Over-the-counter (OTC) codeine-containing analgesics
Despite the increased restrictions on the availability of codeine-containing analgesics, misuse of these products is still prevalent.

See page 4, Facts Behind the Fact Card: OTC (over-the-counter) codeine-containing analgesics

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Over-the-counter (OTC) codeine-containing analgesics

By Lynn Greig

Having to deal with the problem of misuse of over-the-counter (OTC) combination analgesics containing codeine (CACC) is a challenge faced on a daily basis by most (if not all) community pharmacists. Despite the 2010 rescheduling of CACC from S2 (Pharmacy medicines) to S3 (Pharmacist Only medicines), many people are still misusing these products, and are experiencing harms as a result of this misuse.

People who misuse CACC generally do so because they have become dependent on the codeine contained in these products. Many of these people initially start taking CACC in recommended doses for pain, but then gradually increase the number of tablets they are taking and/or the frequency of intake until they are taking excessive doses. They may do this because they are not getting adequate pain relief, or because they find that high doses of codeine make them ‘feel good’. Some people who are dependent on CACC do not take more than the maximum recommended dose, but continue taking the maximum dose regularly for long periods of time (sometimes many years).

A minority take CACC not for pain relief, but purely as a recreational drug. There are increasing reports of serious harms resulting from misuse of CACC. The products that most frequently cause problems are codeine-ibuprofen combinations. The harms are mainly due to excessive doses of ibuprofen and include gastrointestinal ulcers and bleeding, anaemia and renal failure. The paracetamol in these products, if taken in excessive doses, can cause severe and potentially fatal liver damage. People who take analgesics frequently for headaches may eventually develop a condition known as ‘medication overuse headache’ in which they experience an ongoing cycle of rebound headaches after the effects of each dose of analgesic wear off.

There are many factors that make it challenging for pharmacists to adequately address the problem of misuse of CACC. These include time constraints, the difficulty of identifying which customers are codeine-dependent, reluctance to risk causing offence by intervening, and fear that, if they do intervene, customers will switch their allegiance to another pharmacy. The lack of consistency in the procedures used by different pharmacies when supplying CACC, and the difficulty of finding out whether customers are also obtaining CACC elsewhere, add to the obstacles faced by pharmacists trying to address this problem.

This issue of inPHARMation discusses the problem of misuse of CACC from both the customer’s and pharmacist’s perspective. The modes of action and adverse effects of the various components of these medicines are described, and guidelines for the appropriate use of analgesics are provided. Counter Connection emphasises the need for pharmacy assistants to refer all customers requesting CACC to the pharmacist.

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There is increasing concern about the misuse of over-the-counter (OTC) codeine-containing analgesics. In May 2010, OTC combination analgesics containing codeine were deleted from S2 (Pharmacy medicines) and rescheduled to S3 (Pharmacist Only medicines). They are now limited to a maximum of 5 days’ treatment per pack and 12 mg anhydrous codeine (~16 mg codeine phosphate) per dosage unit.1

Yet, despite the increased restrictions on the availability of codeine-containing analgesics, misuse of these products is still prevalent. Pharmacists have a vital role to play in helping to address this problem.

According to the 2010 National drug strategy household survey, analgesics for non-medical use were the fourth most frequently reported drugs used by Australians – behind alcohol, tobacco and cannabis, and equal with ecstasy. Of those reporting recent misuse of analgesics, 75% reported misusing OTC analgesics and 25% prescription analgesics.2,3 Commonly misused analgesics are those containing codeine in combination with paracetamol, ibuprofen or aspirin. Overuse of OTC codeine-containing medicines can result in codeine dependence and adverse effects due to excessive intake of ibuprofen, paracetamol or aspirin.4,5

Codeine

Codeine is a weak opioid analgesic. It binds with opioid receptors at many sites in the central and peripheral nervous systems to produce a number of effects, including respiratory depression, sedation and constipation. Its analgesic effect is largely due to its partial metabolic conversion by cytochrome P450 enzyme 2D6 (CYP2D6) to morphine, which has a 200 times greater affinity for the mu opioid receptor than codeine. Adverse effects of codeine include nausea, vomiting, constipation, drowsiness and dizziness. These are more common with higher or repeated doses. Long-term use of codeine can result in tolerance (requiring increasing doses for efficacy) and dependence.6–9

Genetic variations in the activity of CYP2D6 affect the rate at which people convert codeine to morphine. Poor metabolisers cannot efficiently convert codeine to morphine, and derive no detectable analgesic effect from codeine. Increasing the dose in a poor metaboliser provides no analgesic benefit, but may increase the risk of adverse effects. Ultrafast metabolisers...
rapidly convert codeine to morphine, increasing the risk of opioid toxicity, including life-threatening respiratory depression.\(^6\) See Table 1 for prevalence of CYP2D6 codeine polymorphisms by race.

NSAIDs

Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and aspirin have analgesic, antipyretic and anti-inflammatory effects, mediated by inhibition of cyclooxygenase (COX) enzymes at peripheral sites and in the central nervous system. COX enzymes catalyse the rate-limiting step in the formation of prostaglandins. When inflammation is present, production of COX-2 is increased. Inhibition of COX-2 by NSAIDs produces anti-inflammatory and analgesic effects through a reduction in pro-inflammatory prostaglandins.\(^6,9,10\)

NSAIDs also have effects in other areas of the body, including the\(^6,10,11\):

- **Gastrointestinal tract** – COX-1 mediates the formation of cytoprotective prostaglandins in the gastrointestinal tract. Inhibition of COX-1 can result in gastrointestinal damage, producing adverse effects (see Table 2).
- **Blood** – COX-1 is present in platelets, where it converts arachidonic acid to thromboxane A2, which stimulates platelet aggregation. Inhibition of COX-1 reduces platelet aggregation, increasing the risk of bleeding.
- **Kidneys** – COX-1 and COX-2 are both present in the kidneys. COX-1 promotes renal perfusion through vasodilation and reduced renal vascular resistance. COX-2 plays a role in diuresis and electrolyte excretion. Inhibition of these enzymes can cause reduced renal perfusion, and sodium and fluid retention. The risk of renal toxicity with NSAIDs is increased in patients with pre-existing renal impairment, congestive heart failure or cirrhosis, or who are on a low-salt diet, or taking diuretics, ACE inhibitors, angiotensin II receptor antagonists, aspirin or other nephrotoxic medicines.
- **Vascular system** – sodium and fluid retention and vasoconstriction due to inhibition of COX enzymes can cause an increase in blood pressure and may lead to hypertension.

