

MYDOL 15

Paracetamol 500 mg and Codeine Phosphate Hemihydrate 15 mg

Consumer Medicine Information

WARNINGS

Limitations of use

Because of the risks associated with the use of opioids, MYDOL 15 should only be used in patients for whom other treatment options, including non-opioid analgesics, are ineffective, not tolerated or otherwise inadequate to provide appropriate management of pain

Hazardous and harmful use

MYDOL 15 poses risks of hazardous and harmful use which can lead to overdose and death. Assess the patient's risk of hazardous and harmful use before prescribing and monitor the patient regularly during treatment

Life threatening respiratory depression

Serious, life-threatening or fatal respiratory depression may occur with the use of MYDOL 15. Be aware of situations which increase the risk of respiratory depression, modify dosing in patients at risk and monitor patients closely, especially on initiation or following a dose increase

Concomitant use of benzodiazepines and other central nervous system (CNS) depressants, including alcohol

Concomitant use of opioids with benzodiazepines, gabapentinoids, antihistamines, tricyclic antidepressants, antipsychotics, cannabis or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Limit dosages and durations to the minimum required; and monitor patients for signs and symptoms of respiratory depression and sedation. Caution patients not to drink alcohol while taking MYDOL 15.

Please read this information before you start taking this medicine.

What is in this CMI

This CMI answers some common questions about MYDOL 15. It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking MYDOL 15 against the benefits this medicine is expected to have for you.

Keep this information with the medicine. You may need to read it again.

What are MYDOL 15 used for

This medicine may be addictive if taken for more than a few days at a time.

MYDOL 15 are for the temporary relief of acute moderate pain.

MYDOL 15 contain paracetamol and codeine. Paracetamol and codeine work together to stop the pain messages from getting through to the brain.

Paracetamol also acts in the brain to reduce fever. Your doctor may have given you this medicine for another use.

If you want more information, ask your doctor.

Before you take MYDOL 15

When you must not take it

You should not take MYDOL 15 if you are allergic to paracetamol or codeine or any of the ingredients listed under "Product Description". The symptoms of an allergic reaction may include a rash, asthma attack or hay fever.

Do not take this medicine if you have any of the following conditions:

- acute breathing difficulties such as bronchitis, unstable asthma or emphysema
- chronic constipation
- diarrhoea caused by antibiotics or poisoning

Do not take this medicine if you regularly drink large quantities of alcohol.

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

The medicine may produce withdrawal effects in the newborn baby.

Ask your doctor about taking MYDOL 15 if you are breastfeeding. A small amount of codeine passes into the breast milk. It may cause breathing problems in newborn infants.

Do not use MYDOL 15 if you are breastfeeding or planning on breastfeeding.

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

MYDOL 15 may be used during pregnancy.

However, ask your doctor about the risks and benefits of taking MYDOL 15 while you are pregnant.

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 breast feed.

This medicine passes into breast milk and may affect the baby.

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 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 torn or shows signs of tampering.

Before you start to take it

Do not take MYDOL 15 with other medicines containing paracetamol or codeine, unless advised to do so by a doctor or pharmacist.

You must tell your doctor if:

- You have allergies to any ingredients listed under "Product Description" at the end of this leaflet.
- You have any of these conditions:
 - Lung, Liver or kidney problems
 - Difficulty breathing, wheezing, chronic cough, asthma or other chronic breathing conditions
 - You drink large quantities of alcohol.
 - You have a history of drug or alcohol abuse
 - Recent surgery on the stomach or intestines
 - Head injury
 - Enlarged prostate
 - Low blood pressure
 - Underactive thyroid

You should tell your pharmacist or doctor if you are using any other medicines including any of the following medicines:

- Any medicines causing sleepiness
- Tranquillisers (medicines for anxiety and nerves)

- Medicines which thin the blood (e.g. warfarin)
- Medicines to treat epilepsy.
- Metoclopramide, a medicine used to control nausea and vomiting
- Chloramphenicol, an antibiotic used to treat ear and eye infections.
- Medicines used to relieve stomach cramps or spasms
- Medicines used to prevent travel sickness
- Medicines used to treat Parkinson's disease
- Medicines used to treat high blood pressure
- Medicines for diarrhoea such as kaolin, pectin and loperamide
- Monoamine oxidase inhibitors, medicines used to treat depression, if taken within the last 14 days
- Quinidine, a medicine used to treat abnormal or irregular heart beat
- Phenothiazines and antipsychotic agents, medicines used to treat mental disorders
- Other opioids, used to treat pain or suppress coughs
- Alcohol
- If you are an Ultra rapid metaboliser of CYP2D6
- If you are aged below 18 years of age and have had your tonsils or adenoids removed to treat sleep apnoea.

