



Summary of Investigation Results

NSAIDs that Inhibit Cyclooxygenase (excluding agents contraindicated for pregnant women)

February 25, 2021

Non-proprietary name

See Attachment

Branded name (Marketing authorization holder)

See Attachment

Indications

See Attachment

Summary of revisions

• 1, 3, 7-9, 12-14, 16, 19, 24, 27-31, 35-40, 44-47, 49-53, 55

Cautionary statements should be added to the Use during Pregnancy, Delivery or Lactation section that renal impairment and decreased urine output in fetuses as well as accompanying oligohydramnios have been observed following use of cyclooxygenase inhibitors (oral dosage form or suppository) in pregnant women and that administration of the drugs, if deemed necessary, should be limited to the minimum effective use with amniotic fluid monitored as necessary.

• 2, 4-6, 10, 11, 15, 17, 18, 20-23, 25, 26, 32-34, 41-43, 48, 54

A statement should be added to the Use during Pregnancy, Delivery or Lactation section that renal impairment and decreased urine output, as well as accompanying oligohydramnios, have been observed in fetuses following use of cyclooxygenase

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inhibitors (oral dosage form or suppository) in pregnant women.

Investigation results and background of the revision

Based on the risks of renal impairment and decreased urine output in foetuses, as well as accompanying oligohydramnios observed in the cases of NSAIDs administration to pregnant women, the US FDA decided to take a measure to alert healthcare professionals and consumers that prescribing NSAIDs in women between 20 to 30 weeks of pregnancy should be limited. Specifically, the agency recommends that such prescribing, if determined necessary, be limited to the lowest effective dose and shortest duration possible. In response to the decision, necessity and scope of revision of the Japanese package inserts of NSAIDs were discussed.

Given the reported findings identified in published literature including non-clinical and clinical studies, observational studies, and case reports listed below, MHLW/PMDA ascribed the risks to the effects of cyclooxygenase 2 inhibitors and concluded, in consultation with expert advisors, that revision of the package inserts was necessary for all the NSAIDs that inhibit cyclooxygenase as their pharmacological effects.

- Expression of cyclooxygenase 2 in the kidney of human foetuses has been reported (Pediatr Develop Pathol. 2001; 4: 461-6、 Kidney Int. 2002; 61: 1210-9).
- Dose-dependent AFI* decrease associated with selective inhibitors of cyclooxygenase 2 has been observed in a prospective observational study in high-risk women for premature delivery. (J Obstet Gynaecol 2004; 24: 226-9).
- Decreased renal blood flow and glomerular filtration have been reported as observed in a dose-dependent manner with selective inhibitors of cyclooxygenase 2 in newborn rabbits. (Pediatr Res. 2004; 55: 254-60).

While the US FDA's measure specified women between 20 to 30 weeks of pregnancy as its scope, MHLW/PMDA decided that precaution without specific terms of pregnancy when foetuses are susceptible to the risk of renal impairment, etc. was appropriate in view of the following considerations:

- Terms of pregnancy of the cases reported in the literature, etc. were confined to a certain range. The significant number of prophylactic administrations for premature birth may

probably have affected this.

- Taking into account that foetal urine production begins in the first trimester of pregnancy (8-11 weeks) and that no findings have been obtained to actively support that the effects of NSAIDs that decrease foetal renal blood flow do not occur at 20 weeks of pregnancy or earlier, it could not be determined that the presence or absence of the risk depends on the stage of pregnancy.

For low-dose aspirin prophylaxis and topical use preparations among those reviewed, revision of the package insert as follows was considered necessary.

- Regarding low-dose aspirin prophylaxis (2, 4-6, and 15) to which the US measure does not apply, providing information on the risk was considered necessary because of its systemic therapeutic effects expected by its inhibition of cyclooxygenase. Any additional precaution was not, however, considered necessary in view of the routine use under the supervision of a physician assumed with low-dose aspirin prophylaxis.
- Preparations for topical use (10, 11, 17, 18, 20-23, 25, 26, 32-34, 41-43, 48, 54) exhibit relatively low-levels of exposure compared to those preparations for which systemic effects are expected. Therefore, no additional precautions were considered necessary.