Table 1. Prevalence of CYP2D6 codeine polymorphisms\(^8\)

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Slow metabolisers</th>
<th>Ultrafast metabolisers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Western European</td>
<td>8–10%</td>
<td>1–4%</td>
</tr>
<tr>
<td>Southern European</td>
<td>7–10%</td>
<td></td>
</tr>
<tr>
<td>African</td>
<td>0–20%</td>
<td>5–30%</td>
</tr>
<tr>
<td>Eastern Asian</td>
<td>0–1%</td>
<td></td>
</tr>
<tr>
<td>Arabian</td>
<td>Up to 20%</td>
<td></td>
</tr>
</tbody>
</table>

All NSAIDs except aspirin are competitive, reversible COX inhibitors. Aspirin inhibits COX by a different mechanism, and its action is irreversible. In platelets, aspirin irreversibly inhibits COX-1 for the life of the platelet (8–12 days). Reduced platelet function is therefore cumulative with repeated doses of aspirin, and takes several days to recover after cessation of therapy.\(^9\)

For adverse effects of NSAIDs see Table 2.

Paracetamol

Paracetamol has analgesic and antipyretic effects. Its mechanism of action is still not fully known, but is thought to involve several different pain pathways. These include inhibition of COX enzymes (at a different site to that used by NSAIDs – thus explaining its minimal anti-inflammatory effects), activation of descending serotoninergic pathways, and stimulation of cannabinoid receptors (may explain the feelings of calmness and euphoria reported by many paracetamol users). Its antipyretic effect is thought to be due to inhibition of prostaglandin production in the hypothalamus.\(^9,12\)

The most significant adverse effect of paracetamol is hepatotoxicity, although this is rare at therapeutic doses. Paracetamol overdose is the leading cause of acute liver failure in Australia.\(^13\) About 90% of a dose of paracetamol is metabolised to inactive conjugates and excreted in the urine. The remainder is metabolised by CYP enzymes 2E1 and 3A4 to N-acetyl-p-benzoquinone imine (NAPQI), which is hepatotoxic. Under normal circumstances, NAPQI is immediately conjugated with glutathione and excreted in the urine. With increased paracetamol intake, glutathione may become depleted and NAPQI may accumulate, resulting in hepatotoxicity. Under certain conditions,
therapeutic response.5,17

law enforcement issue, and requires a
this is therefore a health, rather than a
problem.

pseudoephedrine, will not help them
refusing the sale, as is recommended for
people who are misusing over-the-counter (otc) codeine.
many codeine-dependent people
are potentially engaging in a criminal
activity and this is essentially a law
enforcement issue. on the other hand,
people who frequently request otc
codeine-containing analgesics are likely
to be either dependent on codeine
or experiencing chronic pain. simply
refusing the sale, as is recommended for
pseudoephedrine, will not help them
with managing either of these problems.
This is therefore a health, rather than a
law enforcement issue, and requires a
therapeutic response.5,17

A real-time monitoring system similar to
project stop (used for monitoring sales
of pseudoephedrine) may help to identify
people who are misusing otc codeine.
The appropriate response in this case is,
however, different. People purchasing
excessive quantities of pseudoephedrine
are potentially engaging in a criminal
activity and this is essentially a law
enforcement issue. on the other hand,
people who frequently request otc
codeine-containing analgesics are likely
to be either dependent on codeine
or experiencing chronic pain. simply
refusing the sale, as is recommended for
pseudoephedrine, will not help them
with managing either of these problems.
This is therefore a health, rather than a
law enforcement issue, and requires a
therapeutic response.5,17

Another strategy that has been suggested
is a ‘universal precautions’ approach
(originally devised to prevent the spread
of blood-borne viruses). Under this
system, all customers requesting otc
codeine-containing analgesics would
be routinely assessed for indications
of codeine dependence and counselled
about the risks of codeine dependence
and overuse. One advantage of this
approach is that, rather than assessing
risk based on the person’s appearance,
the same standard would be applied to
all customers, ensuring a minimum level
of protection for all. Pharmacists who
are reluctant to risk offending customers
by discussing these issues could claim
‘borrowed protection’, citing their legal
requirements for s3 medicines, or stating
that it is the official pharmacy policy.6,17

therapeutic doses of paracetamol can result
in hepatotoxicity. These include fasting
(which can deplete glutathione stores) and excessive
intake of alcohol (which induces cyp2e1 and
can also deplete glutathione stores).13–15

At therapeutic doses, paracetamol has
minimal effects on renal function. however,
acute renal failure, tubular necrosis and
interstitial nephritis have been reported
following chronic analgesic abuse or
in people with paracetamol-induced
hepatotoxicity.12

Combination analgesics

OTC combination analgesic preparations
available in australia contain codeine
phosphate in doses ranging from 8–15 mg
(equivalent to anhydrous codeine
~6–11.25 mg), combined with either
paracetamol 500 mg, ibuprofen 200 mg or
aspirin 300 mg.6 there is doubt about the
efficacy of codeine in the doses used in
OTC analgesics. the lowest effective dose
of codeine has not yet been established,
but it is generally accepted that doses
below 30 mg are unlikely to be effective.
Therefore, in a person whose pain does not
respond adequately to paracetamol and/
or an NSAID, and who requires codeine
in addition, it may be preferable to give
the codeine as a separate tablet in a
therapeutically effective dose (available as
Prescription Only).6,9,16

