

Mydol 15

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using Mydol 15?

Mydol 15 contains the active ingredients paracetamol and codeine phosphate hemihydrate. Mydol 15 is used to relieve acute moderate pain and fever. For more information, see Section [1. Why am I using Mydol 15?](#) in the full CMI.

2. What should I know before I use Mydol 15?

Do not use if you have ever had an allergic reaction to Mydol 15 or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use Mydol 15?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Mydol 15 and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Mydol 15?

The standard dose for adults and children aged 12 years and over for this medicine is 2 tablets, taken every 4 to 6 hours if necessary. More instructions can be found in Section [4. How do I use Mydol 15?](#) in the full CMI.

5. What should I know while using Mydol 15?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Mydol 15.• Talk to your doctor about pain control if the medicine is not helping.• Tell your doctor if you become pregnant while taking Mydol 15.
Things you should not do	<ul style="list-style-type: none">• Adults: Do not take this medicine for longer than a few days at a time unless advised to by a doctor• Children aged over 12 years: Do not take this medicine for longer than 48 hours at a time, unless advised by a doctor.• Do not take more than the recommended dose unless your doctor tells you to.• Do not take more than 8 tablets a day in a 24 hour period.• Do not give Mydol 15 to children under 12 years.• Do not take high doses of the medicine for long periods of time unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how Mydol 15 affect you.• Mydol 15 may cause dizziness, drowsiness or light-headedness in some people.
Drinking alcohol	<ul style="list-style-type: none">• You must tell your doctor if you drink large quantities of alcohol• Patients treated with this medication should not drink alcohol whilst taking this medication• Drinking alcohol increases the likelihood of becoming drowsy.
Looking after your medicine	<ul style="list-style-type: none">• Keep Mydol 15 in a cool, dry place where the temperature stays below 30°C.

For more information, see Section [5. What should I know while using Mydol 15?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist immediately if you notice any of the following side effects shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue, or other parts of the body, rash, itching or hives on the skin. These are very serious side effects. They may be the signs of an allergic reaction. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice any of the following and they worry you: nausea or vomiting, constipation, drowsiness or dizziness. These are the more common side effects of your medicine. They are usually mild.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING:**Limitations of Use**

Mydol 15 should only be used if your doctor decides other treatment options are not able to effectively manage your pain or you cannot tolerate them.

Hazardous and Harmful Use

Mydol 15 contains codeine which may be habit forming. Mydol 15 poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will assess your risks and monitor you regularly during treatment.

Life Threatening Respiratory Depression

Serious, life-threatening or fatal respiratory depression (shallow or difficulty breathing) may occur with the use of Mydol 15 even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting Mydol 15 and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Concomitant Use of Benzodiazepines and Other Central Nervous System (CNS) Depressants, including Alcohol

Using Mydol 15 with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimize the dose and duration of use and monitor you regularly for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while taking Mydol 15.

Mydol 15

Active ingredient(s): *paracetamol and codeine phosphate hemihydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Mydol 15. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Mydol 15.**

Where to find information in this leaflet:

- [1. Why am I using Mydol 15?](#)
- [2. What should I know before I use Mydol 15?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Mydol 15?](#)
- [5. What should I know while using Mydol 15?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Mydol 15?

Mydol 15 contains the active ingredients paracetamol and codeine phosphate hemihydrate. Mydol 15 is a type of analgesic. Paracetamol and codeine work together to stop the pain messages from getting through to the brain. Paracetamol also acts in the brain to help reduce fever.

Mydol 15 is used to relieve acute moderate pain and fever and is intended for short term use.

2. What should I know before I take Mydol 15?

Warnings and precautions

During the treatment with Mydol 15 tell your doctor straight away if:

If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Do not use Mydol 15 if:

- you are allergic to paracetamol or codeine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

- you have severe and/or acute respiratory diseases
- you have acute breathing difficulties such as bronchitis, unstable asthma or emphysema, respiratory depression (shallow breathing) or respiratory insufficiency (difficulty breathing).
- you have liver failure
- you have Glucose-6-phosphate-dehydrogenase deficiency (an enzyme deficiency)
- you are a known CYP 2D6 ultra-rapid metaboliser (a fast metaboliser of codeine by the CYP 2D6 enzyme)
- you have a history of intolerance to this medicine
- chronic constipation
- you have diarrhoea caused by antibiotics or poisoning

Do not take this medicine if you regularly drink large quantities of alcohol. Do not take Mydol 15 if you have a history of drug dependence, including alcohol dependence.

