other routes of administration promptly.) (1) Intravenous injection and intravenous infusion: When oral administration is impossible, in case of emergency, and when intramuscular injections are inappropriate (2) Intramuscular injection: When oral administration is impossible					
			Indications		Intravenous injection	Intravenous infusion	Intramuscular injection	Other administrations
			1. Internal medicine and pediatrics field					
			(1) Endocrine disease					
			Chronic adrenocortical insufficiency (primary, secondary, pituitary, iatrogenic)				Yes	

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			Acute adrenocortical insufficiency (adrenal crisis)	Yes	Yes	Yes		
			Adrenogenital syndrome, subacute thyroiditis, malignant exophthalmos accompanied by thyroid disease			Yes [§]		
			Thyrotoxicosis [thyroid (toxic) crisis]	Yes	Yes	Yes [§]		
			(2) Rheumatic disease					
			Rheumatoid arthritis, juvenile rheumatoid arthritis (including Still's disease)			Yes	Intraarticular injection	
			Rheumatic fever (including rheumatic carditis)	Yes [§]	Yes [§]	Yes		
			Polymyalgia rheumatica			Yes		

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			(3) Collagen disease				
			Lupus erythematosus (systemic and chronic discoid), systemic vasculitis (including Takayasu's arteritis, polyarteritis nodosa, microscopic polyangiitis, granulomatosis with polyangiitis), polymyositis (dermatomyositis)	Yes [§]	Yes [§]	Yes	
			Scleroderma			Yes [§]	
			(4) Renal disease				
			Nephrosis and nephrotic syndrome	Yes [§]	Yes [§]	Yes [§]	
			(5) Heart disease				
			Congestive cardiac failure	Yes [§]	Yes [§]	Yes [§]	

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			(6) Allergic disease				
			Bronchial asthma (Intramuscular injections are to be used only when the other routes of administration are inappropriate)	Yes	Yes	Yes	Nebulizer
			Asthmatic bronchitis (including pediatric asthmatic bronchitis)			Yes [§]	Nebulizer
			Status Asthmaticus, anaphylactic shock	Yes	Yes		
			allergy/poisoning caused by drugs and other chemical substances (including drug eruption, toxicoderma)	Yes [§]	Yes [§]	Yes [§]	
			Serum sickness	Yes	Yes	Yes [§]	
			(7) Severe infection				

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				Severe infection (in combination with chemotherapy)	Yes	Yes	Yes [§]	
			(8) Blood disease					
				Haemolytic anaemia (immunological or suspected immunological mechanism), leukaemia (acute leukaemia, blast phase chronic myelogenous leukaemia, chronic lymphocytic leukaemia) (including leukaemia cutis), granulocytopenia (essential, secondary), peliosis (thrombocytopenic and non-thrombocytopenic),	Yes	Yes	Yes [§]	

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				aplastic anaemia, haemorrhagic diatheses due to coagulation factor disorder				
				Meningeal leukaemia				Intrathecal injection
			(9) Digestive disease					
				Regional enteritis, ulcerative colitis	Yes [§]	Yes [§]	Yes [§]	Enemas
			(10) Severely debilitating illness					
				Improvement of the general condition of severely debilitating illness (including end stage cancer, sprue)	Yes [§]	Yes [§]	Yes [§]	
			(11) Hepatic disease					
				Fulminant hepatitis (including those cases considered clinically)	Yes	Yes	Yes [§]	

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				severe)				
				Cholestasis-type acute hepatitis		Yes [§]	Yes [§]	
				Hepatic cirrhosis (active type, accompanied by refractory ascites, accompanied by cholestasis)			Yes [§]	
			(12) Lung disease					
				Diffuse interstitial pneumonia (pulmonary fibrosis) (including radiation pneumonitis)	Yes [§]	Yes [§]		Nebulizer
			(13) Tuberculosis disease (in combination with anti-tuberculosis drugs)					
				Tuberculous meningitis				Intrathecal injection
				Tuberculosis pleuritis				Intrathoracic injection

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			(14) Neurological disorder				
			Encephalomyelitis (including encephalitis, myelitis) (In the case of primary encephalitis, it should be used for a short period when symptoms of increased intracranial pressure are observed and patients do not sufficiently respond to other treatments.), myasthenia gravis, multiple sclerosis (including neuromyelitis optica)	Yes	Yes	Yes [§]	Intrathecal injection
			Peripheral neuritis (including Guillain-Barré syndrome)	Yes [§]	Yes [§]	Yes [§]	Intrathecal injection