Codeine dependence

Many people who become dependent
on codeine initially start taking otc
codeine-containing analgesics in
therapeutic doses for pain. They gradually
increase the number of tablets they
are taking, either because they are not
achieving adequate pain relief or because
they enjoy the calming or euphoric effects
produced by the codeine. Some people can
eventually take up to 100 tablets a day.2,17

Studies investigating the characteristics
of dependent codeine users have found that
they are often in their thirties or forties, are
mainly employed and educated beyond
a year 11 level (many have completed
a tertiary degree), often have chronic
pain and/or mental health problems
(e.g. depression, anxiety), and rate their
health as fair or poor.6,17

A 2010 Australian study of people who were
dependent on otc codeine-containing
analgesics found that they fell into one of
three groups4,17:

• Therapeutic dependence group – people
in this group did not exceed the maximum
recommended dose, but continued using
the maximum dose regularly for long
periods of time (in some cases
15–20 years). Despite the fact that they
took the medicine for medical reasons,
and did not take excessive doses, they
still met the DSM IV criteria for codeine
dependence. The thought of not having
codeine made them anxious, and they
would often take the tablets pre-emptively,
to prevent the onset of pain which was
not currently present. they continued to
use the medicine even if it failed to relieve
their pain. Some of them were likely to
be suffering from medication overdose
headache (see Practice point 4).

• High-dose dependence group – most of
these people had initially taken
therapeutic doses and then gradually
increased their use until they were
taking excessive doses – often multiple
packs a day. Some reported that they
had escalated from therapeutic use to
high-dose use because higher doses of
codeine gave them ‘a good feeling’. Many
had experienced severe harms, including
gastrointestinal damage and hospital
admissions, as a result of their codeine use.

• Non-medical/recreational user group
– people in this group were using codeine
purely for its euphoric effects. They were
knowledgeable about the ingredients and
their potential harms, and practised harm
reduction strategies such as extracting
codeine from combination products to
reduce intake of paracetamol.

Consequences of OTC
codeine misuse

There are increasing reports of serious
harms arising from misuse of otc
codeine-containing analgesics.17
The products most commonly implicated
are codeine-ibuprofen combinations.
The harms are mainly due to excessive
intake of ibuprofen. Serious adverse
effects caused by the ibuprofen content
of these products have included
gastrointestinal ulceration, bleeding
and perforation, anaemia, renal failure,
and severe hypokalaemia (due to renal
tubular acidosis, thought to be a result of
ibuprofen-induced inhibition of carbonic
Table 2. Adverse effects of NSAIDs6,9,10,17

<table>
<thead>
<tr>
<th>Body system</th>
<th>Adverse effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal</td>
<td>Nausea, vomiting, dyspepsia, diarrhoea, constipation, GI ulceration, bleeding,</td>
</tr>
<tr>
<td></td>
<td>oesophageal ulceration and strictures</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Increased blood pressure, sodium and fluid retention, hyperkalaemia, hypokalaemia, myocardial infarction, heart failure, stroke</td>
</tr>
<tr>
<td>Renal</td>
<td>Renal impairment, cystitis, glomerulopathy, interstitial nephritis, nephrotic syndrome, acute renal failure</td>
</tr>
<tr>
<td>Neurological</td>
<td>Headaches, dizziness, tinnitus, blurred vision, confusion, hallucinations, depression, tremor, neuropathy</td>
</tr>
<tr>
<td>Haematological</td>
<td>Anaemia, bone marrow depression, decreased platelet aggregation</td>
</tr>
<tr>
<td>Hepatic</td>
<td>Raised liver enzymes, hepatotoxicity, hepatic failure</td>
</tr>
<tr>
<td>Other</td>
<td>Hypersensitivity (e.g. anaphylaxis, asthma, angioedema, urticaria), Stevens-Johnson syndrome, bronchospasm, photosensitivity</td>
</tr>
</tbody>
</table>

Anhydrase20). Severe hypokalaemia can result in potentially serious complications such as cardiac arrhythmias, myopathy, rhabdomyolysis, and neurological problems (e.g. psychosis, delirium, hallucinations).17–21 Paracetamol taken in excessive doses can cause hepatotoxicity. The hepatotoxic dose is generally about 7.5 g. However, some people who start taking therapeutic doses of codeine-paracetamol combination medicines and then gradually escalate their dose appear to develop tolerance to paracetamol’s hepatotoxic effects. They regularly take ‘toxic’ doses of paracetamol without suffering any harm. This phenomenon is known as ‘autoprotection’ and its mechanism is still unclear.22

Other harms resulting from misuse of OTC codeine medicines include17:

- Side effects of regular high doses of codeine (e.g. constipation, dry mouth). Codeine-induced constipation may lead to additional self-medication with repeated doses of laxatives. Codeine-induced xerostomia can lead to dental problems.
- Worsening of health problems due to untreated conditions (e.g. self-medicating for dental pain, instead of visiting the dentist to address the cause of the pain).
- Impaired cognitive function due to excessive doses of codeine, resulting in car accidents or problems at work.
- Social harms resulting from drug dependence (e.g. effects on relationships, loss of employment).

Pharmacy’s role

The customer’s perspective

According to participants interviewed in the 2010 Australian study of people dependent on OTC codeine-containing analgesics, pharmacists’ responses to requests for these products mostly fell into one of two categories – either the respondents were able to buy the product with virtually no pharmacist interaction, or (rarely) the sale was refused with limited discussion. Occasionally, the reason given for refusing the sale was that the product was out of stock (although it was often clearly visible on the shelf). If the pharmacist refused to supply the product, participants would usually succeed in purchasing it at another pharmacy.17

The study participants reported that, generally, if the product was supplied, the pharmacist would just ask them what the product was being used for and would advise them not to take more than the maximum daily dose, with no additional questioning. None of the participants described an occasion where a pharmacist raised concerns about abuse or dependence, or suggested that they seek assistance with OTC codeine dependence. Participants also reported that being well-dressed and looking ‘respectable’ made it much easier for them to obtain OTC codeine.17

