Codeine reclassified as a prescription-only medicine: a community pharmacy perspective

The range of analgesics available over-the-counter (OTC) in pharmacies will be reduced when all codeine-containing products are reclassified as prescription-only medicines from 5 November, 2020. Pharmacists will need to recommend other methods to manage pain and people who are accustomed to buying codeine-containing products from pharmacies will need to be informed about the change.

KEY PRACTICE POINTS:

- From 5 November, 2020, all codeine-containing products previously available OTC will become prescription-only medicines
- The decision to reclassify codeine-containing products was made because the harms associated with the OTC availability of codeine were assessed as outweighing the benefits
- Pharmacists will need to provide people with other ways of managing pain and to discuss the reclassification with people who want to purchase products containing codeine
- Cold and flu preparations that did contain codeine (i.e. Codral products) have been reformulated to be codeine-free and can continue to be sold OTC
- People with severe, persistent or recurrent pain should be encouraged to consult with their general practitioner to investigate and treat any underlying cause

Further information on the reclassification of codeine is available from: "Codeine: all formulations prescription only", **https://bpac.org.nz/2020/codeine.aspx**

All products containing codeine will be prescription-only

From 5 November, 2020, all codeine-containing products previously available over-the-counter (OTC) will become prescription-only medicines.[1] The range of products that pharmacists can offer people who request pain relief will therefore be reduced.

Pharmacies are permitted to dispense, on prescription, medicines containing codeine that are not labelled as prescription-only medicines until 5 May, 2021, in order to use up existing stock.[1] Wholesalers are required to supply pharmacies with appropriately labelled codeine products from 5 February, 2021, although many will begin to do so sooner.[1]

Which products will be reclassified?

The details of the codeine-containing products that will become prescription-only medicines from November 5, 2020, are provided in Table 1. The Codral range of cold and flu preparations has already been reformulated without codeine; the original products are listed in Table 1 as some pharmacies

may still have stock of these formulations. It is likely that some codeine-containing products that are currently available OTC may be withdrawn from the New Zealand market due to a lack of demand once a prescription is required.

Providing pain management in pharmacies

People often visit pharmacies to request medicines for the relief of mild to moderate acute pain associated with headache and migraine, dental issues, back injuries, menstruation and musculoskeletal conditions.

The reclassification of codeine will limit the number of products pharmacists are able to sell to people with pain, and other treatments will need to be recommended. People who are accustomed to purchasing analgesics containing codeine OTC will need to be informed of the change and advised to purchase a different medicine or to consult with their general practitioner.

A general approach to discussing pain relief is:

- Establishing what the person's symptoms are and what, if anything, they have used previously to alleviate them
- Deciding if an OTC analgesic is appropriate for the person
- Considering if any other pharmacy medicines or non-pharmacological interventions might be beneficial
- Considering if there are any underlying health issues that might be contributing to the person's symptoms and how these might influence treatment recommendations
- Considering if a referral to a general practitioner or another health provider is appropriate

Determine if self-management is appropriate

The initial goal in the pharmacy is to distinguish between acute, self-limiting pain that the person can manage themselves with guidance, and long-term or more serious conditions that require consultation with a general practitioner or another health professional, e.g. a dentist.

Table 1: Combination codeine medicines* that will be prescription-only medicines in New Zealand from 5 November, 2020 [2, 3]

Brand name	Amount of codeine	Additional active ingredients	Current status (prior to 5/11/20)
Paracetamol analgesics			
Panadeine	8 mg	Paracetamol 500 mg	Pharmacist Only
Relieve†	8 mg	Paracetamol 500 mg	Prescription Only
Panadeine Extra	15 mg	Paracetamol 500 mg	Pharmacist Only
Mersyndol	9.75 mg	Paracetamol 450 mg, doxylamine succinate 5 mg	Pharmacist Only
Ibuprofen analgesics			
Ibucode Plus, Nurofen Plus, Panafen Plus	12.8 mg	Ibuprofen 200 mg	Pharmacist Only
Codeine-containing cold and flu products‡			
Codral Multi Action	9.5 mg	Paracetamol 500 mg, phenylephrine 5 mg, chlorphenamine 2 mg	Pharmacy Only
Codral Cold & Flu	9.5 mg	Paracetamol 500 mg, phenylephrine 5 mg	Pharmacy Only
Codral Day & Night Cold and Flu**	9.5 mg (day tablet)	Paracetamol 500 mg, phenylephrine 5 mg (day tablet)	Pharmacy Only

* As at September, 2020

† Funded on prescription

‡ Codral products have all now been reformulated as codeine-free and the new formulations can continue to be sold OTC. These products were included in the table as some pharmacies may have remaining stock of codeine-containing formulations.