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				Sydenham's chorea, facial palsy, spinal arachnoiditis			Yes [§]	
			(15) Malignant tumors					
				Malignant lymphoma (lymphosarcoma, reticulosarcoma, Hodgkin's disease, cutaneous reticulosis, mycosis fungoides) and similar diseases (closely related diseases)	Yes	Yes	Yes [§]	Intrathecal injection
				Eosinophilic granuloma	Yes	Yes	Yes [§]	
				Recurrent metastatic breast cancer			Yes [§]	
			(16) Other internal medical diseases					
				Idiopathic hypoglycaemia	Yes	Yes	Yes [§]	
				Fever of unknown origin			Yes [§]	

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			2. Surgical field				
			Adrenalectomy	Yes	Yes	Yes	
			Organ/tissue transplantation, surgical invasion for patients with adrenal cortical insufficiency, snake/insect venom (including severe insect bite and sting)			Yes ^s	
			Pulmonary oedema after invasion	Yes			Nebulizer
			Surgical shock and surgical shock-like state, brain oedema, side effect due to transfusion, bronchospasm (intraoperative)	Yes			
			3. Orthopedic field				

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			Ankylosing spondylitis (rheumatoid spondylitis)			Yes	
			Limb arthritis accompanied by ankylosing spondylitis (rheumatoid spondylitis), osteoarthritis (if symptoms of inflammation are clearly noted), post-traumatic arthritis, non-infectious chronic arthritis, gouty arthritis				Intraarticular injection
			Periarthritis (limited to non-infectious), peritendinitis (limited to non-infectious)				Injection into soft tissues Injection into tendon sheaths Injection into synovial sac

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				Tendonitis (limited to non-infectious)				Injection into soft tissues Injection into tendon sheaths
				Tenosynovitis (limited to non-infectious)				Injection into tendon sheaths
				Bursitis (limited to non-infectious)				Injection into synovial sac
			4. Obstetrical and gynecologic field					
				Hydrotubation for fallopian tube obstruction (infertility)				Injection into fallopian tube
				Prevention of adhesion after salpingoplasty			Yes [§]	Injection into fallopian tube
				Ovulation disorder due to adrenal cortex dysfunction			Yes [§]	
			5. Urological field					
				Prostate cancer (when			Yes [§]	

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			other treatments are ineffective), penile induration				
			6. Dermatological field				
			For indications marked with ‡, it should be used only when the effects of topical drugs are ineffective or when it is assumed that effectiveness cannot be expected. Eczema/dermatitis group‡ (acute eczema, subacute eczema, chronic eczema, contact dermatitis, nummular eczema, autosensitization dermatitis, atopic			Yes§	

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				dermatitis, infancy and childhood eczema, lichen simplex chronicus Vidal, other neurodermatitises, seborrhoeic dermatitis, keratoderma tylodes palmaris progressiva, other hand dermatitises, genital or anal eczema, eczema/dermatitis of auricle and ear canal, eczema/dermatitis around nasal vestibule and alar, etc.) (not recommended in non-severe cases unless absolutely necessary), prurigo group‡ (including strophulus infantum, urticaria-like					
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				lichen, urticaria perstans) (limited to severe cases. Also, local injection is recommended for urticaria perstans), parapsoriasis [‡] (limited to severe case), palmoplantar pustulosis [‡] (limited to severe case), pityriasis rubra pilaris [‡] (limited to severe case), scleredema adultorum, erythema [erythema exudativum multiforme [‡] (limited to severe case), erythema nodosum)], Raynaud's disease, congenital epidermolysis bullosa,				
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			herpes zoster (limited to severe cases), lupus miliaris disseminatus faciei (limited to severe cases), ulcerative chronic pyoderma, sclerema neonatorum				
			Urticaria (excluding chronic case) (limited to severe case), psoriasis and similar symptoms [†] [psoriasis vulgaris (severe cases), psoriatic arthritis, erythrodermic psoriasis, pustular psoriasis, acrodermatitis continua, impetigo herpetiformis, Reiter's syndrome], IgA vasculitis (limited to severe case), Weber-		Yes [§]	Yes [§]	

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				<p>Christian disease, oculomucocutaneous syndrome [ectodermosis erosiva pluriorificialis, Stevens- Johnson syndrome, cutaneous stomatitis, Fuchs' syndrome, Behcet's disease (in the absence of ocular symptoms), Lipschutz' acute vulva ulcer], pemphigus group (pemphigus vulgaris, pemphigus foliaceus, Senear-Usher syndrome, pemphigus vegetans), Duhring dermatitis herpetiformis (including pemphigoid, herpes gestationis),</p>					
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			erythroderma [‡] (including Hebra pityriasis rubra)				
			7. Ophthalmologic field				
			Symptomatic treatment of inflammatory diseases of the inner eye/optic nerve/orbit/ocular muscles (uveitis, chorioretinitis, retinal vasculitis, optic neuritis, orbital pseudotumour, orbital apex syndrome, ophthalmoplegia)	Yes [§]		Yes [§]	Subconjunctival injection Retrolubar injection Ophthalmic administration using eye drops
			Cases where ophthalmic administration using eye drops is inappropriate or ineffective for symptomatic treatment	Yes [§]		Yes [§]	Subconjunctival injection Retrolubar injection