Participants admitted that they strongly wished to avoid questioning by the pharmacist. They would actively employ strategies to avoid questioning, such as going to ‘easy’ pharmacies where fewer questions were asked, or selecting staff members they knew would not ask questions. Some participants felt that being asked questions suggested some

Practice point 3

Helping customers to recognise codeine dependence

The following counselling points may help customers to recognise signs that they are becoming (or have become) dependent on OTC codeine-containing analgesics. Signs of codeine dependence include17:

- taking pain relievers when they have no pain
- needing to take more than the recommended dose
- taking increasing quantities of pain relievers
- needing to take pain relievers for a longer period than that recommended on the pack
- feeling unwell when they stop taking the pain reliever, and much better if they start taking it again
- experiencing codeine withdrawal symptoms such as restlessness, irritability, anxiety, yawning, watery eyes, runny nose, sneezing, sweating, goose bumps, stomach cramps, nausea, vomiting, diarrhoea and disturbed sleep.

Related Fact Cards

- Chronic pain
- Back pain
- Drug overdose
- Medicines and driving
- Migraine
- Opioids for pain relief
- Pain relievers
Medication overuse headache (MOH) is defined as:

- headache occurring on 15 or more days/month
- regular intake of paracetamol, aspirin or NSAIDs on ≥15 days per month for >3 months
- regular intake of triptans, opioids or combination analgesics on ≥10 days per month for >3 months.

MOH affects about 2% of the adult population. It develops as a result of prolonged, frequent use of one or more of the medicines used to treat acute headache. It does not appear to develop in people who regularly take pain relievers for some types of headache (e.g., cluster headache) or for other conditions (e.g., arthritis). People most at risk of developing MOH are those with frequent migraine or tension-type headaches. Combination analgesics containing codeine (CACCs) or other opioids are the most common cause of MOH.\(^{5,25,26}\)

Customers should be advised that, if they need to use medicine for headaches on more than 2–3 days per week, they should consult a doctor. Treatment involves withdrawal of the overused medicine. This may require specialist management at a pain or headache clinic. Medicine withdrawal can lead to increased headache (withdrawal response) lasting for several days, after which headaches should gradually decrease over a period of weeks or months. For people overusing a combination analgesic containing an opioid, withdrawal symptoms may also include nausea and vomiting. Withdrawal symptoms can be alleviated by short-term use of NSAIDs (e.g., naproxen), anti-emetics (e.g., metoclopramide) or oral prednisolone. Migraine prophylaxis is usually ineffective in the presence of MOH, but may become effective following drug withdrawal.\(^{6,25}\)

The pharmacist’s perspective
Factors identified by community pharmacists that make it challenging for them to address the problem of OTC codeine misuse include:\(^{14}\):

- Insufficient time to adequately discuss the issue of OTC codeine use with all customers requesting OTC codeine-containing analgesics.
- Lack of privacy for discussing these issues in the pharmacy.
- The difficulty of establishing whether a customer’s therapeutic need is genuine.
- A lack of confidence in identifying codeine dependence and a reluctance to risk causing offence by intervening if they are not certain that a person is codeine dependent.
- Fear that, if they adopt a more thorough procedure in responding to requests for OTC codeine products, customers will switch their allegiance to less stringent pharmacies.
- The lack of consistency in the procedures adopted by different pharmacies when supplying OTC codeine products – resulting in misunderstanding, resentment, and customers feeling that they are being discriminated against.
- Reluctance by codeine-dependent customers to engage in discussion, possibly because they do not consider their OTC codeine use to be problematic.

Guidelines for appropriate analgesic use
The cause of the pain should be determined so that the appropriate therapy can be recommended. For example, neuropathic pain usually does not respond to simple analgesics and may require the use of analgesic adjuvants (e.g., tricyclic antidepressants or anti-epileptic medicines). Non-pharmacological strategies (e.g., cognitive behavioural therapy, specific exercises, massage, relaxation techniques, transcutaneous electrical nerve stimulation, occupational therapy) should be tried before starting pharmacotherapy.\(^{6}\)

Paracetamol is the analgesic of choice for mild to moderate persistent pain. People who report that paracetamol is not effectively controlling their pain may be using inadequate doses. Increasing the dose and/or taking regular doses may improve efficacy. Dosing in persistent pain should be regular, not ‘as required’. Patients on regular doses may find it more convenient to use the extended-release formulation, reducing the number of doses to three per day. They should be advised not to exceed the maximum daily dose (4 g for adults) and to avoid other paracetamol-containing preparations (e.g., cold and flu medicines).\(^{16}\)

If paracetamol does not adequately control the pain, or if the patient has an inflammatory condition, an NSAID may be recommended. The person should be assessed to determine whether use of an NSAID is appropriate (see Table 3). They should be informed about correct dosing and signs of adverse effects (e.g., dark stools, swollen ankles, heartburn,
Table 3. Assessing patients for suitability to use OTC NSAIDs6,9,16,27

