MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Classification of Naproxen

Submission to the Medicines Classification Committee

Medsafe
February 2023

MANATŪ HAUORA

Te Kāwanatanga o Aotearoa
New Zealand Government

Contents

Part A

International Non-proprietary Name of medicine

Naproxen
Naproxen sodium

Proprietary name (s)

Below are naproxen products which are currently marketed in NZ:

Proprietary name	Sponsor	TT50 number	Classification
Naprogesic	Bayer New Zealand Limited,	TT50-3539/1a	Pharmacy-only
Sonaflam	Multichem NZ Limited	TT50-6983	Pharmacy-only
Naprosyn SR	Clinect NZ Pty Limited	TT50-2275/3a	Prescription
Noflam	Viatris Limited	TT50-3573	Prescription

Name and contact details of company/organisation/individual submitting to MCC

Pharmacovigilance Team, Clinical Risk Management, Medsafe,
Email: medsafeadrquery@health.govt.nz

Present classification of the medicine

Naproxen is classified as a pharmacy-only medicine when sold in solid dose form containing 250 mg or less per dose form in packs of not more than 30 tablets or capsules.

Naproxen is classified as a prescription medicine, except when sold as a pharmacy-only medicine

Dose form, strength, and pack size

Name	Dose form	Strength (s)	Pack size (s)
Pharmacy-only products			
Naprogesic	Tablet	275mg naproxen sodium	4 tablets, 12 tablets, 24 tablets
Sonaflam	Film coated tablet	275mg naproxen sodium	12 tablets, 24 tablets
Prescription products			
Naprosyn SR	Modified release tablet	1000mg, 750mg naproxen	7 tablets, 90 tablets, 28 tablets.
Noflam	Tablet	250mg, 500mg naproxen	100 tablets, 500 tablets.

(250mg naproxen is equivalent to 275mg naproxen sodium)

Classification status in other countries

Naproxen and/or naproxen sodium is available over the counter (OTC) in other countries, including the United Kingdom (UK), Australia, Canada, and USA (United States).

In Australia, naproxen is available as a pharmacy only, restricted and prescription medicine.

The Australian Poisons Standard October 2022 specifies the following:

- *Schedule 2 (Pharmacy Medicine):* in divided preparations containing 250 mg or less of naproxen per dosage unit in packs of 30 or less dosage units.
- *Schedule 3 (Pharmacist Only Medicine):* in a modified release dosage form or 600 mg or less of naproxen per dosage unit in packs of 16 or less dosage units when labelled not for the treatment of children under 12 years of age.
- *Schedule 4 (Prescription medicine):* except when included in Schedule 2 or 3.

In the UK, naproxen is a pharmacy medicine indicated for the treatment of primary dysmenorrhoea in women aged between 15 and 50 years.

Further information on naproxen OTC products in other countries is outlined in Table 1, in Part B.

Dates of original consent to distribute (OTC only)

Approved and marketed:

- Naprogesic: 12 November 1992
- Sonaflam: 11 March 2004

Approved but not currently marketed:

- SonaTab: 19 August 2021

Previous products that have been approved and date the approval lapsed:

- Aleve (approved: 8 July 1999, lapsed: 9 September 2011)
- Naprogesic tablet (organic coating) (approved: 27 July 1986, lapsed: 20 August 1999).

Part B

Background

Naproxen belongs to a class of medicines called non-steroidal anti-inflammatories (NSAIDs). NSAIDs work by reducing the production of prostaglandins through inhibition of the enzymes cyclo-oxygenase (COX). They have analgesic and anti-inflammatory properties and may be used for acute pain or chronic inflammatory conditions [1].

NSAIDs are commonly used to manage pain and inflammation caused by injury, or by conditions such as gout, rheumatoid arthritis, osteoarthritis, headache, dental pain, and period pain. For some indications, NSAIDs are available over the counter (OTC), and provide an easily accessible analgesic option [2].

The purpose of this report to is provide further information relating to current naproxen pharmacy-only medicines in New Zealand.

Indication

Medicines that are sold as pharmacy-only, do not require input from a health professional. The indications for use should be easily self-diagnosed, and self-managed by the consumer [3].

Treatment of acute minor pain and/or inflammation are appropriate indications to be managed with pharmacy-only medicines. Symptoms of such conditions are likely not to persist and can be managed by intermittent, short-term use of NSAIDs [3].

Information about the indication and doses of naproxen OTC products in NZ and overseas are outlined in Table 1.

