

Mersyndol Forte®

Paracetamol, codeine phosphate hemihydrate, doxylamine succinate

Consumer Medicine Information

WARNINGS

Limitations of use

Mersyndol 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

Mersyndol 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 Mersyndol 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 Mersyndol Forte.

What is in this leaflet

This leaflet answers some common questions about Mersyndol Forte. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking Mersyndol Forte against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Mersyndol Forte is used for

Mersyndol Forte has pain relieving, fever reducing and calmative effects.

Mersyndol 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 or pain from injury or surgery and headache pain. In addition the calmative properties of Mersyndol Forte may be especially useful in the treatment of tension headache, migraine and period pain.

Mersyndol Forte is available only with a doctor's prescription.

Mersyndol Forte is not recommended for use in children under the age of 12 years.

Before you take Mersyndol Forte

When you must not take it

Do not take Mersyndol Forte if you have an allergy to paracetamol, codeine phosphate

hemihydrate, doxylamine succinate or any of the ingredients listed at the end of this leaflet.

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

- Severe and/or acute respiratory disease
- Acute breathing difficulties such as bronchitis, unstable asthma, emphysema, respiratory depression (shallow breathing) or respiratory insufficiency (difficulty breathing)
- Glucose-6-phosphate-dehydrogenase deficiency (an enzyme deficiency)
- Ultra-rapid metaboliser of CYP 2D6
- Known intolerance to medicines used to treat or prevent pain
- Diarrhoea caused by antibiotics or poisoning
- Liver failure

Do not take Mersyndol Forte if you have a history of drug dependence, including alcohol dependence.

Do not take Mersyndol Forte if you are already taking Monoamine inhibitors (MAOIs), or within 14 days of stopping MAOIs

Do not take Mersyndol Forte if you have experienced systemic allergy (generalised rash or shortness of breath) to morphine or oxycodone.

Do not take Mersyndol Forte if you are aged below 18 years of age and have had your tonsils or adenoids removed to treat sleep apnoea.

Mersyndol Forte is not recommended for children under 12 years.

Do not take Mersyndol Forte during the third trimester of pregnancy.

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

This medicine contains codeine, which may produce withdrawal effects in the newborn baby.

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

Mersyndol Forte passes into breast milk and there is a possibility your baby may be affected.

Do not take Mersyndol Forte after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take Mersyndol Forte if the packaging is torn, shows signs of tampering, or if it doesn't look quite right.

If you are not sure whether you should start taking Mersyndol Forte, contact your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- aspirin or any other NSAID medicine

- any other substances, such as foods, preservatives or dyes

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- Liver problems
- Kidney problems
- Heart or lung problems
- Low blood pressure
- Difficulty breathing, wheezing, chronic cough, asthma, or other chronic breathing conditions
- Chronic alcohol use including recent cessation of alcohol intake
- Opioid dependence
- Low glutathione reserves
- Gilbert's syndrome
- Recent stomach, intestine or urinary tract surgery
- Gall bladder problems or your gall bladder has been removed
- Multiple sclerosis
- Obstructive and inflammatory bowel disease or other bowel problems
- Prostate problems
- Underactive thyroid
- Adrenocortical insufficiency (eg Addison's disease)
- Head injury
- Fits or seizures
- Brain tumours
- 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.

Tell your pharmacist or doctor if you are pregnant or plan to become pregnant.

Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Mersyndol Forte.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines including any 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.

Some medicines can interfere with Mersyndol Forte including:

- Any medicine causing sleepiness or drowsiness
- Benzodiazepines (medicines used as sedatives or to treat anxiety)
- Medicines containing alcohol (ethanol), e.g. some cough syrups
- Cough suppressants or antitussives
- Medicines used to treat alcohol and/or opioid dependence (e.g. naltrexone or buprenorphine)
- Medicines used to treat depression
- Monoamine inhibitors (MAOIs), or within 14 days of stopping MAOIs
- Some types of antihistamines
- Gabapentinoids (medicines used for epilepsy or neuropathic pain)
- Cannabis
- Medicines used to stop or prevent vomiting (anti-emetics)
- Warfarin, a medicine used for blood clots
- Medicines used to treat diarrhoea, nausea or vomiting
- Propantheline, a drug used to treat stomach ulcers
- Medicines used to treat epilepsy or fits
- Other pain relief medication
- Medicines used to treat high blood pressure
- Cholestyramine (medicine used to treat bile problems and/or high cholesterol)
- Chelating resin