<table>
<thead>
<tr>
<th>Patients at high risk of adverse effects</th>
<th>Potential drug interactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Elderly: increased risk of gastrointestinal ulceration, heart failure and renal impairment</td>
<td>• ACE inhibitors/angiotensin II antagonists: reduced antihypertensive effect, increased risk of renal impairment and hyperkalaemia; risk further increased if also taking thiazide diuretic; avoid combination in renal impairment and elderly patients; monitor blood pressure, weight, serum creatinine and potassium</td>
</tr>
<tr>
<td>• Active/previous GI bleeding/ulceration: contraindicated</td>
<td>• Alendronate: increased risk of gastric ulceration; avoid or monitor carefully</td>
</tr>
<tr>
<td>• Heart failure: avoid, risk of exacerbation</td>
<td>• Beta-blockers: impaired antihypertensive effect; avoid or monitor BP</td>
</tr>
<tr>
<td>• Hypertension: may be exacerbated; use with caution</td>
<td>• Corticosteroids: increased risk of gastric ulceration</td>
</tr>
<tr>
<td>• Asthma: use with caution; risk of bronchospasm</td>
<td>• Cyclosporin: increased risk of nephrotoxicity</td>
</tr>
<tr>
<td>• Aspirin-induced asthma: contraindicated</td>
<td>• Lithium: reduced lithium clearance and increased risk of lithium toxicity; avoid if possible; otherwise, monitor serum lithium concentration</td>
</tr>
<tr>
<td>• Pregnancy: category C – avoid use; contraindicated in third trimester</td>
<td>• Loop/thiazide diuretics: reduced diuretic effect; increased risk of nephrotoxicity; avoid or monitor BP, renal function and weight</td>
</tr>
<tr>
<td>• Pre-existing renal impairment: increased risk of NSAID-induced renal impairment; may cause acute renal failure</td>
<td>• Methotrexate: reduced methotrexate clearance and increased risk of toxicity; avoid with antineoplastic doses of methotrexate</td>
</tr>
<tr>
<td>• Surgery: increased risk of post-surgical bleeding, renal impairment and cardiovascular events; consider stopping NSAID 2–3 days before surgery, especially if there is a significant risk of postoperative bleeding</td>
<td>• Potassium supplements/potassium sparing diuretics: increased risk of hyperkalaemia and renal impairment; monitor serum potassium and creatinine</td>
</tr>
<tr>
<td>• Coagulation disorders: increased risk of bleeding</td>
<td>• Thiazolidinediones: increased risk of fluid retention and heart failure</td>
</tr>
<tr>
<td>• Inflammatory bowel disease: risk of exacerbation</td>
<td>• Warfarin: increased risk of bleeding; avoid combination or monitor for GI bleeding and bruising</td>
</tr>
</tbody>
</table>

OTC NSAIDs are indicated only for acute symptom relief, not long-term therapy. The lowest effective dose should be used for the shortest possible time (preferably ≤2 weeks). In chronic conditions such as osteoarthritis, a NSAID can be taken intermittingly (e.g. before activity or during a flare in pain) in addition to regular paracetamol. In rheumatoid arthritis, fish oil in doses sufficient to provide at least 2.7 g of omega-3 fatty acids daily may reduce NSAID requirements.6,9

In people whose pain does not respond adequately to paracetamol and/or an NSAID, or who are at high risk of NSAID-induced adverse effects, addition of a weak opioid such as codeine can be considered. However, as it is generally accepted that doses of codeine below 30 mg are unlikely to be effective, there may be no advantage in taking an OTC combination analgesic containing codeine. Adequate pain relief is more likely to be achieved if the codeine is prescribed as a separate tablet in a therapeutically effective dose.6,9

For further information about the appropriate use of OTC analgesics see Guidance for provision of a Pharmacist Only medicine – combination analgesics containing codeine in APF23.

Conclusion

Pharmacists have an important role to play in helping to address the problem of misuse of OTC codeine-containing analgesics. This role can only be properly fulfilled if all pharmacists are consistent in:

• discussing the issue of codeine dependence with all customers requesting OTC codeine-containing analgesics and
• providing timely information about the harms that can result from overuse of codeine-containing analgesics – before codeine dependence has had a chance to develop.
References


Assessment questions for the pharmacist

OTC codeine-containing analgesics

Personal ID number: ____________________________

Full name: _______________________________________

Pharmacy: _______________________________________

Address: _________________________________________

Suburb: __________________________________________

State: ____________________________ Postcode: _______

Circle one correct answer from each of the following questions.

Before undertaking this assessment, you need to have read the Facts behind the Fact Card article and the associated Fact Cards.

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Please retain a copy for your own purposes. Photocopy if you require extra copies.

1. Which of the following statements regarding OTC analgesics is CORRECT?
   a) Poor metabolisers of codeine are at increased risk of opioid toxicity with therapeutic doses of codeine.
   b) The risk of renal toxicity with NSAIDs is increased in people who are taking diuretics, ACE inhibitors or angiotensin II receptor antagonists.
   c) About 90% of a dose of paracetamol is metabolised by CYP2E1 and 3A4 to N-acetyl-p-benzoquinone imine (NAPOI), which is hepatotoxic.
   d) Aspirin, like ibuprofen, is a competitive, reversible inhibitor of cyclooxygenase (COX) enzymes.

2. People dependent on OTC codeine-containing analgesics fall into one of three groups. Those in the therapeutic dependence group:
   a) Generally start taking therapeutic doses and then gradually increase their use until they are taking excessive doses.
   b) Often practise harm reduction strategies, such as extracting codeine from combination products to reduce intake of paracetamol or ibuprofen.
   c) Continue taking the maximum recommended dose regularly for long periods of time.
   d) Do not meet the DSM IV criteria for codeine dependence.

3. Which of the following is NOT likely to be an adverse effect of ibuprofen resulting from overdose of OTC combination analgesics?
   a) Severe hypotension.
   b) Severe hypokalaemia.
   c) Anaemia.
   d) Renal failure.

4. When counselling customers about the appropriate use of OTC analgesics, which of the following points is CORRECT?
   a) It is generally accepted that only doses of codeine ≥30 mg are likely to be effective.
   b) If paracetamol does not adequately control pain, non-pharmacological strategies should be tried next.
   c) To reduce NSAID requirements, patients with osteoarthritis can take fish oil in doses sufficient to provide at least 2.7 g of omega-3 fatty acids per day.
   d) People taking regular analgesics for cluster headaches are at high risk of developing medication overuse headache.

5. Which would be the MOST appropriate response for a customer who frequently requests Nurofen Plus, (containing ibuprofen 200 mg and codeine phosphate 12.8 mg) telling you it is for her headaches?
   a) Tell her you cannot supply it as it is out of stock.
   b) Supply it, but advise her not to exceed the maximum daily dose.
   c) Tell her you cannot supply it as she is likely to be suffering from medication overuse headache.
   d) Ask her if she is aware of the risk of codeine dependence and the potential dangers of taking too much ibuprofen.
Because of concerns that over-the-counter (OTC) analgesics (painkillers) containing codeine are being misused, in May 2010 OTC analgesics containing codeine were removed from S2 (Pharmacy medicines) and rescheduled to S3 (Pharmacist Only medicines). They are now limited to a maximum of 5 days’ treatment per pack and 12 mg codeine (~16 mg codeine phosphate) per dosage unit. Yet, despite the increased restrictions on the availability of codeine-containing analgesics, many people are still misusing these products.