Naprogesic and Sonaflam are pharmacy-only products in NZ, that contain naproxen sodium. There are similarities between the indications and doses of these products, when compared to naproxen prescription products outlined in Table 2.

Table 1: Information on over the counter (OTC) naproxen products, by country, indication, dosing instructions and maximum daily dose

Product	Tablet strength	Age for use	Indication	Dosing instructions	Maximum daily dose (275mg naproxen sodium = *250mg naproxen)*
New Zealand					
Naprogesic[1]	275mg naproxen sodium	Adolescents onset of puberty	Temporary relief from the aches and pains associated with period pain such as abdominal cramps, headache, and lower back pain.	2 tablets with food, followed by 1 tablet every 6-8 hours as required	1375mg *(= 1250mg naproxen)*
Sonaflam[2]	275mg naproxen sodium	Adults and children >12 years	Headaches, fever, minor aches, and pains	1 or 2 caplets, then 1 caplet every 8-12 hours	825mg *(=750mg naproxen)*
			Pain with inflammation, musculoskeletal disorders, post-operative, and period pain	1 or 2 caplets, then 1 caplet every 6-8 hours.	1375mg *(=1250mg naproxen)*
			Migraines	3 caplets, at the first sign of migraine. 1 or 2 caplets throughout the day as necessary, but not within 30 minutes of the initial dose	1375mg *(=1250mg naproxen)*
			Acute gout	3 caplets at once, then 1 caplet every 8 hours as needed until attack has passed	1375mg day 1, then 875mg *(=1250mg naproxen, then 750mg naproxen)*
Australia					
Naprogesic[3]	275mg naproxen sodium	Adolescents onset of puberty	Temporary relief from the aches and pains associated with period pain such as abdominal cramps, headache and lower back pain.	2 tablets with food, followed by one tablet every 6-8 hours as required.	1375mg *(= 1250mg naproxen)*
Pain Relief Naproxen Liquid capsules[4]	275mg naproxen sodium	Adults and children > 12 years	Temporary relief of pain and/or inflammation associated with muscular aches and pains, sprains and strains, backache, osteoarthritis, rheumatic pain, arthritis, headache, period pain, dental pain, and cold & flu. Reduces fever.	1 tablet every 8 – 12 hours. For the first dose may take 2 tablets. Maximum of two tablets in any 8-to-12-hour period.	825mg *(=750mg naproxen)*
Aleve[5]	220mg naproxen sodium	Adults and children > 12 years	Temporary relief of pain and/or inflammation associated with back pain, shoulder pain, muscle pain, osteoarthritis, joint pain, period pain, headaches, body pain, sprains and strains, arthritic, joint, and rheumatoid conditions, dental pain, sinus pain, cold & flu. Temporarily relieves stiffness associated with osteoarthritis. Reduces fever.	1 tablet (for first dose 2 tablets may be taken), every 8-12 hours as required.	660mg *(=600mg naproxen)* > 65 years: 440mg (except when directed by a doctor) *(=400mg naproxen)*

UK					
Boots period pain relief 250mg[6]	250mg naproxen	Women aged 15 – 50 years	Dysmenorrhea	On the first day 2 tablets should be taken initially, then 1 tablet every 6 – 8 hours if needed.	*750mg* (*naproxen)*
US					
Naproxen sodium 220mg[7]	220mg naproxen sodium	Adults and children > 12 years	Temporally relief of minor aches and pains due to; minor pain of arthritis, muscular aches, backache, menstrual cramps, headache, toothache, the common cold, and temporarily reduces fever.	2 tablets within the first hour, then 1 tablet every 8 – 12 hours. Maximum of two tablets in any 8-12 hour period.	660mg *(=600mg naproxen)*
Canada					
Maxidol liquid gels[8]	220mg naproxen sodium	Adults and children > 12 years	Reduction of fever and the treatment of pain	1 capsule every 8 – 12 hours. For individuals aged > 65 years, 1 capsule every 12 hours.	660mg *(=600mg naproxen)* >65 years: 440mg *(=400mg naproxen)*

Source:

1. Bayer New Zealand Limited. Naprogesic Tablet 275mg Package Label (accessed 16 January 2023).
2. Multichem NZ Limited. Sonaflam 275mg Package Label (accessed 16 January 2023).
3. Bayer Australia Ltd. Naprogesic Tablet 275mg NPS Medicinewise. URL: https://www.nps.org.au/medicine-finder/naprogesic (accessed 16 January 2023)
4. Deep Heat Australia. Pain Relief Naproxen Liquid Capsules. URL: https://www.deepheat.com.au/products/pain-relief-naproxen-liquid-capsules (accessed 16 January 2023)
5. Bayer. Aleve- Product Information. URL: https://www.alevepain.com.au/aleve (accessed 16 January 2023)
6. The Boots Company PLC. 2013. *Boots Period Pain Relief 250mg Gastro-Resistant tablets.*4 February 2013. URL: https://www.medicines.org.uk/emc/product/3935/smpc (accessed 16 January 2023)
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8. Pharmscience Inc. 2021. *Naproxen Menstrual Pain Relief Canada Label.* 24 Jan 2021. URL: https://pdf.hres.ca/dpd_pm/00061020.PDF (accessed 16 January 2023)

Gout

Gout is a common form of inflammatory arthritis. Individuals who have gout may experience an acute gout attack which can cause severe pain in the affected joint (s). Symptoms can improve with administration of anti-inflammatory medicines, such as NSAIDs. Noflam, a prescription naproxen product, is indicated for the treatment of acute gout (Table 2). A gout attack may recur in the majority of patients and long-term preventative therapy is often needed to prevent future attacks [4].

Gout is diagnosed and managed by a health professional. Management of an acute gout attack without input from a health professional, may prevent correct diagnosis and delay appropriate preventative treatment.

Individuals who have gout may be older, have other health conditions, and/or be taking other medicines. These factors may affect the appropriateness of NSAID for an acute gout attack [4].

Acute gout is listed as an indication for use on the Sonaflam packaging. However, is not listed as an indication for OTC naproxen products available overseas, or for other NSAID OTC products in NZ.

Medsafe asks the MCC to discuss whether the indication for treatment of acute gout is appropriate for a pharmacy medicine.

Musculoskeletal disorders

Musculoskeletal disorders refer to a wide range of conditions that can affect the muscles, bones, and joints. Such conditions vary in severity and management, of which some may not be appropriate to be managed without a health professional [5].

Rheumatoid arthritis (RA), osteoarthritis (OA), and ankylosing spondylitis are types of musculoskeletal disorders and are listed as indications in prescription naproxen products [6, 7]. OA and RA are chronic inflammatory conditions, that require long term management and monitoring. NSAIDs are often used for symptom management at the lowest effective dose, and either on an as needed basis to manage symptom flares, or maintenance doses for longer durations. Such dosing should be reviewed by a doctor and on clinical response of the patient [6, 8]. NSAIDs do not provide adequate benefit on their own for long-term control of disease or prevention of joint injury [9, 10].

NSAID OTC products in NZ, such as ibuprofen, list ‘arthritic pain’, ‘joint pain’, and/or ‘rheumatic pain’. These terms are easier for consumers to understand when self-selecting medicines. Those who purchase NSAIDs for arthritic conditions, such as OA or RA, should preferably be diagnosed initially by a doctor, who can assess the benefit risk of ongoing use as part of the patient's management plan [8].

The indication ‘musculoskeletal disorders’ is included for Sonaflam. This term may be confusing for consumers to relate to. Some musculoskeletal disorders correspond to long term chronic inflammatory conditions, where longer durations of NSAIDs maybe needed. Such conditions are not appropriate to be self-managed without a health professional.

Medsafe asks the MCC to discuss whether the indication for treatment of musculoskeletal disorders is appropriate for a pharmacy medicine.

Table 2: Information on prescription naproxen products, by country, indication, dosing instructions and maximum daily dose

