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Summary of investigation results

Triamcinolone acetonide

March 24, 2015

Non-proprietary name

Triamcinolone acetonide (for intramuscular injection, intraarticular injection, and intradermal injection)

Brand name (Marketing authorization holder)

Kenacort-A Intramuscular Intraarticular Suspension Liquid Injection 40 mg/1 mL and Kenacort-A Intradermal Intraarticular Suspension Liquid Injection 50 mg/5 mL (Bristol-Myers K.K.)

Indications

See annex

Summary of revision

'Tendon rupture' should be added in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of adverse events suggestive of tendon rupture have been reported in patients treated with triamcinolone acetonide in Japan. Following an investigation based on the opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 11 cases of adverse events suggestive of tendon rupture have been reported (including 9 cases in which causality could not be ruled out). No fatalities have been reported.

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Annex

Brand name (Marketing authorization holder)	**Indications**
Kenacort-A Intramuscular Intraarticular Suspension Liquid Injection 40 mg/1 mL	Intramuscular injection: ● Chronic adrenocortical insufficiency (primary, secondary, pituitary, and iatrogenic), adrenogenital syndrome*, subacute thyroiditis*, and thyrotoxicosis* (thyroid crisis) ● Rheumatoid arthritis, juvenile rheumatoid arthritis (including Still's disease), rheumatic fever (including rheumatic carditis), and polymyalgia rheumatica ● Lupus erythematosus (systemic and chronic discoid), systemic vasculitides (including aortitis syndrome, periarteritis nodosa, polyarteritis, and Wegener's granulomatosis), polymyositis (dermatomyositis), and scleroderma* ● Nephrosis and nephrotic syndrome* ● Congestive cardiac failure* ● Bronchial asthma (to be used only when other routes of administration, except intramuscular injection, are inappropriate), allergies to drugs and other chemicals/drug toxicity (including drug eruption and toxicoderma)*, and serum sickness* ● Severe infections (to be used concomitantly with chemotherapy)* ● Haemolytic anaemia (immune haemolytic anaemia or haemolytic anaemia with an immune mechanism)*, leukaemia (acute leukaemia, transformation of chronic myeloid leukaemia, chronic lymphocytic leukaemia) (including leukaemia cutis)*, granulocytopenia (essential and secondary)*, purpura (thrombocytopenic and non-thrombocytopenic)*, aplastic anaemia*, and haemorrhagic diathesis due to coagulation factor disorders* ● Regional enteritis* and ulcerative colitis* ● Improvement of general symptoms in severely debilitating disease (including terminal stage of cancer and sprue)* ● Cirrhosis (active, with refractory ascites, and/or with cholestasis)* ● Encephalomyelitis (including encephalitis and myelitis) (regarding primary encephalitis, this drug should be used for short term only when the patient has intracranial hypertension and does not sufficiently respond to other drugs)*, peripheral neuritis (including Guillain–Barre syndrome)*, myasthenia gravis*, multiple sclerosis (including neuromyelitis optica)*, chorea minor*, facial palsy*, and spinal arachnoiditis* ● Malignant lymphoma (lymphosarcoma, reticulum cell sarcoma,

Brand name (Marketing authorization holder)	**Indications**
	Hodgkin's disease, cutaneous reticulosis, and mycosis fungoides) and variants (related diseases)*, eosinophilic granuloma* ● Idiopathic hypoglycemia* ● Adrenalectomy*, organ transplant/tissue transplant*, surgery in the setting of adrenal cortex insufficiency* ● Snake venom/insect venom (including serious insect sting)* ● Ankylosing spondylitis (rheumatoid spondylitis) ● Prevention of adhesions after tuboplasty ● Prostate cancer (when the patient does not respond to other therapies) and recurrence and/or metastasis of breast cancer* ● Eczema and dermatitis*† (acute eczema, subacute eczema, chronic eczema, contact dermatitis, nummular eczema, autosensitization dermatitis, atopic dermatitis, pediatric eczema, lichen simplex chronicus Vidal, other neurodermatitis, seborrhoeic dermatitis, keratodermia tylodes palmaris progressiva, other dermatitis of the fingers, genital or anal eczema, dermatitis/eczema of the auricle or ear canal, dermatitis/eczema of the nasal vestibule or around nasal ala, etc.) (if possible, this drug should not be administered to patients with non-serious symptoms), urticaria (excluding chronic urticaria) (to be administered only to patients with serious symptoms), psoriasis and variants (psoriasis [with serious symptoms], arthropathic psoriasis, erythrodermic psoriasis, pustular psoriasis, acrodermatitis continua, impetigo herpetiformis, Reiter's syndrome) * †, palmoplantar pustulosis (to be administered to only patients with serious symptoms) * † , lichen planus * † (to be administered to only patients with serious symptoms), scleredema adultorum*, erythema* (erythema exsudativum multiforme† and erythema nodosum) (regarding erythema exsudativum multiforme, this drug should be administered to only patients with serious symptoms), oculomucocutaneous syndrome* (ectodermosis erosiva pluriorificialis, Stevens–Johnson syndrome, dermatostomatitis, Fuchs' syndrome, Behcet's syndrome [without ophthalmic symptoms], Lipschutz ulcus vulvae acutum), pemphigus (pemphigus vulgaris, pemphigus foliaceous, Senear–Usher syndrome, and pemphigus vegetans), Dermatitis herpetiformis (including pemphigoid and herpes gestationis)*, herpes zoster* (to be administered to only patients with serious symptoms), erythroderma (including Hebra pityriasis rubra) * † ● Prurigo* † (including pediatric strophulus, urticarial lichen, and urticaria perstans) (to be administered to only patients with serious