You ask a lady searching in the analgesics section of the pharmacy if you can help her. She says she is looking for Nurofen Tension Headache tablets. Asking her questions according to the What Stop Go protocol, you find out that she wants them for herself and that she has no medical conditions and takes no other medicines. She tells you that she takes the tablets for tension headaches, which she gets about 4 times a week. You ask her when she started getting these headaches and she says about 5 months ago, when she lost her job. Although she now has a new job, the headaches are still occurring, with increasing frequency.

Pain
Pain can be either acute or chronic:
- Acute pain is a normal response to an injury. It begins suddenly and usually does not last for long.
- Chronic (ongoing) pain lasts beyond the normal healing time – generally for more than 3 months. It can be due to an illness (e.g. arthritis, cancer) or a serious injury (e.g. a car accident). Sometimes there seems to be no explanation for chronic pain. This does not necessarily mean that a reason does not exist, but that it cannot be found using current medical technologies.

Codeine
Codeine is a weak opioid analgesic. Stronger opioid analgesics (also known as narcotics) include morphine and pethidine. These have a higher potency than other types of analgesics and are used to relieve severe pain. Codeine has about one-sixth of the analgesic strength of morphine. Its analgesic effect occurs because a small amount of a dose of codeine is converted to morphine in the body. It is used for relief of moderate to severe pain which has not been relieved by non-opioid analgesics such as paracetamol, aspirin or ibuprofen. It is not yet known with certainty how much codeine is required to produce an analgesic effect, but it is thought that 30 mg is the lowest dose that can effectively relieve pain.

The main adverse effects of codeine are nausea, vomiting, constipation, dizziness and drowsiness. Higher doses can cause

This education module is independently researched and compiled by PSA-commissioned authors and peer reviewed.
respiratory depression, which is potentially fatal. The risk of respiratory depression is greater if the person also takes sleeping tablets or tranquilisers or drinks alcohol. Prolonged use of codeine can result in dependence. If a person who has codeine dependence suddenly stops taking it, they may experience withdrawal symptoms such as nausea, diarrhoea, sweating, anxiety, loss of appetite and shivering.

Some people lack the enzyme that metabolises (converts) codeine to morphine. These people are called slow metabolisers and they get no detectable pain relief from a dose of codeine. If they take a higher dose, they still receive no analgesic benefit, but increase their risk of adverse effects. In contrast, another group of people have too much of the enzyme that converts codeine to morphine. They are called ultra-rapid metabolisers. In these people, a dose of codeine can result in increased morphine production and potentially dangerous opioid effects (e.g. respiratory depression). See Table 1 in Facts behind the Fact Card for the percentages of people in different population groups who are slow or ultra-fast codeine metabolisers.

Codeine is only available as an OTC medicine in combination with other ingredients – either another analgesic (e.g. paracetamol, ibuprofen, aspirin), or cold and flu medicines (e.g. decongestants, antihistamines, expectorants). In cold and flu medicines, codeine is present as a cough suppressant rather than an analgesic.

**NSAIDs**

Non-steroidal anti-inflammatory drugs (NSAIDs) available in OTC medicines include aspirin, ibuprofen, naproxen and diclofenac. NSAIDs work by blocking the production of prostaglandins – hormone-like chemical messengers that have various functions in the body. These include:

- causing dilation of blood vessels
- promoting blood clotting
- stimulating pain receptors at sites of injury
- promoting or reducing inflammation
- helping to protect the gastrointestinal tract from stomach acid.

NSAIDs can be useful to relieve pain in conditions with significant inflammation (e.g. rheumatoid arthritis, gout). However, by interfering with the production of prostaglandins, they can cause side effects in many other parts of the body, including the:

- gastrointestinal tract – e.g. nausea, diarrhoea, heartburn and stomach ulcers
- blood – increased risk of bleeding due to interference with blood clotting
- kidneys – e.g. kidney damage, salt and fluid retention
- blood vessels – increased blood pressure.

Factors that can increase a person’s risk of developing gastrointestinal problems due to NSAIDs include:

- being 65 years of age or over
- a history of gastrointestinal problems
- taking certain other medicines e.g. corticosteroids, warfarin
- taking NSAIDs for a long time
- taking high doses of NSAIDs
- drinking excessive amounts of alcohol
- cigarette smoking.

Other people who should avoid NSAIDs or use them with caution include:

- people with heart problems, high blood pressure or kidney problems
- people with asthma – NSAIDs can sometimes worsen asthma
- pregnant women – NSAIDs should be avoided, especially in the third trimester
- people suffering from dehydration (e.g. after excessive vomiting) – may result in kidney failure
- people taking certain other medicines (e.g. medicines for high blood pressure or osteoporosis).

**Paracetamol**

It is still not known exactly how paracetamol works. It acts in the central nervous system (the brain) to reduce pain and fever. It does not reduce inflammation. When taken in recommended doses, paracetamol is a safe medicine. It is the recommended first-choice analgesic for mild to moderate pain, and is also effective for reducing fever. The effects of a dose of paracetamol last for 3–4 hours.

Taking more than the recommended dose of paracetamol (for adults – 1 g/dose and 4 g/24 hours) does not increase its analgesic effect, but does increase the possibility of adverse effects. The most serious adverse effect is liver damage. Paracetamol overdose is the leading cause of acute liver failure in Australia. Factors that can increase the risk of liver damage include:

- taking paracetamol more often than recommended, or using higher-than-recommended doses for a prolonged period of time
- being malnourished or dehydrated (e.g. fasting, vomiting)
- drinking excessive amounts of alcohol.