Regarding salts for patch tests, no revision of the package insert was considered necessary this time given their characteristics such as intended uses or methods of use.

Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

Cases involving foetal renal impairment and oligohydramnios

2

A total of 5 cases have been reported to date (A causal relationship between the drug and event could not be established in any of the cases.) No patient mortalities have been reported to date.

Cases involving events other than foetal renal impairment and oligohydramnios

No cases have been reported to date.

*: An index of amniotic fluid volume determined by dividing the uterine cavity into four and adding up the
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depth of amniotic fluid of each quadrant (the longest length from the uterine wall to the foetus)

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	Branded name	Marketing authorization holder	Indications
1.	Aspirin (Therapeutic category 114: Antipyretics, analgesics and anti-inflammatory agents)	Aspirin "Yoshida", and the others	Yoshida Pharmaceutical Company Limited, and the others	<ul style="list-style-type: none">• Rheumatoid arthritis, rheumatic fever, osteoarthritis, ankylosing spondylitis, peri-arthritis, fibrositis, postoperative pain, toothache, symptomatic neuralgia, arthralgia, lumbago, myalgia, pain caused by sprain, contusion, and gout, headache, painful menses• Antipyresis/analgesia in the following diseases: Acute upper respiratory tract inflammation (including acute upper respiratory tract inflammation accompanied by acute bronchitis)• Kawasaki disease (including cardiovascular sequelae of Kawasaki disease (*not applicable to certain drugs))
2.	Aspirin (Therapeutic category 339: Other agents relating to blood and body fluids)	Bayaspirin tablets 100 mg, and the others	Bayer Yakuhin Ltd., and the others	<ul style="list-style-type: none">• Prevention of thrombus and embolus formation in the following diseases: Angina pectoris (chronic stable angina, unstable angina) Myocardial infarction Ischemic cerebrovascular disorder (transient ischaemic attack (TIA), cerebral infarction)• Prevention of thrombus/embolus formation after coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA)• Kawasaki disease (including cardiovascular sequelae of Kawasaki disease)
3.	Aspirin/dialuminate (Therapeutic category 114:	Bufferin Combination Tablet A330	Lion Corporation	Headache, toothache, ,painful menses, antipyresis of common cold, rheumatoid arthritis, rheumatic fever, ,symptomatic neuralgia

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	Antipyretics, analgesics and anti-inflammatory agents)			
4.	Aspirin/dialuminate (Therapeutic category 339: Other agents relating to blood and body fluids)	Bassamin-A81, and the others	Teva Takeda Pharma Ltd., and the others	<ul style="list-style-type: none">• Prevention of thrombus/embolus formation in the following diseases: Angina pectoris (chronic stable angina pectoris, unstable angina) Myocardial infarction Ischemic cerebrovascular disorder (transient ischaemic attack (TIA), cerebral infarction)• Prevention of thrombus/embolus formation after coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA)• Kawasaki disease (including cardio vascular sequelae of Kawasaki disease)
5.	Aspirin/vonoprazan fumarate	Cabpirin Combination Tablets	Takeda Pharmaceutical Company Limited.	Prevention of thrombus/embolus formation in the following diseases or after surgery (limited to patients with a history of gastric ulcer or duodenal ulcer): <ul style="list-style-type: none">• Angina pectoris (chronic stable angina pectoris, unstable angina, myocardial infarction, ischemic cerebrovascular disorder (transient ischaemic attack (TIA), cerebral infarction)• After coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA)
6.	Aspirin/lansoprazole	Takelda Combination Tablets	Teva Takeda Yakuhin Ltd.	Prevention of thrombus/embolus formation in the following diseases or after surgery (limited to patients with a history

