

Mevadol Forte

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 Mevadol Forte?

Mevadol Forte contains the active ingredients paracetamol, codeine phosphate hemihydrate and doxylamine succinate. Mevadol Forte is for the short-term management of severe pain where your doctor decides other treatment options are ineffective, are not recommended, not tolerated, or otherwise inappropriate to manage your pain. For more information, see Section [1. Why am I using Mevadol Forte?](#) in the full CMI.

2. What should I know before I use Mevadol Forte?

Do not take Mevadol Forte if you have ever had an allergic reaction to Mevadol Forte or any of the ingredients listed at the end of this 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 Mevadol Forte?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Mevadol Forte 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 Mevadol Forte?

- The usual dose for adults and children between 12 and 18 years is one or two tablets every 4-6 hours as needed for relief.
- More instructions can be found in Section [4. How do I use Mevadol Forte?](#) in the full CMI.

5. What should I know while using Mevadol Forte?

Things you should do	- Remind any doctor, surgeon, dentist or pharmacist you visit that you are using Mevadol Forte. - Keep all your appointments, including those for blood tests. - Call your doctor straight away if you feel you need to change the dose, take it for longer periods of time, or you feel very unwell when you are not taking it and feel better when you are taking it again.
Things you should not do	- Do not take more than 8 tablets in a 24-hour period. - Do not stop taking Mevadol Forte or change the dose without checking with your doctor, or use it to treat any other complaints unless your doctor or pharmacist tells you to. - Do not give Mevadol Forte to anyone else, even if they have the same condition as you. - Do not take high doses of Mevadol Forte for long periods of time unless your doctor tells you to.
Driving or using machines	Do not drive a car, operate machinery, or do anything else that could be dangerous while taking Mevadol Forte.
Drinking alcohol	Do not drink alcohol while taking Mevadol Forte.
Looking after your medicine	Store below 25°C. Store in a cool, dry place away from direct sunlight.

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

6. Are there any side effects?

Common side effects include skin rash, constipation, nausea, vomiting, dizziness, drowsiness, sweating, blurred vision. Serious side effects include, wheezing, difficulty breathing or shallow breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives. 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

Mevadol Forte should only be used if your doctor decides other treatment options are ineffective, not tolerated or otherwise inadequate to provide appropriate management of pain.

Hazardous and harmful use

Mevadol Forte contains codeine which may be habit forming. Misuses, abuse, or addiction may lead to overdose and death. Your doctor will assess your risks and monitor your treatment regularly.

Life threatening respiratory depression

Serious, life-threatening, or fatal respiratory depression (shallow or difficulty breathing) may occur with the use of Mevadol Forte. Your doctor will assess your risk of respiratory depression and monitor your treatment regularly.

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

Using opioids while taking benzodiazepines (medicines used as sedatives or to treat anxiety), gabapentinoids (medicines used for epilepsy or neuropathic pain), antihistamines, antidepressants, antipsychotics, cannabis or other central nervous system (CNS) depressants, including alcohol, may result in extreme drowsiness and sleepiness, respiratory depression (shallow or difficulty breathing), coma, and death. Your doctor will limit your dosage and duration of use and monitor you regularly. Do not drink alcohol while taking Mevadol Forte.

Mevadol Forte

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

Consumer Medicine Information (CMI)

This leaflet provides important information about using Mevadol Forte. **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 Mevadol Forte.**

Where to find information in this leaflet:

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

1. Why am I using Mevadol Forte?

Mevadol Forte contains three active ingredients,

- **paracetamol,**
- **codeine phosphate hemihydrate, and**
- **doxylamine succinate.**

Paracetamol is an analgesic (pain-relieving medicine) and antipyretic (lowers body temperature). Codeine phosphate hemihydrate is a potent analgesic that helps to relieve pain. The body must convert codeine into morphine before it can provide pain relief. Doxylamine succinate is an antihistamine which can help to relieve tension and nausea associated with pain. This may be especially useful in the treatment of tension headache, migraine and period pain.

Mevadol Forte is used for the short-term management of severe pain for which other treatment options have

failed, are not recommended, not tolerated or are otherwise inappropriate to provide sufficient management of pain. This may include toothache and other dental pain, pain from injury or surgery, or headache pain.

2. What should I know before I use Mevadol Forte?

Warnings

Do not use Mevadol Forte if:

- you are allergic to paracetamol, codeine phosphate hemihydrate, doxylamine succinate 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 or have had any of the following medical conditions:
 - Severe and/or acute respiratory diseases,
 - such as bronchitis, acute asthma, emphysema, acute chronic obstructive pulmonary disease (COPD).
 - Other problems with breathing such as, shallow breathing, difficulty breathing, or slow breathing.
 - Glucose-6-phosphate-dehydrogenase deficiency (an enzyme deficiency that may lead to anaemia)
 - you very rapidly metabolise codeine into morphine.
 - Known intolerance to paracetamol.
 - Severe liver disease or liver failure
- if you have diarrhoea caused by antibiotics or poisoning.
- if you are in the third trimester of pregnancy or in

labour, especially if the baby is premature.