A common cause of paracetamol-induced liver damage is inadvertently taking two paracetamol-containing preparations (e.g. a painkiller and a cold and flu medicine).

Taking excessive doses of paracetamol for a prolonged period of time can also cause serious kidney problems (including kidney failure).

**Combination analgesics**

OTC combination analgesics products available in Australia contain codeine phosphate in doses ranging from 8–15 mg, combined with either paracetamol 500 mg, ibuprofen 200 mg or aspirin 300 mg. There is doubt about whether codeine in the doses used in OTC analgesics is effective as a pain reliever. Therefore, in a person whose pain does not respond to paracetamol and/or an NSAID, and who requires codeine in addition, it may be preferable to give the codeine separately in an effective dose (available only on prescription).

**Codeine dependence**

Many people who become dependent on codeine initially start taking OTC codeine-containing analgesics in recommended doses for pain. They gradually increase the number of tablets they are taking, either because they are not getting adequate pain relief or because high doses of codeine make them ‘feel good’. Some people eventually take as many as 100 tablets a day.
Consequences of OTC codeine misuse

There are increasing reports of serious harms resulting from misuse of OTC codeine-containing analgesics. The harms are mainly due to excessive doses of ibuprofen. Serious adverse effects caused by the ibuprofen include gastrointestinal ulcers and bleeding, anaemia, kidney failure, and severe hypokalaemia (low blood potassium levels). Severe hypokalaemia can result in heart arrhythmias, muscle damage, and mental problems (e.g. psychosis, delirium, hallucinations).

Paracetamol taken in excessive doses can cause potentially fatal liver damage. The toxic dose is generally about 7.5 g. However, some people who start taking therapeutic doses of codeine-paracetamol medicines and then gradually increase their dose develop tolerance to paracetamol’s toxic effects. They regularly take ‘toxic’ doses of paracetamol without suffering any harm. This is known as ‘autoprotection’ and it is not known how it occurs.

Other harms resulting from misuse of OTC codeine medicines include:

- Side effects of regular high doses of codeine (e.g. constipation, dry mouth). Codeine-induced constipation may lead to additional self-medication with repeated doses of laxatives, and dry mouth can lead to dental problems.
- Worsening of health problems due to untreated conditions (e.g. self-medicating for dental pain, instead of visiting the dentist to address the cause of the pain).
- Impaired mental function due to excessive doses of codeine, resulting in car accidents or problems at work
- Social harms resulting from drug dependence (e.g. effects on relationships, loss of employment).

Medication overuse headache

People who take analgesics frequently for headaches may eventually develop a condition known as ‘medication overuse headache’ (MOH), in which they experience an ongoing cycle of rebound headaches after the effects of each dose of analgesic wear off. MOH does not appear to develop in people who regularly take pain relievers for other conditions (e.g. arthritis).

People most at risk of developing MOH are those with frequent migraine or tension-type headaches. Combination analgesics containing codeine or other opioids are the most common cause of MOH.

The treatment of MOH is to stop taking the overused medicine. This may require specialist management at a pain or headache clinic. When the person first stops taking the medicine, they may have an increase in headaches for several days, after which headaches should gradually decrease over a period of weeks or months. People who have been overusing a combination analgesic containing codeine may experience codeine withdrawal symptoms.

Customers who need to use medicine for headaches on more than 2–3 days per week should be referred to the pharmacist, as they may be suffering from MOH.

Guidelines for appropriate analgesic use

The cause of the pain should be determined so that the correct treatment can be recommended. For example, a certain type of pain called neuropathic pain usually does not respond to analgesics and may require the use of other prescribed medicines.

Paracetamol is the analgesic of choice for mild to moderate pain. People with chronic pain (e.g. osteoarthritis) should take paracetamol regularly, not ‘as required’. They may find it more convenient to use the extended-release formulation, reducing the number of doses to 3 per day. They should be advised not to exceed the maximum daily dose (4 g for adults) and to avoid taking other paracetamol-containing preparations (e.g. cold and flu medicines).

If paracetamol does not control the person’s pain, or if they have an inflammatory condition (e.g. rheumatoid arthritis), an NSAID may be recommended. They should be assessed to determine whether it is safe for them to use a NSAID (see above). They should be informed about correct dosing and signs of adverse effects (e.g. dark stools, swollen ankles, heartburn, stomach pain, worsening asthma).

OTC NSAIDs should be used only for short-term pain relief, not regular treatment of chronic pain. The lowest effective dose should be used for the shortest possible time (preferably no longer than 3 days). In chronic conditions such as osteoarthritis a NSAID can be taken occasionally ‘when required’ (e.g. before activity or during a temporary increase in pain) in addition to regular paracetamol.

In people at high risk of NSAID adverse effects, or whose pain does not respond to paracetamol and/or an NSAID, addition of codeine may be considered. However, as it is generally accepted that doses of codeine below 30 mg are unlikely to be effective, there may be no advantage in taking an OTC analgesic containing codeine. OTC analgesics containing codeine are S3 (Pharmacist Only) medicines. Therefore, all customers requesting OTC medicines containing codeine must be referred to the pharmacist.

You advise the customer that it is possible she may be suffering from medication overuse headache. Therefore, although she has no medical conditions and takes no other medicines that make ibuprofen unsuitable for her, you suggest that she have a chat with the pharmacist. You give her a Headache Fact Card to read while she is waiting to speak to the pharmacist.
Assessment questions for the pharmacy assistant

OTC codeine-containing analgesics

Personal ID number: — — — — — —
Full name: ............................................................................................................................................................
Pharmacy: ..............................................................................................................................................................
Address: ..................................................................................................................................................................
Suburb: ..............................................................................................................................................................
State: ..............................................................................................................................................................
Postcode: ..............................................................................................................................................................

Circle one correct answer from each of the following questions.

Before undertaking this assessment, you need to have read the Counter Connection article and the associated Fact Cards.

The pass mark for each module is five correct answers. Participants receive one credit for each successfully completed module. On completion of 10 correct modules participants receive an Achievement Certificate.