Product	Tablet strength	Age for use	Indication	Dosing instructions	Maximum daily dose *(275mg naproxen sodium = 250mg naproxen)*
New Zealand					
Noflam[1]	250mg 500mg naproxen	Adults	Rheumatoid arthritis, osteoarthritis, ankylosing spondylitis,	500 – 1000 daily. Reduced for maintenance treatment.	1000mg *(naproxen)*
			Acute gout	750mg initially, followed by 500mg in 8 hours, and then 250mg every 8 hours until attack has passed.	N/a
			Dysmenorrhoea	500mg initially, followed by 250mg every 6-8 hours if needed	As per dosing regimen – 1250mg day 1, then 1000mg *(naproxen)*
			Adult usage other indications (eg analgesia, acute muscular skeletal disorders)	500mg initially, followed by 250mg every 6-8 hours if needed	As per dosing regimen – 1250mg day 1, then 1000mg *(naproxen)*
		>5 years	Paediatric – Juvenile rheumatoid arthritis	10mg/kg/day	N/a
Naprosyn SR[2]	750mg 1000mg Naproxen	>5 years	Rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, and other musculoskeletal disorders	750mg or 1000mg daily	1000mg *(naproxen)*
Australia					
Anaprox 550[2]	500mg Naproxen sodium	>5 years	Acute migraine headache	825 mg at the first symptom of an impending headache. An additional 275 mg to 550 mg dose can be given at least an hour after the initial dose, if necessary	1375mg *(= 1250mg naproxen)*
			Acute pain states with inflammatory component	550 mg initially followed by 275 mg every six to eight hours as required.	1375mg *(= 1250mg naproxen)*
			Rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, and chronic pain states with an inflammatory component	550 mg to 1100 mg daily	1100mg *(= 1000mg naproxen)*

Source:

1. Viatris Ltd. 2022. *Noflam New Zealand Data Sheet.* 7 July 2022. URL: https://www.medsafe.govt.nz/profs/Datasheet/n/Noflamtab.pdf (accessed 16 January 2023)
2. Clinect. 2022. *Naprosyn SR New Zealand Data Sheet*. 30 June 2022. URL: https://www.medsafe.govt.nz/profs/Datasheet/n/NaprosynSRtab.pdf (accessed 16 January 2023)
3. Atnahs Pharma Australia Pty Ltd. 2021. *Anaprox 550 (naproxen sodium) Australian Product Information*. 20 September 2021. URL: https://www.ebs.tga.gov.au (accessed 16 January 2023)

Post operative pain

Sonaflam is recommended to be used for post operative pain. The package label includes examples of post operative pain, such as following dental or minor surgery.

Ibuprofen and diclofenac pharmacy-only products, and overseas naproxen OTC products are not indicated for post operative pain (Table 1).

As per the data sheet, Voltaren Rapid 25mg, a restricted medicine, is indicated for post operative pain [11]. Supply of a restricted medicine requires discussion with a pharmacist. If there are reasons why the medicine may not be appropriate, and/or symptoms require further investigation, referral to a doctor may be recommended.

Post operative pain not adequately managed may be associated with negative consequences. Assessment of post operative pain by a health professional is beneficial to rule out any underling complications [12].

Medsafe asks the MCC to discuss whether the indication for treatment of post-operative pain is appropriate for a pharmacy medicine.

Dose

Daily doses

Doses of medicines that are pharmacy only are often lower and/or used for shorter durations than when supplied on a prescription [3].

Naprogesic and Sonaflam contain naproxen sodium 275mg, which is equivalent to naproxen 250mg. Naproxen sodium is absorbed faster compared to naproxen [6].

A dose of naproxen sodium 825mg per day, is recommended if using Sonaflam for headaches, fever, minor aches, and pain. This dosing is lower than doses of naproxen that may be used in NZ and Australian prescription products. In Australia (excluding Naprogesic), UK, USA and Canada, the maximum daily dose range of naproxen OTC products reviewed in Table 1 is 825mg of naproxen sodium or less for all indications.

Doses of up to 1375mg of naproxen sodium per day may be used as per Naprogesic and Sonaflam package instructions, including in children aged > 12 years of age (Sonaflam) and in adolescents from onset of puberty (Naprogesic). The higher dosing regimen for Sonaflam is recommended for pain related to inflammation, musculoskeletal disorders, post-operative pain, period pain, migraines, and acute gout.

The dosing regimens of both Naprogesic and some indications of Sonaflam are similar to those for prescription naproxen products in NZ and Australia (Refer to Table 1 and Table 2).

Noflam and Naprosyn SR are prescription only naproxen products in NZ. The maximum daily dose (all indications) for these medicines in the data sheet is 1250mg of naproxen day one, followed by 1000mg (Noflam) and 1000mg (Naprosyn SR). This is equivalent to 1375mg and 1100mg of naproxen sodium [6, 8]. There are currently no naproxen sodium prescription products in NZ. Anaprox 550 is a prescription medicine in Australia, containing naproxen sodium 550mg. It is recommended that the total daily dose should not exceed 1375 mg for acute pain and inflammatory states [7].