These medicines may be affected by MYDOL 15 or affect how well MYDOL 15 work.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

You should also tell your pharmacist or doctor about any other medicines that you have bought without a prescription from either your pharmacy, supermarket or health food shop.

If you have not told your doctor about any of these things, tell him/her before you take any MYDOL 15

How to take MYDOL 15

The label on your pack of MYDOL 15 will tell you how to take your medicine and how often. If you are unsure about the directions ask your doctor or pharmacist.

How much to take

The usual doses of MYDOL 15 are:

Adults and children over 2 years: 2 tablets.

This dosage may be repeated in 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.

How long to take it

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.

Keep the recommended dose. If **MYDOL 15** are not adequately controlling your pain, do not increase the dose. Please see your doctor.

How to take it

Swallow tablets whole with a little water or other liquid.

The directions given to you by your pharmacist or doctor may be different from the information in this leaflet. If you are unsure what dose to take ask your pharmacist or doctor.

If you forget to take it

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 missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much **MYDOL 15**.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers of these places handy.

If you take too many tablets you may feel nauseous, light headed, dizzy or drowsy.

While you are taking MYDOL 15

Things you must do

Take **MYDOL 15** exactly as your doctor has told you to.

Tell all your doctors, dentists and pharmacists that you are taking **MYDOL 15**.

Tell your doctor if you become pregnant while taking **MYDOL 15**.

Things you must NOT do

Do not use this medicine to treat any other complaint unless your doctor or pharmacist says it is safe. Do not give this medicine to anyone else even if they have the same symptoms as you.

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.

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

Things to be careful of

MYDOL 15 may cause dizziness or drowsiness in some people, especially after the first dose.

If affected do not drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or drowsy. Children should not ride bikes if affected and should be supervised to avoid potential harm. Do not drink alcohol.

Drinking alcohol increases the likelihood of becoming drowsy.

MYDOL 15 may be habit forming if taken in high doses for extended periods of time. Too much paracetamol may cause delayed, serious liver damage. Please ask your doctor or pharmacist if you are concerned about this.

Please ask your doctor or pharmacist if you are concerned about this.

About 8% of people are poor metabolisers of codeine. **MYDOL 15** may not work as well if you are one of those people.

Side Effects

Tell your doctor as soon as possible if you do not feel well while taking **MYDOL 15**.

Like other medicines, **MYDOL 15** can cause some side effects. If they occur, they are most likely minor and temporary. However, sometimes they are serious and need medical treatment.

Ask your doctor to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

Stomach problems such as:

- Nausea
- Vomiting
- Stomach pain
- Constipation

If you are taking **MYDOL 15** regularly, you may also need to take laxatives to prevent constipation.

Difficulty thinking or working because of:

- Dizziness
- Drowsiness

Be careful driving or operating machinery until you know how **MYDOL 15** affect you.

The above list includes the more common side effects of your medicine. They are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- Cough suppression
- Unusual or extreme mood swings
- Flushing of the face
- Fast heart beat

The above list includes serious side effects that may require medical attention. Serious side effects are rare for low doses of this medicine when used for a short period of time.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

If you believe **MYDOL 15** are not working well for you, do not increase the dose. Please see your pharmacist or doctor.

Some people may get other side effects not listed above.

Tell your doctor if you notice anything else that is making you feel unwell.

After taking MYDOL 15

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the box or the blister pack they will not keep well.

Keep **MYDOL 15** in a cool dry place where the temperature stays below 30°C.

Heat and dampness can destroy some medicines. Do not leave **MYDOL 15** in the car on hot days.

Do not store **MYDOL 15** or any other medicine in the bathroom or near a sink.

Keep **MYDOL 15** 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.

Disposal

If your doctor tells you to stop taking the tablets, ask your pharmacist what to do with any tablets that are left over.

This is not all the information that is available on **MYDOL 15**. If you have any more questions or are not sure about anything, ask your doctor or pharmacist.

Product Description

MYDOL 15 (AUST R 188381) come as white to off white capsule shaped uncoated tablets, plain on one side and breakline on the other side.

It is available in pack of 10 tablets, 12 tablets, 24 tablets, 30 tablets, and 40 tablets.

Active ingredients:

Each tablet contains:

Paracetamol 500 mg

Codeine Phosphate Hemihydrate 15 mg

Other ingredients:

Starch - Potato, Lactose monohydrate, Povidone, Docusate Sodium, Silica - colloidal anhydrous, Magnesium Stearate.

MYDOL 15 do not contain any gluten, sucrose, tartrazine or any azo dyes.

Name and Address of the sponsor

MYDOL 15 are supplied in Australia by:

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