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				of gastric ulcer or duodenal ulcer): • Angina pectoris (chronic stable angina pectoris, unstable angina), myocardial infarction, ischemic cerebrovascular disorder (transient ischaemic attack (TIA), cerebral infarction • After coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA)
7.	Ampiroxicam	Flucam Capsules 13.5 mg, 27 mg	Pfizer Japan Inc.	Analgesia/anti-inflammation in the following diseases and symptoms: Rheumatoid arthritis Osteoarthritis, Lumbago Periarthritis scapulohumeralis Cervico-omo-brachial syndrome
8.	Isopropylantipyrine	Yoshipyrine	Yoshida Pharmaceutical Company Limited	Used in the preparation of antipyretic/analgesic
9.	Ibuprofen	Brufen Tablets 100, 200, Brufen Granule 20%, and the others	Kaken Pharmaceutical Co., Ltd., and the others	• Anti-inflammation/analgesia in the following diseases and symptoms: Rheumatoid arthritis, arthralgia and arthritis, neuralgia and neuritis, back and low back pain, cervicobrachial syndrome, adnexitis, dysmenorrhea, erythema (erythema nodosum, erythema multiforme exudativum, erythema annulare centrifugum) • Post-operative or post-traumatic anti-inflammation/analgesia

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				<ul style="list-style-type: none"> • Antipyresis/analgesia in the following diseases: Acute upper respiratory tract inflammation (including acute upper respiratory tract inflammation accompanied by acute bronchitis)
10.	Ibuprofen piconol	a. Vesicum Ointment 5%, Vesicum Cream 5% b. Staderm Ointment 5%, Staderm Cream 5%	a. Hisamitsu Pharmaceutical Co., Inc. b. Torii Pharmaceutical Co., Ltd.	<ul style="list-style-type: none"> • Acute eczema, contact dermatitis, atopic dermatitis, chronic eczema, rosacea-like dermatitis/perioral dermatitis • Herpes zoster • Acne vulgaris (*cream only)
11.	Indometacin	a. Idomethine Kowa Gel 1%, Idomethine Kowa Sol 1%, Idomethine Kowa Cream 1%, Idomethine Kowa Pap b. Inteban Ointment 1%, Inteban Cream 1%, Inteban Solution for Cutaneous Application c. Catlep Tape 35 mg, 70 mg, Catlep Pap 70 mg d. Laction Pap 70 mg	a. Kowa Company, Ltd. b,c. Teikoku Seiyaku Co., Ltd. d. Teika Pharmaceutical Co., Ltd. e. Hisamitsu Pharmaceutical Co., Inc. f. Towaseiyaku Co., Ltd.	Analgesia and anti-inflammation in the following diseases and symptoms: Osteoarthritis Periarthritis scapulohumeralis Tendonitis/tenosynovitis Peritendinitis Humerus epicondylitis (tennis elbow, etc.) Myalgia Post-traumatic swelling/pain

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		e. Inside Pap 70 mg f. Korifumecin Pap 70 mg g. Zempack Pap 70 h. Hapstar - ID 70 mg i. Intenurse Pap 70 mg	g. Kyukyu Pharmaceutical Co., Ltd. h. Oishi Koseido Co., Ltd. i. Toko Pharmaceutical industries Co., Ltd., and the others	
12.	Ethenzamide	Ethenzamide "Yoshida"	Yoshida Pharmaceutical Company Limited	Used in the preparation of antipyretic/analgesic
13.	Etodolac	a. Osteluc Tablets 100, 200	a. Aska Pharmaceutical Co., Ltd.	• Anti-inflammation/analgesia in the following diseases and symptoms: Rheumatoid arthritis, osteoarthritis, lumbago, periarthritis scapulohumeralis, cervicobrachial syndrome, tenosynovitis • Post-operative or post-traumatic anti-