- Chloramphenicol, an antibiotic used to treat ear and eye infections
- Medicines used to help you relax, sleep or relieve anxiety, such as barbiturates and sedatives
- Phenothiazines and antipsychotic agents, medicines used to treat mental disorders
- Flucloxacillin, zidovudine or rifampicin, drugs used to treat infections
- CYP 2D6 inhibitors such as fluoxetine, paroxetine, bupropion, cinacalcet, methadone
- CYP 3A4 inducers such as rifampin

Your doctor and pharmacist may have more information on medicines to be careful with or to avoid while taking Mersyndol Forte.

How to take Mersyndol Forte

How much to take

The usual adult dose is one or two tablets every 4 to 6 hours as needed for relief. Do not exceed 8 tablets in a 24 hour period.

Mersyndol Forte is not recommended for children under 12 years of age.

Follow all directions given to you by your doctor and pharmacist carefully.

Their directions may differ from the information contained in this leaflet.

How to take it

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

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone in Australia 13 11 26; in New Zealand 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Mersyndol Forte. Do this even if there are no signs of discomfort or poisoning.

While you are using Mersyndol Forte

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Mersyndol Forte.

Things you must not do

Do not give Mersyndol Forte to anyone else, even if they have the same condition as you.

Do not take Mersyndol Forte to treat any other complaints unless your doctor or pharmacist tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Mersyndol Forte affects you.

Mersyndol Forte may cause drowsiness in some people. Do not drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy. If drowsiness occurs do not drive or operate machinery.

Avoid alcohol while you are taking Mersyndol Forte.

Mersyndol Forte may be dangerous if you take large amounts over a long period of time.

Do not take high doses of the medicine for long periods of time unless your doctor tells you to.

This medicine contains codeine, and is a potential drug of abuse, misuse

and addiction. Addiction can occur even in people taking recommended doses.

Abrupt discontinuation or rapid decreasing of this medicine may result in serious withdrawal symptoms in those who have developed a dependency to codeine.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Mersyndol Forte.

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

- Skin rash
- Constipation
- Nausea and vomiting
- Drowsiness
- Sweating
- Blurred vision
- Increased sensitivity to pain or increased levels of pain

These are the more common side effects of Mersyndol Forte. They are usually mild.

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

- Shortness of breath
- Mouth ulcers, fever and sore throat
- Bleeding, bruising more easily
- Unusual or extreme mood swings
- Dizziness, light-headedness
- Flushing of the face
- 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
- Hepatitis (symptoms include loss of appetite, itching, yellowing of the skin and eyes,

light coloured bowel motions,
dark coloured urine)

The above list includes serious side effects that may require medical attention. These side effects are rare.

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

- Wheezing, difficulty breathing, or shallow breath
- 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. These side effects are very rare.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using Mersyndol Forte

Storage

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

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

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Mersyndol Forte or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it where 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 or pharmacist tells you to stop taking Mersyndol Forte or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Mersyndol Forte is a round, white tablet with M on one side and MERSYNDOL FORTE with a break line on the other side.

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

Ingredients

- Paracetamol 450 mg
- Codeine phosphate hemihydrate 30 mg
- Doxylamine succinate 5 mg
- Sodium starch glycollate
- Purified talc
- Magnesium stearate
- Compresso Pap - 90 CPF (Gag) (PI 11304)

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

Manufacturer

Mersyndol Forte is supplied in Australia by:

sanofi-aventis australia Pty Ltd
12-24 Talavera Road
Macquarie Park NSW 2113
Australia

Australian Registration Number:
AUST R 10109

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