Other NSAIDs sold as pharmacy only medicines such as diclofenac and ibuprofen in NZ have a recommended daily dose that is lower than doses that may be used on prescription. The conditions of classification of ibuprofen and diclofenac include a maximal daily dose requirement when sold as pharmacy-only medicines [13].

Medsafe asks the MCC to discuss whether the doses of naproxen in pharmacy-only products is appropriate for a pharmacy medicine.

Dose regimens

Overseas OTC naproxen products, and OTC products containing other NSAIDs in NZ have one dosing regimen for all indications.

Sonaflam uses different dosing regimens for different conditions. When multiple indications and dosing regimens are listed a consumer is required to self-diagnose their condition and follow the recommended dose regimen. A consumer must be able to distinguish between different types of pain, for example between a 'migraine' and a 'headache', or 'minor aches and pains' and 'pain with inflammation'. Medication errors may occur, including taking a higher dose of the medicine, when this may not be required due to incorrect self-diagnosis.

The dosing regimen that Sonaflam uses for migraine is similar to the prescription product Anaprox 550 in Australia. Use of this regimen, compared to standard dosing for pain and/or inflammation may be confusing for a consumer without further guidance from a health professional.

Medsafe asks the MCC to discuss whether multiple dosing instructions for different conditions is appropriate for a pharmacy medicine.

Considerations for population of use

Naprogesic is indicated for period pain. Consumers using the product are likely to be pre-menopausal females. Given the nature of period pain, pain relief is generally only required for a few days during menstruation. The package leaflet for Naprogesic includes that it is suitable for adolescents from the onset of normal puberty. Menstruation may start in younger girls than 12 years of age [14].

Sonaflam is used for different types of pain and/or inflammation for adults and children aged over 12 years of age. A wide age range of consumers, including older adults may be use the product. There are currently no warnings for Sonaflam relating to use in older adults, nor are there reduced dosage recommendations, as seen in some overseas naproxen OTC products.

Safety concerns

Use of NSAIDs, including naproxen, may increase the risk of adverse effects such as cardiovascular events, gastrointestinal complications, renal failure, and hypersensitivity reactions [15].

The risk of experiencing adverse effects when taking NSAIDs is likely increased when using higher doses and/or for long durations. It is recommended that NSAIDs are used short term, and at the lowest effective dose [15]. Those who are susceptible to toxicity, such as the older adults, are recommended to use lower doses, or use an alternative analgesic [6, 8].

When naproxen is supplied to a patient on prescription the benefits and risks of treatment are discussed. If naproxen is appropriate, the individual should be provided with additional information, including potential side effects and what to do if these occur, ensuring the medicine is taken correctly and safely.

Naprogesic and Sonaflam have similar indications and doses to that of prescription products. However, no health professional is required to be part of the supply of the medicine.

Medsafe considers there is potential that use of higher doses of naproxen without input from a health professional may exposure consumers to a greater risk of adverse effects.

Warnings and Contraindications

Contraindications, precautions for use, and adverse effects for naproxen outlined in the data sheet, also apply to OTC naproxen products [6].

Individuals with comorbidities such as cardiovascular disease, type 2 diabetes or reduced renal function are at increased risk of NSAID-related complications [15]. Use of certain medicines with NSAIDs including anti-platelets, anti-coagulants, angiotensin-converting-enzyme (ACE) inhibitors, diuretics, other NSAIDs, steroids and selective serotonin reuptake inhibitor (SSRI), may also increase the risk of toxicity [15].

To ensure the safe and effective use of medicines available OTC, product packaging and/or package insert contain warnings for use. This information is used to advise consumers when it may not be safe to use the medicine.

The Label Statement Database (LSD) lists the warning and advisory statements that are required on medicine and related product labels under the regulations in NZ. Compared with other NSAIDs, current required statements for OTC naproxen only relate to pregnancy [16].

Medsafe is planning to undertake a LSD consultation for warnings statements required for NSAIDs when sold as OTC medicines.

Medsafe welcomes any proposed warnings from the MCC that may arise on discussion of this report.

Previous MCC meetings

The scheduling of naproxen has been discussed at several previous MCC meetings. In 1999, naproxen was reclassified to a pharmacy only medicine with no limits on indications [17].

At the February 2007 MCC meeting, a recommended maximum daily dose was added into the classification for diclofenac and ibuprofen as pharmacy only medicines. The National Drugs and Poisons Schedule Committee (NDPSC) in Australia had recommended that NZ harmonise with Australia on recommended daily dose limits for these medicines. At the time, the MCC noted that naproxen and mefenamic acid pharmacy only medicines did not have a recommended daily dose and took action to explore if this should be changed and referred to the NDPSC [18].