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		b. Osteluc Tablets 100, 200, Hypen Tablets 100 mg, 200 mg, and the others	b. Nippon Shinyaku Co., Ltd., and the others	inflammation/analgesia
14.	Esflurbiprofen/mentha oil	Loqoa tape	Taisho Pharmaceutical Co., Ltd.	Analgesia/anti-inflammation in osteoarthritis
15.	Clopidogrel sulfate/aspirin	ComPlavin Combination Tablets, and the others	Sanofi K.K., and the others	The following ischaemic heart diseases for which percutaneous coronary Intervention (PCI) is indicated: Acute coronary syndromes (unstable angina, non-ST-elevation myocardial infarction, ST-elevation myocardial infarction) Stable angina pectoris, old myocardial infarction
16.	Ketoprofen (Therapeutic category 114: Antipyretics, analgesics and anti-inflammatory agents)	a. Capisten IM 50 mg b. Ketoprofen Suppositories 50 mg "JG", Ketoprofen Suppositories 75 mg "JG", and the others	a. KISSEI PHARMACEUTICAL CO., LTD. b. Choseido Pharmaceutical Co., Ltd., and the others	a. 1. Analgesia/anti-inflammation in the following diseases and conditions: Post-operation, traumatic injury, various cancer types, gout attack, symptomatic neuralgia 2. When emergency antipyresis is required b. • Analgesia/anti-inflammation/antipyresis in the following diseases and symptoms: Rheumatoid arthritis, osteoarthritis, lumbago, cervico-omobrachial syndrome, symptomatic neuralgia • Post-traumatic or post-operative analgesia/anti-

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				inflammation
17.	Ketoprofen (Therapeutic category 264: Analgesics, anti-itchings, astrigents and anti-inflammatory agents)	a. Sector Gel 3%, Sector Lotion 3%, Sector Cream 3% b. Mohrus Tape 20 mg, Mohrus Tape L 40 mg, Mohrus Pap 30 mg, 60 mg, Mohrus Paps XR 120 mg, 240 mg c. Miltax Pap 30 mg, and the others	a,b. Hisamitsu Pharmaceutical Co., Inc. c. Nipro Pharma Corporation, and the others	Analgesia/anti-inflammation in the following diseases and symptoms: Osteoarthritis, periarthritis scapulohumeralis, tendonitis/tenosynovitis, peritendinitis, humerus epicondylitis (tennis elbow, etc.), myalgia, post-traumatic swelling/pain
18.	Salicylic acid (Therapeutic category 265: Anti-dermo-infectives)	5% Salicylic Acid Ointment Toho, 10% Salicylic Acid Ointment Toho, and the others	Toho Pharmaceutical Co., Ltd. , and the others	Psoriasis, tinea (tinea superficialis capitis, trichophytia maculovesiculosa, trichophytia pompholyticiformis, tinea cruris), tinea versicolor, pityriasis rubra, erythrasma, keratosis (ichthyosis vulgaris, congenital ichthyosis, keratosis pilaris, congenital palmoplantar keratoderma (tumor), Darier's disease, Toyama pityriasis circinata), eczema (accompanied by keratinization), perioral dermatitis, palmoplantar pustulosis, pityriasis Hebra, atopic dermatitis, acne, furuncle, axillary odor, hyperhidrosis, and other hyperkeratotic dermatitises