Do not take Mydol 15 during the third trimester of pregnancy.

Do not take codeine during labour, especially if the baby is premature. The medicine may produce withdrawal effects in the newborn baby.

Do not take it if you are breastfeeding or planning to breastfeed.

Do not use MYDOL 15 in children under 12 years.

Ask your doctor or pharmacist about taking MYDOL 15 if you are over 65 years of age and have kidney or respiratory problems.

Do not give Mydol 15 to children aged between 12-18 years who have undergone tonsillectomy and/or adenoidectomy to treat sleep apnoea.

Do not take Mydol 15 if you are allergic to morphine or oxycodone.

Do not use it after the expiry date (EXP) printed on the pack. If you take it after the expiry date it may have no effect at all, or worse, have an entirely unexpected effect.

Do not use MYDOL 15 if the packaging is damaged or shows signs of tampering.

Check with your doctor if you have or had had any of the following medical conditions:

- heart, lung, liver or kidney problems
- low blood pressure
- difficulty breathing, wheezing, chronic cough, asthma, or other chronic breathing conditions
- compromised respiratory function (due to emphysema, kyphoscoliosis or obesity)
- known analgesic intolerance
- chronic alcohol use including recent cessation of alcohol intake
- history of drug or alcohol abuse
- pre-existing opioid dependence
- low glutathione reserves
- Gilbert's syndrome
- stomach, gallbladder, urinary or bowel conditions
- chronic constipation

- recent surgery on the stomach or intestines or urinary tract surgery
- enlarged prostate
- problems with your adrenal gland or underactive thyroid
- multiple sclerosis
- head injury or trauma
- convulsions, fits or seizures

Tell your doctor or pharmacist if you plan to have surgery.

Tell your doctor or pharmacist if you drink large quantities of alcohol.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Do not take Mydol 15 during the third trimester of pregnancy.

Do not take MYDOL 15 during labour, especially if the baby is premature.

The medicine may produce withdrawal effects in the newborn baby.

Do not use MYDOL 15 if you are breast feeding or planning to breastfeed.

A small amount of codeine passes into the breast milk. It may cause breathing problems in newborn infants.

Addiction

You can become addicted to Mydol 15 even if you take it exactly as prescribed. Mydol 15 may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you taking Mydol 15. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking Mydol 15 suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to Mydol 15 may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety

- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

Mydol 15 given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

3. What if I am taking other medicines?

Other medicines and paracetamol

Please inform your doctor or pharmacist if you are taking:

- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may affect how Mydol 15 works:

- medicines causing sleepiness or drowsiness
- tranquillisers (medicines for anxiety and nerves)
- gabapentinoids, hypnotics, cannabis and centrally-active anti-emetics
- benzodiazepines (medicines used as sedatives or to treat anxiety)
- medicines containing alcohol (ethanol), e.g. some cough syrups
- medicines used to treat depression
- anticholinergics (medicines for stomach cramps/spasms, travel sickness, Parkinson's disease)
- phenothiazine and antipsychotic agents (medicines used to treat mental illnesses)
- monoamine oxidase inhibitors (medicines used to treat depression) taken within the last 10 days
- salicylates or non-steroidal anti-inflammatory drugs (NSAIDs), such as aspirin or ibuprofen
- medicines which thin the blood (e.g. warfarin)
- medicines to treat epilepsy
- other pain relief medication
- medicines used to treat high blood pressure
- medicines used to relax muscles
- medicines used to treat diarrhoea, nausea or vomiting
- propantheline, a medicine used to treat stomach ulcers
- cholestyramine (medicine used to treat bile problems and/or high cholesterol)
- chelating resin
- medicines used to treat alcohol and/or opioid dependence (e.g. naltrexone, buprenorphine or methadone)
- chloramphenicol (medicine used to treat ear and eye infections)
- flucloxacillin, zidovudine or rifampicin (medicines used to treat infections).

- medicines used to control electrolytes levels in kidney disease

These medicines may be affected by Mydol 15, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Mydol 15.

4. How do I use Mydol 15?

How much to take

- **Adults and children over 12 years:** Take 2 tablets every 4-6 hours if necessary. You should not take more than 8 tablets in a 24 hour period.
- **MYDOL 15** are not recommended for children under 12 years.