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				of inflammatory diseases of the external and anterior segment of the eye (blepharitis, conjunctivitis, keratitis, scleritis, iridocyclitis)				
				Post-operative inflammation of ophthalmologic field	Yes [§]		Yes [§]	Subconjunctival injection Ophthalmic administration using eye drops
			8. Otorhinolaryngological field					
				Acute/chronic otitis media	Yes [§]	Yes [§]	Yes [§]	Injection into middle ear cavity
				Serous otitis media/eustachian tube stenosis	Yes [§]	Yes [§]	Yes [§]	Injection into middle ear cavity Injection into auditory tube

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			Meniere's disease and Meniere's syndrome, acute sensorineural hearing loss, post-therapy after oral surgery field surgery	Yes	Yes	Yes	
			Vasomotor (nervous) rhinitis, allergic rhinitis, pollinosis (hay fever)			Yes	Nebulizer Injection into nasal cavity Injection into nasal turbinate
			Sinusitis/nasal polyps			Yes	Nebulizer Injection into nasal cavity Injection into sinus Injection into nasal polyp
			Progressive gangrenous rhinitis	Yes	Yes	Yes	Nebulizer Injection into

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							nasal cavity Injection into sinus Injection into larynx/trachea
			Laryngitis/laryngeal oedema	Yes	Yes	Yes	Nebulizer Injection into larynx/trachea
			Pharyngeal polyp/nodule	Yes [§]	Yes [§]	Yes [§]	Nebulizer Injection into larynx/trachea
			Oesophageal inflammation (corrosive oesophagitis, after directoscope use) and after oesophageal dilation procedure	Yes	Yes	Yes	Nebulizer Injection into esophagus
			Post-therapy of otorhinolaryngological field surgery	Yes	Yes	Yes	Injection into soft tissues Nebulizer

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								Injection into nasal cavity Injection into sinus Injection into nasal turbinate Injection into larynx/trachea Injection into middle ear cavity Injection into esophagus
				Refractory stomatitis and glossitis (cases that cannot be cured with local therapy)				Injection into soft tissues
				Dysosmia	Yes [§]	Yes [§]	Yes [§]	Nebulizer Injection into nasal cavity

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			Acute/chronic (repetitive) sialoadenitis	Yes [§]	Yes [§]	Yes [§]	Injection into salivary gland duct				
		Rinderon Injection 20 mg (2%), 100 mg (2%)	Emergency relief in haemorrhagic shock or intra- and postoperative shock								
h.	Betamethasone sodium phosphate (enemas)	Steronema Enema 3 mg, 1.5 mg	Regional enteritis, ulcerative colitis								
i.	Betamethasone acetate/betamethas one sodium phosphate	Rinderon Suspension	Indication/ administration	Intramuscular injection	Intraarticular injection	Injection into soft tissues	Injection into tendon sheaths	Injection into synovial sac	Local intradermal injection	Injection into nasal cavity	Injection into nasal turbinate

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			Rheumatoid arthritis		Yes							
			Periarthritis (limited to non-infectious)			Yes	Yes	Yes				
			Tendonitis (limited to non-infectious)			Yes	Yes					
			Tenosynovitis (limited to non-infectious)				Yes					
			Peritendinitis (limited to non-infectious)			Yes	Yes	Yes				
			Bursitis (limited to non-infectious)					Yes				
			Osteoarthritis (if symptoms of inflammation are clearly noted)		Yes							
			Post-traumatic arthritis		Yes							
			Alopecia areata [‡] (limited to malignant type)						Yes			
			Early keloid and prevention of keloid [‡]						Yes			
			Allergic rhinitis	Yes							Yes	Yes
			For the indications marked with ‡, it should be used only when topical drugs are ineffective or when it is assumed that effectiveness cannot be expected.									
j.	Betamethasone/d-chlorpheniramine maleate	Celestamine Combination Tablets, Celestamine Combination Syrup	Urticaria (excluding chronic cases), acute and acute exacerbation phases in the eczema/dermatitis group, drug eruption, allergic rhinitis									