** This product contains two different formulations of tablet for day and night; only the day formulation tablet contains codeine

Pharmacy Only = Can only be sold from a licensed pharmacy but can be self-selected from shelves

Pharmacist Only = Can only be sold by a pharmacist (not available for self-selection)

Pain-related questions that may help in forming treatment recommendations include:

- Is there an event that caused the pain or known reason for the pain?
- How long has the pain been present?
- How severe is the pain and what does it feel like?
- Where is the pain and is it radiating?
- Is the pain constant or intermittent?
- What alleviates the pain?
- What makes the pain worse?
- What is the pain stopping them from doing?

Additional factors that may influence pain management strategies include co-morbidities, any medicines or complementary and alternative treatments the person may be taking, and potential contraindications to medicines, e.g. intolerance to non-steroidal anti-inflammatory medicines (NSAIDs), including aspirin.

If self-management is appropriate, people should be advised to consult their general practitioner if their pain has not improved significantly in an agreed time frame or if their pain is increasing.

It may be appropriate to consider the possibility of codeine misuse if a person becomes belligerent or distressed when informed that codeine is no longer available without prescription.

Further information on codeine misuse is available from: "Codeine: all formulations prescription-only", **https://bpac.org.nz/2020/codeine.aspx**

Recommend non-codeine analgesics

General advice when recommending oral analgesics includes:

- Avoid prolonged use or higher than recommended doses (especially paracetamol)
- Avoid concurrent use of products that contain the same class of analgesic
- NSAIDs should be used with caution in frail older people, people with renal impairment and people who are dehydrated or malnourished
- Begin with the lowest strength analgesic and increase if pain is not controlled (eliminating pain completely is often not a realistic goal of treatment)
- Consider other medicines the person is taking and if there are any potential medicine interactions

Musculoskeletal pain can be treated with paracetamol or a NSAID*, i.e. ibuprofen, diclofenac or naproxen. Paracetamol and a NSAID can also be taken concurrently (or in a staggered dosing regimen) if pain is not controlled with one medicine alone. It is important that people are made aware that paracetamol and NSAIDs may have different recommended dosing intervals, e.g. paracetamol is dosed four to six hourly whereas naproxen is dosed six hourly to once daily, depending on the formulation. Combination paracetamol + ibuprofen products are available (Table 2) or individual medicines can be purchased if more flexibility in the dosing regimen is required. Topical NSAIDs may be appropriate for people with mild musculoskeletal pain that does not involve deep tissue. A range of rubefacients are also available that increase blood circulation near the skin which may reduce discomfort, however, there is limited evidence supporting their use. People may also apply heat or cooling packs to painful areas to either increase blood circulation or attempt to reduce inflammation. In general, people with musculoskeletal pain benefit from staying active, assuming this does not exacerbate an injury or the underlying condition. A consultation with a physiotherapist may be beneficial for patients with injuries or reduced mobility. Strapping tape, support bandages or braces for joints may also provide limited benefit, where appropriate.

* There is a theoretical risk that initiating a NSAID immediately after an injury could delay healing, particularly if taken in the rest phase of the circadian cycle (i.e. taken before going to sleep),[4] therefore it may be appropriate to recommend delaying initiation to see if the pain is self-limiting and/or avoiding NSAIDs at night.

Tension-type headache may be relieved with a NSAID (including aspirin if aged ≥ 16 years). Paracetamol is less effective but may be preferable for some patients.[5] People should be advised to limit analgesic use for headache to fewer than 15 days per month to avoid medication overuse headache;[5] although if headache is experienced this frequently, the person should be referred to their general practitioner.

Acute migraine may be treated with a NSAID (including aspirin if aged ≥ 16 years), preferably in a soluble or liquid form (for more rapid absorption).[5] People who are unable to tolerate NSAIDs can use paracetamol, but it is less effective for acute migraine.[5] Two 50 mg tablets of sumatriptan (Sumagran Active) can also be purchased as a Pharmacist-only medicine, provided the person meets the following criteria:

- They have been previously diagnosed with migraine by a doctor and the symptoms have not changed
- Their symptoms are consistent with a diagnosis of migraine using an assessment tool: **www.psnz.org.nz/Folder?Action=View%20File&Folder_id=169&File=Sumagran%20Active%20Patient%20Questionnaire%202018.pdf**

People with frequent or debilitating migraine should be advised to consult with their general practitioner about prophylactic medicines.