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19.	Sodium salicylate/dibucaine combination drug	Neo Vitacain Injection 2 mL, 5 mL, Neo Vitacain Injection Syringe 2 mL, 5 mL	VITACAIN PHARMACEUTICAL Co., LTD.	Symptomatic neuralgia, myalgia, lumbago, periarthritis scapulohumeralis
20.	Methyl salicylate	Methyl Salicylate 「Toho」	Toho Pharmaceutical Co., Ltd.	Analgesia/anti-inflammation in the following: Arthralgia, myalgia, contusion, sprain
21.	Methyl salicylate/glycyrrhetic acid combination stick	Stickzenol A	Mikasa Seiyaku co., ltd	Analgesia/anti-inflammation in the following: Contusion, sprain, myalgia, arthralgia, fracture pain, insect sting
22.	Methyl salicylate/diphenhydramine combination drug (8)	Air-Salonpas	Hisamitsu Pharmaceutical Co., Inc.	Analgesia/anti-inflammation in the following: Sprain, contusion, myalgia, arthralgia, fracture pain
23.	Salicylic acid adhesive plaster	Speelko M	NICHIBAN Co., Ltd.	Keratin exfoliation of warts, corns, tyloma
24.	Zaltoprofen	a. Soleton Tablets 80 b. Peon tablets 80, and the others	a. Nippon Chemiphar Co., Ltd.	• Anti-inflammation/analgesia in the following diseases and symptoms: Rheumatoid arthritis, osteoarthritis, lumbago, periarthritis scapulohumeralis, cervico-omo-brachial syndrome • Post-operative, post-traumatic, or post-tooth extraction

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			b. Zeria Pharmaceutical Co., Ltd., and the others	anti-inflammation/analgesia
25.	Diclofenac sodium	a. Voltaren Lotion 1%, Voltaren Gel 1%, Voltaren Tape 15 mg, 30 mg b. Naboal Gel 1%, Naboal Tape 15 mg, Naboal Pap 70 mg, Naboal Tape L 30 mg, Naboal Pap 140 mg	a. DOJIN IYAKU-KAKO CO., LTD. b. Hisamitsu Pharmaceutical Co., Inc.	Analgesia/anti-inflammation in the following diseases and symptoms: Osteoarthritis, peri-arthritis scapulohumeralis, tendonitis/tenosynovitis, peritendinitis, humerus epicondylitis (tennis elbow, etc.), myalgia (myofascial low back pain), post-traumatic swelling/pain
26.	Suprofen	a. Sulprotin Ointment 1%, Sulprotin Cream 1% b. Topalgic Ointment 1%, Topalgic Cream 1% c. Srendam Ointment 1%	a. Teva Takeda Pharma Ltd. b. Alfresa Pharma Corporation c. Sun Pharma Japan Limited	Acute eczema, contact dermatitis, atopic dermatitis, chronic eczema, asteatotic eczema, rosacea-like dermatitis/perioral dermatitis, herpes zoster

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27.	Sulpyrine hydrate	Sulpyrine Injection 250 mg "NP", and the others	Nipro Corporation, and the others	Emergency antipyresis when other antipyretics would be ineffective or use of them is impossible
28.	Celecoxib	Celecox Tablets 100 mg, 200 mg, and the others	Astellas Pharma Inc., and the others	<ul style="list-style-type: none">• Anti-inflammation/analgesia in the following diseases and symptoms: Rheumatoid arthritis, osteoarthritis, lumbago, periarthritis scapulohumeralis, cervico-omo-brachial syndrome, tendonitis/tenosynovitis• Post-operative, post-traumatic, or post-tooth extraction anti-inflammation/analgesia
29.	Tiaprofenic acid	Surgam Tablets 100 mg, 200 mg	Sanofi K.K.	<ul style="list-style-type: none">• Anti-inflammation/analgesia in the following diseases and symptoms: Rheumatoid arthritis, osteoarthritis, periarthritis scapulohumeralis, cervico-omo-brachial syndrome, lumbago• Antipyresis/analgesia in the following diseases: Acute upper respiratory tract inflammation (including acute upper respiratory tract inflammation accompanied by bronchitis acute)• Post-operative or post-traumatic anti-inflammation/analgesia
30.	Nabumetone	Relifen Tab. 400 mg	Sanwa Kagaku Kenkyusho Co., Ltd	Anti-inflammation/analgesia in the following diseases and symptoms: Rheumatoid arthritis, osteoarthritis, lumbago, cervico-omo-brachial syndrome, periarthritis scapulohumeralis