Brand name (Marketing authorization holder)	**Indications**
	symptoms. Localized injection is appropriate for urticaria perstans) ● Symptomatic therapy for inflammatory diseases of the eye, optic nerve, orbit, eye muscle* (uveitis, chorioretinitis, retinal vasculitis, optic neuritis, orbital inflammatory pseudotumor, orbital apex syndrome, and ophthalmoplegia), symptomatic therapy for inflammatory diseases of the outer ocular area and anterior eye segment when the ophthalmic topical treatment is not appropriate or sufficient (blepharitis, conjunctivitis, keratitis, scleritis, and iridocyclitis) * ● Acute/chronic otitis media*, serous otitis media/eustachian tube stenosis*, allergic rhinitis, pollinosis (hay fever), sinusitis/nasal polyps, pharyngitis/laryngeal oedema, laryngeal polyp/nodules*, esophagitis (corrosive esophagitis after endoscopy) *, and post-treatment for esophageal dilation and otorhinolaryngological surgery ● Post-treatment for oral surgery Intraarticular injection: ● Rheumatoid arthritis, juvenile rheumatoid arthritis (including Still's disease) ● Acroarthritis associated with ankylosing spondylitis (rheumatoid spondylitis), osteoarthritis (when inflammatory symptom is obvious), traumatic arthritis, and noninfectious chronic arthritis Injection into soft tissue: ● Periarthritis (only noninfectious periarthritis), tendonitis (only noninfectious tendonitis), peritendinitis (only noninfectious peritendinitis) ● Post-treatment for otorhinolaryngological surgery ● Refractory stomatitis and glossitis (when the patient does not recover with local treatment) Intratendovaginal injection: ● Periarthritis (only noninfectious periarthritis), tendonitis (only noninfectious tendonitis), tenosynovitis (only noninfectious tenosynovitis), and peritendinitis (only noninfectious peritendinitis) Intrasynovial bursa injection: ● Periarthritis (only noninfectious periarthritis), peritendinitis (only noninfectious peritendinitis), and bursitis (only noninfectious bursitis)

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Brand name (Marketing authorization holder)	**Indications**
	Nebulizer ● Bronchial asthma ● Diffuse interstitial pneumonia (pulmonary fibrosis) (including radiation pneumonitis) ● Allergic rhinitis, pollinosis (hay fever), sinusitis/nasal polyps, laryngitis/laryngeal oedema, laryngeal polyp/nodules, esophagitis (corrosive esophagitis after endoscopy), and post-treatment for esophageal dilation and otorhinolaryngological surgery Injection in the nasal cavity ● Allergic rhinitis, pollinosis (hay fever), sinusitis/nasal polyps, and post-treatment for otorhinolaryngological surgery Injection into the paranasal sinus ● Sinusitis/nasal polyps, and post-treatment for otorhinolaryngological surgery Injection into nasal turbinate ● Allergic rhinitis, pollinosis (hay fever), and post-treatment for otorhinolaryngological surgery Injection into nasal polyp ● Sinusitis/nasal polyps Injection in the larynx/trachea ● Laryngitis/laryngeal oedema, laryngeal polyp/nodules, and post-treatment for otorhinolaryngological surgery Injection in the middle ear cavity ● Acute/chronic otitis media*, serous otitis media/eustachian tube stenosis, and post-treatment for otorhinolaryngological surgery Injection into the eustachian tube ● Serous otitis media/eustachian tube stenosis Injection into the oesophagus ● Esophagitis (corrosive esophagitis after endoscopy), and post-treatment