Further information is available from: "Diagnosing and managing headache in primary care" **https://bpac.org.nz/2017/headache.aspx**

Dysmenorrhoea can be managed with a NSAID. There is little evidence that one NSAID provides superior pain relief to another;[6] commonly used options are naproxen 275 mg tablets, mefenamic acid 250 mg capsules (Ponstan) or ibuprofen. Paracetamol is less effective than NSAIDs for dysmenorrhoea.[6] People can be advised to discuss other management strategies with their general practitioner, e.g. hormonal contraceptives.

Dental pain can be treated with a NSAID, usually ibuprofen, as the first-line choice and paracetamol can be recommended if a NSAID is contraindicated;[7] consultation with a dentist should be advised, or if this is not possible, a general practitioner.

"Cold and flu" symptoms

Codeine was previously present in a small number of cough and cold preparations, however these products have now been reformulated to be codeine-free, therefore the management of winter illnesses will not be greatly affected by the reclassification of codeine. It is unclear what the intended purpose of codeine was in these products; it may have been to provide analgesia for sore throat and general aches and pains, or to act as a cough suppressant (which codeine is indicated for).

There are multiple other products that can be recommended to treat the symptoms of cold and flu, including analgesia such as paracetamol or ibuprofen. There is limited evidence supporting the use of cough syrups for the relief of acute cough.[8] N.B. All oral "cough and cold" preparations are

Table 2: Analgesic medicines available over-the-counter in community pharmacies in New Zealand, displayed by suggested use in adults

Condition	Analgesic
Musculoskeletal pain	■ Paracetamol (oral) 500 mg and 665 mg* ■ Ibuprofen (oral) 200 mg and 400 mg* ■ Ibuprofen (oral) 150 mg or 200 mg + paracetamol 500 mg ■ Ibuprofen (topical) 5% ■ Naproxen sodium (oral) 275 mg ■ Diclofenac (oral) 12.5 mg and 25 mg* ■ Diclofenac (topical) 1% and 2% ■ Capsaicin (topical) 0.025% and 0.075%
Tension-type headache	■ Ibuprofen (oral) 200 mg and 400 mg* ■ Naproxen sodium (oral) 275 mg ■ Diclofenac (oral) 12.5 mg and 25 mg* ■ Aspirin (dispersible) 300 mg and 500 mg ■ Paracetamol (oral) 500 mg ■ Paracetamol (oral) 500 mg + 65 mg caffeine
Acute migraine	■ Ibuprofen (oral liquid) 200 mg/5mL ■ Ibuprofen (oral) 200 mg and 400 mg* ■ Aspirin (dispersible) 300 mg and 500 mg ■ Naproxen sodium (oral) 275 mg ■ Diclofenac (oral) 12.5 mg and 25 mg* ■ Paracetamol (soluble) 500 mg ■ Paracetamol (oral liquid) 250 mg/5mL ■ Paracetamol (oral) 500 mg ■ Sumatriptan (oral) 50 mg*
Dysmenorrhoea	■ Naproxen sodium (oral) 275 mg ■ Mefenamic acid 250 mg ■ Ibuprofen (oral) 200 mg and 400 mg* ■ Diclofenac (oral) 12.5 mg and 25 mg*
Dental pain	■ Ibuprofen (oral) 200 mg and 400 mg* ■ Diclofenac (oral) 12.5 mg and 25 mg* ■ Paracetamol (oral) 500 mg

* Pharmacist Only

contraindicated in children aged under six years.[9] People who report a persistent (e.g. > four weeks) or worsening cough, or blood in their sputum, should be advised to consult with their general practitioner.