- if you are breastfeeding or planning to breastfeed.
- if you have a history of drug dependence, including alcohol dependence.
- if you are already taking Monoamine Oxidase Inhibitors (MAOIs) such as selegiline or moclobemide, or within 14 days of stopping MAOIs.
- if you have experienced allergy (generalised rash or shortness of breath) to morphine or oxycodone.
- the person going to take the tablets is under 12 years.
- if you are aged between 12 and 18 years of age and have had your tonsils or adenoids removed to treat sleep apnoea.

Check with your doctor if you:

- have allergies to:
 - any other medicines
 - aspirin or any other non-steroidal anti-inflammatory drugs (NSAID)
 - any other substances, such as foods, preservatives or dyes
- have or have had any medical conditions, especially the following:
 - Liver problems
 - Gilbert's syndrome
 - Kidney problems
 - Problems with your pancreas
 - Heart problems
 - Low blood pressure
 - Lung problems, difficulty breathing, wheezing, chronic cough, asthma, or other chronic breathing conditions
 - Sleep problems such as sleep apnoea
Mevadol Forte can cause sleep-related breathing disorders such as sleep apnoea and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day.
 - Intolerance to pain relieving medicine
 - Chronic alcohol use, or if you recently stopped taking alcohol
 - Opioid dependence
 - A history of drug and/or alcohol abuse. Caution is particularly recommended for use in adolescents and young adults with a history of drug and/or alcohol abuse.
 - Malnutrition and other sources of low levels of glutathione
 - Mild-to-moderate hepatocellular insufficiency
 - Severe renal insufficiency
 - Gilbert's syndrome
 - Recent stomach, intestine or urinary tract surgery
 - Gall bladder problems or your gall bladder has been removed
 - Obstructive and inflammatory bowel disease or other bowel problems
 - Chronic constipation

- Multiple sclerosis
- Prostate problems
- Retaining urine
- Problems passing urine
- Underactive thyroid
- Adrenal gland problems such as Addison's disease
- Head injury
- Brain tumour, stroke or other problems with the brain
- Fits or seizures
- Pain due to nerve problem
- Take any medicines for any other condition

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 Mevadol Forte during the third trimester of pregnancy.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Use in children

Do not give Mevadol Forte to children under 12 years.

3. What if I am taking other medicines?

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.

Tell your doctor or pharmacist if you are taking any other medicines, which contain paracetamol, codeine or doxylamine.

Do not take Mevadol Forte with Monoamine Oxidase inhibitors (MAOIs), such as selegiline or moclobemide, or within 14 days of stopping MAOIs.

Some medicines can interfere with Mevadol Forte including:

- Medicines causing sleepiness or drowsiness, such as sedatives or tranquilisers
- Benzodiazepines (medicines used as sedatives or to treat anxiety). The use of opioids and benzodiazepines together may increase the risk of drowsiness, difficulties in breathing, coma and may be life-threatening.
- Medicines containing alcohol (ethanol), such as some cough syrups
- Cough suppressants or antitussives

- Medicines used to treat alcohol and/or opioid dependence, such as naltrexone or buprenorphine
- Medicines used to treat depression
- Phenothiazines and antipsychotic agents (medicines used to treat mental disorders)
- Some types of antihistamines
- Aspirin or any other non-steroidal anti-inflammatory drugs (NSAID)
- Gabapentinoids, gabapentin and pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)
- Cannabis
- Medicines used to stop or prevent vomiting (anti-emetics), such as metoclopramide or domperidone
- Medicines used to treat diarrhoea, such as kaolin or loperamide
- Medicines used to thin the blood, such as warfarin
- Propantheline (medicine used to treat stomach ulcers)
- Medicines used to treat epilepsy or fits, such as phenytoin
- Other pain relief medication
- Medicines used to treat high blood pressure
- Colestyramine (medicine used to treat bile problems or lower cholesterol)
- Chelating resin
- Chloramphenicol, an antibiotic used to treat ear and eye infections
- Neuromuscular blocking agents such as cisatracurium (medicines used during surgical procedures)
- Flucloxacillin, zidovudine or rifampicin (medicines used to treat infections)
- Medicines known to alter your heart beats, namely change your heart's ECG

Medicines that may decrease the effect of Mevadol Forte include:

- Medicines that inhibit the liver enzyme, CYP 2D6 inhibitors such as fluoxetine, paroxetine, bupropion, cinacalcet, and methadone.
- Medicines that increase the activity of the liver enzyme, CYP 3A4 inducers such as rifampicin

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

4. How do I use Mevadol Forte?

How much to take

- **Adults and children between 12 and 18 years**
- The usual adult dose is one or two tablets every 4 to 6 hours as needed for relief.
- Do not take more than 8 tablets in a 24-hour period.