Brand name (Marketing authorization holder)	**Indications**
	for esophageal dilation and otorhinolaryngological surgery NOTE *This drug should be used in patients who are not able to use the oral treatment. †This drug should be used only when the patient does not, or is not expected to, sufficiently respond to topical treatment.
Kenacort-A Intradermal Intraarticular Suspension Liquid Injection 50 mg/5 mL	Intraarticular injection: ● Rheumatoid arthritis, juvenile rheumatoid arthritis (including Still's disease) ● Acroarthritis associated with ankylosing spondylitis (rheumatoid spondylitis), osteoarthritis (when inflammatory symptom is obvious), traumatic arthritis, and noninfectious chronic arthritis Injection into soft tissue: ● Periarthritis (only noninfectious periarthritis), tendonitis (only noninfectious tendonitis), peritendinitis (only noninfectious peritendinitis) ● Post-treatment for otorhinolaryngological surgery ● Refractory stomatitis and glossitis (when the patient does not recover with local treatment) Intratendovaginal injection: ● Periarthritis (only noninfectious periarthritis), tendonitis (only noninfectious tendonitis), tenosynovitis (only noninfectious tenosynovitis), and peritendinitis (only noninfectious peritendinitis) Intrasynovial injection: ● Periarthritis (only noninfectious periarthritis), peritendinitis (only noninfectious peritendinitis), and bursitis (only noninfectious bursitis) Topical intradermal injection ● Eczema and dermatitis† (acute eczema, subacute eczema, chronic eczema, contact dermatitis, nummular eczema, autosensitization dermatitis, atopic dermatitis, pediatric eczema, lichen simplex chronicus Vidal, other neurodermatitis, seborrhoeic dermatitis, keratodermia tylodes palmaris progressiva, other dermatitis of the fingers, genital or anal eczema, dermatitis/eczema of the auricle or ear

Brand name (Marketing authorization holder)	**Indications**
	canal, dermatitis/eczema of the nasal vestibule or around nasal ala, etc.) (If possible, this drug should not be administered to patients with non-serious symptoms. Topical injection should be used in only patients with serious infiltration or lichen), prurigo (including pediatric strophulus, urticarial lichen, and urticaria perstans) † (to be administered to only patients with serious symptoms), psoriasis and variants (psoriasis [with serious symptoms], arthropathic psoriasis, erythrodermic psoriasis, pustular psoriasis, acrodermatitis continua, impetigo herpetiformis, Reiter's syndrome) †, lichen planus (to be administered to only patients with serious symptoms) †, circumscribed scleroderma, areata alopecia (to be administered to only patients with serious symptoms) †, and early stage of keloid and prevention of keloid† ● Post-treatment for otorhinolaryngological surgery Nebulizer ● Bronchial asthma ● Diffuse interstitial pneumonia (pulmonary fibrosis) (including radiation pneumonitis) ● Allergic rhinitis, pollinosis (hay fever), sinusitis/nasal polyps, laryngitis/laryngeal oedema, laryngeal polyp/nodules, esophagitis (corrosive esophagitis after endoscopy), and post-treatment for esophageal dilation and otorhinolaryngological surgery Injection in the nasal cavity ● Allergic rhinitis, pollinosis (hay fever), sinusitis/nasal polyps, and post-treatment for otorhinolaryngological surgery Injection into paranasal sinus ● Sinusitis/nasal polyps, and post-treatment for otorhinolaryngological surgery Injection into nasal turbinate ● Allergic rhinitis, pollinosis (hay fever), and post-treatment for otorhinolaryngological surgery Injection into nasal polyp ● Sinusitis/nasal polyps

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Brand name (Marketing authorization holder)	**Indications**
	Injection in the larynx/trachea ● Laryngitis/laryngeal oedema, laryngeal polyp/nodules, and post-treatment for otorhinolaryngological surgery Injection in the middle ear cavity ● Acute/chronic otitis media, serous otitis media/eustachian tube stenosis, and post-treatment for otorhinolaryngological surgery Injection into the eustachian tube ● Serous otitis media/eustachian tube stenosis Injection into the oesophagus ● Esophagitis (corrosive esophagitis after endoscopy) and post-treatment for esophageal dilation and otorhinolaryngological surgery NOTE †This drug should be used only when the patient does not, or is not expected to, sufficiently respond to topical treatment.

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