Further information on managing winter illnesses is available from: "Cold season: managing without antibiotics", **https://bpac.org.nz/2018/cold-season.aspx**

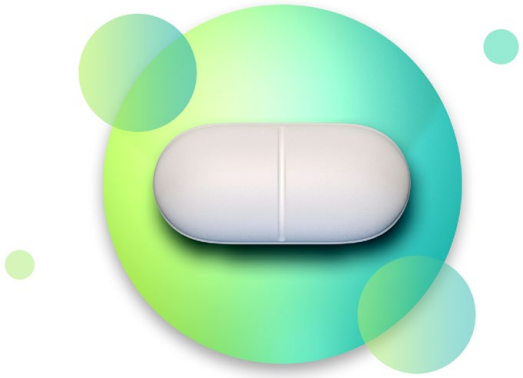
Confirm understanding and offer follow-up advice

After a treatment decision has been made, confirm the person understands any recommended medicine regimen, e.g. dose, frequency and duration. Consumer medicine information is provided by the manufacturer for approved medicines; patient medicine information for a range of medicines is also available from the New Zealand Formulary, including some versions in Te Reo Māori (an index of leaflets is available from: **https://nzf.org.nz/nzf_70421**). In general, people should be advised to return to the pharmacy if their symptoms have not resolved in an agreed timeframe or to consult their general practitioner, particularly if their symptoms worsen.

Acknowledgement: Thank you to **Ann Roslyn (Roz) Hutton**, Medicines Information Pharmacist, Christchurch Medicines Information Service, Canterbury DHB, **Ying Sun**, Community Pharmacist & Pharmacy Manager, Dunedin and the **Clinical Risk** and **Product Regulation Teams** of **Medsafe** for expert review of this article

Article supported by Medsafe.

N.B. Expert reviewers do not write the articles and are not responsible for the final content. bpac^{nz} retains editorial oversight of all content.



This article is available online at:
www.bpac.org.nz/2020/codeine-rx.aspx

Other "cold and flu" preparations with recent or proposed regulatory changes

- The Medicines Adverse Reactions Committee (MARC) has recommended that pholcodine be reclassified from a Pharmacy only medicine to a Pharmacist only medicine and this is being considered by the Medicines Classification Committee (MCC).[10]
- Dextromethorphan was reclassified as a Pharmacist only medicine in 2019.[11]
- Gees linctus (opium tincture and squill oxymel) was reclassified as a prescription medicine in 2019.[11]

References

1. Medsafe. Reclassification of codeine. 2020. Available from: www.medsafe.govt.nz/profs/class/ReclassificationOfCodeine.asp (Accessed Aug, 2020).
2. Medsafe. Classification of codeine: Information paper for the Medicines Classification Committee. 2019. Available from: www.medsafe.govt.nz/profs/class/Agendas/Agen63/MCC63_53a_Reclassificationofcodeine.pdf (Accessed Aug, 2020).
3. New Zealand Formulary (NZF). NZF v100. Available from: www.nzf.org.nz (Accessed Oct, 2020).
4. Al-Waeli H, Nicolau B, Stone L, et al. Chronotherapy of non-steroidal anti-inflammatory drugs may enhance postoperative recovery. Sci Rep 2020;10. doi:https://doi.org/10.1038/s41598-019-57215-y
5. British Association for the Study of Headache (BASH). Guidelines for all healthcare professionals in the diagnosis and management of migraine, tension-type headache, cluster headache, medication-overuse headache. 2010. Available from: www.bash.org.uk/wp-content/uploads/2012/07/10102-BASH-Guidelines-update-2_v5-1-indd.pdf (Accessed Aug, 2020).
6. Marjoribanks J, Ayeleke RO, Farquhar C, et al. Nonsteroidal anti-inflammatory drugs for dysmenorrhoea. Cochrane Database Syst Rev 2015;:CD001751. doi:10.1002/14651858.CD001751.pub3
7. Becker DE. Pain management: Part 1: Managing acute and postoperative dental pain. Anesth Prog 2010;57:67–78; quiz 79–80. doi:10.2344/0003-3006-57.2.67
8. Smith SM, Schroeder K, Fahey T. Over-the-counter (OTC) medications for acute cough in children and adults in community settings. Cochrane Database Syst Rev 2014;(11):CD001831.
9. Medsafe. Reminder: using cough and cold medicines in children is inappropriate. Prescriber Update 37(2): 18. 2016. Available from: www.medsafe.govt.nz/profs/PUArticles/June2016/CoughAndColdMedicinesInChildrenInappropriate.htm (Accessed Aug, 2020).
10. Medsafe. Agenda for the 64th meeting of the Medicines Classification Committee. 2020. Available from: www.medsafe.govt.nz/profs/class/Agendas/Agen64/agen64.htm (Accessed Sep, 2020).
11. Medsafe. Medicines classification update: November 2018. 2019. Available from: www.medsafe.govt.nz/profs/PUArticles/June2019/Medicines-classification-update-November-2018.htm (Accessed Sep, 2020).