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31.	Naproxen	Naixan Tablets 100 mg	Mitsubishi Tanabe Pharma Corporation	<ul style="list-style-type: none">• Anti-inflammation, analgesia, and antipyresis in the following diseases: Rheumatoid arthritis, osteoarthritis, gout attack, ankylosing spondylitis, lumbago, peri-arthritis scapulohumeralis, cervicobrachial syndrome, tendonitis/tenosynovitis, dysmenorrhea, herpes zoster• Post-operative or post-traumatic anti-inflammation, analgesia• Post-tooth extraction or post-minor operative anti-inflammation, analgesia in the dental/oral surgery fields
32.	Cataplasms/Gel Patches (3-14)	<ul style="list-style-type: none">a. MS reishippu 「TAIHO」b. MS Cool Cataplasms "Takamitsu", and the others	<ul style="list-style-type: none">a. OKAYAMA TAIHO Pharmaceutical Co., Ltd.b. TAKAMITSU, and the others	Analgesia/anti-inflammation in the following: Sprain, contusion, myalgia, arthralgia, fracture pain
33.	Cataplasms/Gel Patches (4-12)	Honesip, and the others	SIOE PHARMACEUTICAL CO., LTD., and the others	Analgesia/anti-inflammation in the following: Sprain, contusion, myalgia, arthralgia, fracture pain

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34.	Cataplasms/Gel Patches (5-11)	GS PLASTER C 「YUTOKU」	YUTOKU PHARMACEUTICAL IND. Co., LTD.	Analgesia/anti-inflammation in the following: Sprain, contusion, myalgia, arthralgia, fracture pain
35.	Non-pyrine common cold medicine (2)	Pelex combination granule	TAIHO Pharmaceutical Co., Ltd.	Improvement and alleviation in the following symptoms accompanying common cold or upper respiratory inflammation: Nasal discharge, nasal congestion, pharyngeal/laryngeal pain, cough, sputum, headache, arthralgia, myalgia, pyrexia
36.	Non-pyrine common cold medicine (3)	Pediatric Pelex combination granule	TAIHO Pharmaceutical Co., Ltd.	Improvement and alleviation in the following symptoms accompanying common cold or upper respiratory inflammation: Nasal discharge, nasal congestion, pharyngeal/laryngeal pain, cough, sputum, headache, arthralgia, myalgia, pyrexia
37.	Non-pyrine common cold medicine (4)	PL Combination Granules, and the others	Shionogi Pharma Co., Ltd., and the others	Improvement and alleviation in the following symptoms accompanying common cold or upper respiratory inflammation: Nasal discharge, nasal congestion, pharyngeal/laryngeal pain, headache, arthralgia, myalgia, pyrexia
38.	Non-pyrine common cold medicine (5)	PL Combination Granules for Infant	Shionogi Pharma Co., Ltd.	Improvement and alleviation in the following symptoms accompanying common cold or upper respiratory inflammation: Nasal discharge, nasal congestion, pharyngeal/laryngeal pain, headache, arthralgia, myalgia, pyrexia

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39.	Pyrazolone-based antipyretics, analgesics and anti-inflammatory combination drug (4)	SG Combination Granules	Shionogi Pharma Co., Ltd.	Antipyresis for common cold, ear pain, sore throat, painful menses, headache, toothache, symptomatic neuralgia, traumatic pain
40.	Piroxicam (Therapeutic category 114: Antipyretics, analgesics and anti-inflammatory agents)	Baxo Capsule 10, 20, and the others	FUJIFILM Toyama Chemical Co., Ltd., and the others	Anti-inflammation, analgesia in the following diseases and symptoms: Rheumatoid arthritis Osteoarthritis Lumbago Periarthritis scapulohumeralis Cervico-omo-brachial syndrome
41.	Piroxicam (Therapeutic category 264: Analgesics, anti-itchings, astringents and anti-inflammatory agents)	a. Baxo Ointment 0.5% b. Feldene Ointment 0.5%	a. FUJIFILM Toyama Chemical Co., Ltd. b. Pfizer Japan Inc.	Analgesia/anti-inflammation in the following diseases and symptoms: Osteoarthritis, periarthritis scapulohumeralis, tendonitis/tenosynovitis, peritendinitis, humerus epicondylitis (tennis elbow, etc.), myalgia (myofascitis, etc), post-traumatic swelling/pain