The NDPSC reviewed whether naproxen and mefenamic acid pharmacy-only medicines should have a maximum daily dose. As part of the discussion, the scheduling of diclofenac and ibuprofen in Australia was discussed. Information submitted to the NDPSC pre-meeting

stated that adverse events, particularly gastrointestinal and renal, with NSAIDs as a class were dose related. Given this, it would appear reasonable to set a maximum daily dose to help minimise the risk of adverse effects [19].

Prescription product information in Australian for naproxen includes that the maximum daily dose for all indications should not exceed 1250mg. Points raised in the discussion included a recent Therapeutic Goods Administration (TGA) review of NSAIDs found that OTC doses of NSAIDs administered for long periods of time were associated with increased cardiovascular risk, and that serious gastrointestinal events are well documented with NSAID treatment. It was noted that when naproxen was first down scheduled in NZ it was for the indication of dysmenorrhoea only, and that this patient group were in a different risk category. The naproxen indications have since been broadened, but the maximal daily dose not altered to reflect this, and perhaps the dysmenorrhoea dose may not be appropriate for other indications [19].

The NDPSC agreed that the current scheduling of naproxen (and mefenamic acid) remained appropriate given that the setting of maximal daily doses was an issue for the regulator, that there was no scientific evidence presented requiring a change to the schedule entry and there was no requirement under Section 52E of the Therapeutic Goods Act 1989 which required consistency across a class of schedule entries [19].

The full minutes from the NDPSC meeting can be found here.

No further action on this topic was taken by the MCC [20].

Benefit risk analysis

While it is currently not known if the indications and/or dosing of naproxen pharmacy-only products available in NZ may be influential in increasing the risk for adverse outcomes in individuals who use these medicines, there may be potential benefits in updating the classification of naproxen.

Additional information has become available relating to the risks associated with NSAID use since naproxen was first classified as a pharmacy-only medicine for all indications in 1999.

The Medicines Adverse Reaction Committee (MARC) most recently reviewed NSAIDs and the risk of cardiovascular events in 2019. They concluded that all systemically administered NSAIDS are associated with an increased risk of serious cardiovascular events, including myocardial infarction (MI) and stroke. To minimise the potential risk of adverse events in patients taking an NSAID, the lowest effective dose should be used for the shortest duration [21].

A lower dose range for naproxen pharmacy-only products is likely appropriate for the types of pain and/or inflammation managed by a consumer without a health professional. Conditions that require higher doses and/or regular use of naproxen, should involve health professional consultation.

Higher doses of naproxen, such as doses that may be used on prescription, may increase the risk of adverse effects. Certain population groups, such as older adults, are likely more susceptible. When a health professional is involved, the patient can be informed of side effects and what to do if these occur.

Naproxen OTC products overseas and other pharmacy-only NSAIDs such as ibuprofen and diclofenac available in NZ use daily doses that are lower than prescription products.

Conclusion

NSAIDs such as diclofenac, ibuprofen, and naproxen are available as OTC medicines in NZ.

Conditions that can be managed by pharmacy-only medicines should be easily identifiable and require short term/intermittent relief of pain and/or inflammation.

Naproxen products available OTC in NZ have similar indications and dose recommendations to that of NZ and Australian prescription naproxen products.

Diclofenac and ibuprofen when sold as pharmacy-only medicines in NZ use lower doses than those which may be used on prescription. Similarly, naproxen products in other countries, use lower doses when supplied without prescription.

Doses and indications of naproxen pharmacy-only products in NZ must be appropriate to provide the benefits of acute pain relief at safe and effective doses, and for suitable indications.

Classification sought

As outlined by this report, the MCC are asked to discuss the following points:

- whether the indication for treatment of acute gout is appropriate for a pharmacy medicine.
- whether the indication for treatment of musculoskeletal disorders is appropriate for a pharmacy medicine.
- whether the indication for treatment of post-operative pain is appropriate for a pharmacy medicine.
- whether the doses of naproxen in pharmacy-only products is appropriate for a pharmacy medicine.
- whether multiple dosing instructions for different conditions is appropriate for a pharmacy medicine.

The MCC are asked to consider on review of the above if the classification of naproxen containing medicines should be updated taking into account the Australian classifications, appropriate indications and appropriate daily dosing.

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