When to take Mydol 15

- If you are not sure when to take it, ask your doctor or pharmacist.

How to take Mydol 15

- Swallow tablets whole with a little water or other liquid.

How long to take Mydol 15

- **Adults:** Do not take this medicine for longer than a few days at a time, unless advised to by a doctor.
- **Children aged over 12 years:** Do not take this medicine for longer than 48 hours at a time, unless advised to by a doctor
- Ask your doctor or pharmacist if you are not sure how long to take the medicine for.

If you forget to take Mydol 15

If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much Mydol 15

If you think that you have used too much [medicine name], you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Mydol 15?

Things you should do

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

If you become pregnant while you are taking given this medicine, stop taking it and tell your doctor or pharmacist immediately.

Remind any doctor, dentist or pharmacist you visit that you are using Mydol 15.

Things you should not do

- **Do not take more than the recommended dose unless your doctor tells you to.**

Adults and children over 12 years should not take more than 8 caplets a day.

Do not take high doses of the medicine for long periods of time unless your doctor tells you to. Taking more than the recommended dose may cause liver damage. Codeine may be habit forming.

- **Do not give this medicine to anyone else, even if they have the same condition as you.**
- **Do not use this medicine to treat any other complaints unless your doctor tells you to.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Mydol 15 affects you.

Mydol 15 may cause dizziness, drowsiness or light-headedness and problems with vision in some people, especially after the first dose.

Drinking alcohol

Do not drink alcohol while taking Mydol 15.

Drinking alcohol increases the likelihood of becoming drowsy.

Looking after your medicine

- Store below 30°C
- Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it. A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal: <ul style="list-style-type: none">• Nausea• Vomiting• Indigestion• Stomach pain• Constipation Head and Neurology: <ul style="list-style-type: none">• Drowsiness• Dry mouth• Headache• Ringing in the ears Skin: <ul style="list-style-type: none">• Sweating	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Metabolism: <ul style="list-style-type: none">• Symptoms of rapid breathing, rapid heart rate and changes in consciousness caused by pyroglutamic acidosis (an accumulation of pyroglutamic acid due to low levels of a protein called glutathione) Allergy: <ul style="list-style-type: none">• Shortness of breath• Wheezing or difficulty breathing• Swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing• Skin rash, itching, hives• Flushing of the face Heart: <ul style="list-style-type: none">• Fast heartbeat Skin:	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

<ul style="list-style-type: none"> Painful red areas with blisters and peeling layers of skin which may be accompanied by fever and/or chills Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals Yellowing of the skin and eyes (jaundice) <p>Infection:</p> <ul style="list-style-type: none"> Mouth ulcers, fever and sore throat <p>Bleeding:</p> <ul style="list-style-type: none"> Bleeding, bruising more easily <p>Head and Neurology:</p> <ul style="list-style-type: none"> Unusual or extreme mood swings Dizziness, light-headedness Fainting Confusion Seizures <p>Liver:</p> <ul style="list-style-type: none"> Hepatitis (symptoms include loss of appetite, itching, yellowing of the skin and eyes, light coloured bowl motions, dark coloured urine) <p>Urinary:</p> <ul style="list-style-type: none"> Problems passing urine Dark coloured urine <p>Eyes:</p> <ul style="list-style-type: none"> Blurred vision <p>Frequency "Not known" (frequency cannot be estimated from the available data): "A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)"</p>	
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Mydol 15 contains

Active ingredients (main ingredients)	Paracetamol, Codeine phosphate hemihydrate
Other ingredients (inactive ingredients)	Potato starch, Lactose monohydrate, Povidone, Docusate Sodium, Colloidal anhydrous silica, Magnesium Stearate
Potential allergens	MYDOL 15 does not contain any gluten, sucrose, tartrazine or any azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What Mydol 15 looks like

Mydol 15 are white to off white capsule shaped uncoated tablets which are plain on one side and have a break line on the other side (Aust R 188381).

Who distributes Mydol 15

Pharmacor Pty Ltd

Suite 803, Tower A, The Zenith,
821 Pacific Highway,
Chatswood NSW 2067
Australia

Web: www.pharmacor.com.au

Email: medinfo@pharmacor.com.au

Phone: 1300 138 805

Australian Registration Number:

MYDOL 15 tablets blister pack

AUST R 188381

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