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42.	Felbinac	a. Napageln Ointment 3%, Napageln Lotion 3%, Napageln Cream 3% b. Seltouch Tape 70, Seltouch Pap 70, 140, and the others	a,b. Teikoku Seiyaku Co., Ltd., and the others	Analgesia/anti-inflammation in the following diseases and symptoms: Osteoarthritis Myofascial low back pain (a. only) Periarthritis scapulohumeralis Tendonitis/tenosynovitis Peritendinitis Humerus epicondylitis (tennis elbow, etc.) Myalgia Post-traumatic swelling/pain
43.	Adrenal extract/heparinoid combination drug	Zestak Cream	Mikasa seiyaku co., ltd	Osteoarthritis (excluding deep joints), relief of swelling/pain of small joint caused by rheumatoid arthritis, myofascial low back pain, periarthritis scapulohumeralis, tendonitis/tenosynovitis/peritendinitis, post-traumatic swelling/pain
44.	Bucolome	Paramidin Capsules 300 mg	Aska Pharmaceutical. Co., Ltd.	<ul style="list-style-type: none"> • Post-operative or post-traumatic relief of inflammation and swelling • Anti-inflammation/analgesia/antipyresis in the following diseases: Rheumatoid arthritis, osteoarthritis, Cystitis Erythema multiforme exudativum Acute sinusitis, acute otitis media Acute uterine adnexitis Management of hyperuricemia of gout

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No.	Non-proprietary name	Branded name	Marketing authorization holder	Indications
45.	Pranoprofen	Niflan Tablets 75 mg, and the others	Mitsubishi Tanabe Pharma Corporation, and the others	<ul style="list-style-type: none">• Anti-inflammation/analgesia in the following diseases and symptoms: Rheumatoid arthritis, osteoarthritis, lumbago, cervico-omobrachial syndrome, pericementitis, gout attack• Antipyresis/analgesia in the following diseases: Acute upper respiratory tract inflammation (including acute upper respiratory tract inflammation accompanied by bronchitis acute)• Post-traumatic, post-manor operative, or post tooth extraction anti-inflammation/analgesia
46.	Flufenamate aluminum	Opyrin tab. 125 mg, 250 mg	Taisho Pharmaceutical Co., Ltd.	<ul style="list-style-type: none">• Anti-inflammation, analgesia, antipyresis in the following diseases: Rheumatoid arthritis, osteoarthritis, spinal osteoarthritis, lumbago, scapula periartthritis, arthritis, symptomatic neuralgia• Anti-inflammation, analgesia in the following diseases: After tooth extraction, dental pulpitis, pericementitis• Anti-inflammation in the following inflammatory diseases: Cystitis, prostatitis, herpes zoster, eczema/dermatitis, erythema, post-operative or post-traumatic inflammatory reactions in various medical fields• Antipyresis/analgesia in the following diseases: Acute upper respiratory tract inflammation (including acute upper respiratory tract inflammation accompanied by acute bronchitis)