Please submit your assessment by 30 April 2015
Please retain a copy for your own purposes.
Photocopy if you require extra copies.

Submit answers
Submit online at www.psa.org.au/selfcare
Fax: 02 6285 2869
Mail: Self Care Answers
Pharmaceutical Society of Australia
PO Box 42
DEAKIN WEST ACT 2600

1. Chronic pain:
   a) Is a normal response to an injury.
   b) Usually does not last for long.
   c) Generally lasts for more than 3 months.
   d) Can always be explained.

2. Which of the following statements regarding codeine is CORRECT?
   a) Codeine is a stronger opioid analgesic than morphine and is used for severe pain.
   b) The lowest dose of codeine that can effectively relieve pain is thought to be 30 mg.
   c) People who are ultra-rapid metabolisers get no detectable pain relief from a dose of codeine.
   d) The most common adverse effect of codeine is diarrhoea.

3. Which of the following counselling points about OTC analgesics is CORRECT?
   a) People with heart problems or high blood pressure should avoid NSAIDs or use them with caution.
   b) Paracetamol is useful to relieve pain in conditions with significant inflammation (e.g. rheumatoid arthritis).
   c) The most significant adverse effect of ibuprofen is liver damage.
   d) A person with chronic pain (e.g. osteoarthritis) should take a NSAID regularly, rather than ‘as required’.

4. Which of the following statements regarding the harms that can result from misuse of OTC codeine-containing analgesics is INCORRECT?
   a) The harms resulting from misuse of OTC codeine-containing analgesics are mainly due to excessive doses of paracetamol.
   b) Regular high doses of codeine can cause dependence, constipation and dry mouth.
   c) Excessive intake of ibuprofen can result in gastrointestinal ulcers and bleeding, anaemia and kidney failure.
   d) When a person regularly takes toxic doses of paracetamol without suffering any ill effects, this is known as ‘autoprotection’.

5. Medication overuse headache:
   a) Should be suspected if a person regularly takes ibuprofen for headache on ≥5 days per month.
   b) Commonly develops in people who regularly take pain relievers for arthritis.
   c) Is most commonly caused by regular intake of combination analgesics containing codeine or other opioids.
   d) Is usually treated with regular use of a combination analgesic containing codeine and paracetamol.

6. A customer comes into the pharmacy and asks you for a strong pain reliever. She says she is getting regular headaches that are no longer relieved by paracetamol or ibuprofen. Which would be the MOST appropriate response?
   a) Advise her to take regular doses of paracetamol plus ibuprofen ‘when required’.
   b) Tell her she most likely has medication overuse headache and she should immediately stop taking all pain relievers.
   c) Sell her some Nurofen Plus (containing ibuprofen 200 mg and codeine phosphate 12.8 mg), warning her not to take more than the recommended dose.
   d) Refer her to the pharmacist.
John bell says

What’s coming up in inPHARMation?

next month’s edition of inPhARmation will focus on sleep. Everyone needs a good night’s sleep to be at their best during the day. However, many factors can reduce the quality and quantity of sleep a person gets, including their sleeping environment, diet, medicines and medical conditions. Some people suffer from sleep disorders that make it hard to get refreshing sleep. Pharmacists and pharmacy assistants can help customers manage sleeping problems. The articles in the April edition of inPhARmation will discuss the signs and symptoms of common sleep disorders and the sleep habits, medicines and devices that can promote or improve sleep.

Self Care achievers

Self Care presents certificates to staff who successfully complete a year of Counter Connection modules. We would like to congratulate the following people:

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Year 12
Cheryl Ackland

Year 11
Louise Rannalls

Year 10
Sally Bearman

Year 9
Bridie Florence
Debra Hume
Laura Donaldson

Year 8
Christine Keneally
Jan Hanson
Janice England
Louise Hunt
Mary Martella
Sharon Guiste

Year 7
Karen Whelan
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Nadean Hinschen
Noela Sieb

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Kendall Murphy
Kim Shaw
Kylee Parmenter
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Lauren Chick
Linda Thomas
Lisa Griggs
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Morgan Preston
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Shannon Salo
Shaye Robeck
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Amanda Tabone
Amanda Vale
Amber Gillies
Amelia Wood
Angela Larby
Anne Budini
Ara Watson
Blair Arnold
Carolyn Garner
Chelsea Kemp
Chloe Bacak
Dakota McCarthy
Dayna Gelsi
Elena Sakolevas
Ella Kelly
Ellie Merrett
Elyse Burdak
Emily Bowland
Gayle Hunt
Helen Joyce
Holly Theile
Jaeme-leigh Anderson
Jeanette Flynn
Jenny Karikis
Joanne Miller
Juanita Love
Julie Wignell
Kathleen Mercado
Kimberly Clifton
Kylie Walton
Lana Huynh
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Laura Trillini
Lauren Scarmar
Priscilla Han
Liam Birch
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Merin Rayner
Nicola Rix
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Rachael Lee
Rachelle Abba
Roisin Megahay
Rosie Ward
Rukshshana Nisha
Sana Zafirah
Sandy Kelly
Sara Saunders
Shaye Robeck
Suzie Janeska
Stefan Veljovic
Suzanne Wright
Theresa Collins
Wendy Moss

Conferences

The Third BioCeuticals Research Symposium
Interconnected Drivers of Health and Disease
17–19 April 2015
Hilton Hotel, Sydney, NSW

PSA Victorian Pharmacy Conference
Knowledge, People, Innovation
18–19 April 2015
Parkville, Melbourne, Victoria
www.psa.org.au

40th PSA Offshore Refresher Conference
30 April–10 May 2015
Berlin and Paris
www.psa.org.au/refresher

Connecting Asthma Care Conference
2015 Asthma Australia conference
4–5 May 2015
Sofitel Hotel Brisbane, Queensland

13th National Rural Health Conference
24–27 May 2015
Darwin Convention Centre, NT
www.ruralhealth.org.au/conference

National health calendar dates

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<td>March</td>
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