- Mevadol Forte must not be used in children under 12 years.
- Follow the instructions provided and use Mevadol Forte until your doctor tells you to stop. Their directions may differ from the information contained in this leaflet.

How to take Mevadol Forte

- Swallow the prescribed dose of Mevadol Forte whole with a glass of water. It can be taken with or without food.

If you forget to take Mevadol Forte

If you miss your dose at the usual time, 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.

Remember to wait 4 to 6 hours between doses.

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

If you use too much Mevadol Forte

If you think that you have used too much Mevadol Forte, 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.

Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally used Mevadol Forte that was prescribed for you. If someone takes an overdose they may experience one or more of the following symptoms:

- Slow, unusual or difficult breathing
- Drowsiness, dizziness or unconsciousness
- Slow or weak heartbeat
- Nausea or vomiting
- Convulsions or fits
- Mental impairment

Other signs of overdose can include problems with the 'nervous system' caused by damage to the white matter of the brain (known as toxic leukoencephalopathy).

5. What should I know while using Mevadol Forte?

Things you should do

Remind any doctor including surgeons, dentist or pharmacist you visit that you are taking Mevadol Forte.

Keep all your appointments, including those for blood tests.

If your pain gets worse after you take this medicine do not take more without first talking to your doctor.

Talk to your doctor, if the pain you have increases, if you feel more sensitive to pain, or if you have new pain after taking this medicine.

Call your doctor straight away if you:

- Feel you need to take the medicine for longer periods of time
- Feel you need to take more than the prescribed dose
- Feel very unwell when you stop taking the medicine but feel better when you start taking the medicine again.
- Experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

Things you should not do

- Do not give Mevadol Forte to anyone else, even if they have the same condition as you.
- Do not take Mevadol Forte to treat any other complaints unless your doctor tells you to.
- Do not take high doses of the medicine for long periods of time unless your doctor tells you to.
- Do not stop taking Mevadol Forte or change the dose without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Mevadol Forte affects you.

Mevadol Forte may cause drowsiness, dizziness, affect eyesight, or hand-eye coordination in some people. Do not drive a car, operate machinery, or do anything else that could be dangerous while taking Mevadol Forte.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol and codeine taken together may increase the risk of sedation, respiratory problems, coma or may be life-threatening.

Do not drink alcohol while you are taking Mevadol Forte.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

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

- Store below 25°C.

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

- do not store it 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
Skin related: • Skin rash • Sweating Gastrointestinal related: • Constipation • Nausea • Vomiting • Severe abdominal pain • Have difficulty swallowing, regurgitation, chest pain that is not related to your heart, especially if you have been using this medicine for a long time General: • Drowsiness • Blurred vision Head and neurology related: • Increased sensitivity to pain or increased levels of pain Reproductive related: • Low libido • Impotence or erectile dysfunction • Loss of menstrual cycle • Infertility Sleep Related: • Sleep apnoea General: • Weakness • Anorexia • Fatigue • Low blood pressure	Speak to your doctor if you have any of these less serious side effects and they worry you. These side effects are usually mild.

Serious side effects

Serious side effects	What to do
Heart related: - Irregular heartbeat Head and neurology related: - Unusual or extreme mood swings - Headache - Dizziness, light-headedness Liver related: - Hepatitis (symptoms include loss of appetite, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine) General: - Flushing of the face - Shortness of breath - Mouth ulcers, fever and sore throat - Stomach pain - Slow or shallow breathing - Painful red areas with blisters and peeling layers of skin which may be accompanied by fever and/or chills Bleeding related: - Bleeding, bruising more easily - Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals Metabolism related: - 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). Allergic reactions: - Swelling of the face, lips, tongue or other parts of the body - Rash, itching or hives on the skin - Wheezing, difficulty breathing, or shallow breathing	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.

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 Mevadol Forte contains

Active ingredient (main ingredient)	Paracetamol - 450 mg Codeine phosphate hemihydrate - 30 mg Doxylamine succinate - 5 mg
Other ingredients (inactive ingredients)	Sodium starch glycolate Purified talc Magnesium stearate Microcrystalline cellulose Hypromellose
Potential allergens	No

Mevadol Forte does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

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

What Mevadol Forte looks like

Mevadol Forte is a round, white to off-white uncoated tablet with 'PCD' on either side of the break line on one side and plain on the other side.

Mevadol Forte is available in a blister pack of 20 tablets.

Not all pack sizes may be available.

Australian Registration Number: AUST R 310164

Who distributes Mevadol Forte

Arrotex Pharmaceuticals Pty Ltd

15 -17 Chapel Street

Cremorne VIC 3121

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