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47.	Flurbiprofen (Therapeutic category 114: Antipyretics, analgesics and anti-inflammatory agents)	Froben Tablets 40, Froben Granule 8%	Kaken Pharmaceutical Co., Ltd.	<ul style="list-style-type: none"> • Analgesia/anti-inflammation in the following diseases and symptoms: Rheumatoid arthritis, osteoarthritis, lumbago, dental pulpitis, pericementitis • Post-tooth extraction or post-minor surgery analgesia/anti-inflammation in the field of dentistry
48.	Flurbiprofen (Therapeutic category 264: Analgesics, anti-itchings, astrigents and anti-inflammatory agents)	a. Yakuban tape 20 mg, 40 mg, 60 mg b. Zepolas Tape 20 mg, 40 mg, Zepolas Pap 40 mg, 80 mg c. Adofeed Pap 40 mg d. Fulruban Pap 40 mg, and the others	a. TOKUHON Corporation b. mikasa seiyaku co., ltd c. LEAD CHEMICAL Co., Ltd. d. Taikyo pharmaceutical co., ltd.	Analgesia/inflammation in the following diseases and symptoms: Osteoarthritis, periartthritis scapulothumeralis, tendonitis/tenosynovitis, peritendinitis, humerus epicondylitis (tennis elbow, etc.), myalgia, post-traumatic swelling/pain
49.	Flurbiprofen axetil	Ropion Intravenous 50 mg	Kaken Pharmaceutical Co., Ltd.	Analgesia in the following diseases and conditions: After surgery, various cancer types
50.	Migrenin	Migrenin "Kenei"	KENEI Pharmaceutical Co., Ltd.	Headache
51.	Mefenamic acid	Pontal Syrup 3.25%, Pontal Capusules 250 mg, Pontal	Daiichi Sankyo Co., Ltd., and the others	<ul style="list-style-type: none"> • Post-surgery or traumatic relief of inflammation and swelling • Analgesia, anti-inflammation, antipyresis in the following

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		Powder 50%, Pontal Fine Granules 98.5%, and the others		diseases and symptoms: Osteoarthritis, lumbago, symptomatic neuralgia, headache (when other agents are ineffective), sinusitis, painful menses, postpartum pain, toothache • Antipyresis/analgesia in the following diseases: Acute upper respiratory tract inflammation (including acute upper respiratory tract inflammation accompanied by acute bronchitis)
52.	Mofezolac	Disopain Tablets 75	Nipro ES Pharma co., Ltd.	• Anti-inflammation/analgesia in the following diseases and symptoms: Lumbago, cervicobrachial syndrome, periarthritis scapulohumeralis • Post-operative, post-traumatic, or post-tooth extraction anti-inflammation/analgesia
53.	Loxoprofen sodium hydrate (Therapeutic category 114: Antipyretics, analgesics and anti-inflammatory agents)	Loxonin Tablets 60 mg, Loxonin Fine Granules 10%, and the others	Daiichi Sankyo Co., Ltd., and the others	• Anti-inflammation/analgesia in the following diseases and symptoms: Rheumatoid arthritis, osteoarthritis, lumbago, periarthritis scapulohumeralis, cervico-omo-brachial syndrome, toothache • Post-operative, post-traumatic, or post-tooth extraction anti-inflammation/analgesia • Antipyresis/analgesia in the following diseases Acute upper respiratory tract inflammation: (including acute upper respiratory tract inflammation accompanied by acute bronchitis)

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54.	Loxoprofen sodium hydrate (Therapeutic category 264: Analgesics, anti-itchings, astringents and anti-inflammatory agents)	a. Loxonin Gel 1% b. Loxonin Tape 50 mg, 100mg, Loxonin Pap 100 mg, and the others	a. Daiichi Sankyo Co., Ltd. b. LEAD CHEMICAL Co., Ltd., and the others	Anti-inflammation/analgesia in the following diseases and symptoms: Osteoarthritis, myalgia, post-traumatic swelling/pain
55.	Lornoxicam	Lorcam tab. 2 mg, 4 mg, and the others	Taisho Pharmaceutical Co., Ltd., and the others	<ul style="list-style-type: none">• Anti-inflammation/analgesia in the following diseases and symptoms: Rheumatoid arthritis, osteoarthritis, lumbago, cervico-omobrachial syndrome, peri-arthritis scapulohumeralis• Post-operative, post-traumatic, or post-tooth extraction anti-inflammation/analgesia

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