

Midrid 325mg/65mg Capsules

(paracetamol, isometheptene mucate)

Read all of this information carefully before you start taking this medication.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Midrid is and what it is used for

Midrid 325mg/65mg Capsules (hereinafter referred to as Midrid) is used for the treatment of migraine and throbbing headaches. Midrid belongs to a group of medicines called analgesics which are used for the relief of pain. The active ingredients in Midrid each work in a different way to stop the pain. The throbbing pain sometimes felt during a migraine is linked to swollen blood vessels (vasodilation) in the head. Paracetamol works directly on the pain, whereas isometheptene returns the blood vessels to normal and as a result helps to take away the pain.

2. Before you take Midrid

Do not take Midrid if you have or have had:

- an allergic reaction to paracetamol, isometheptene mucate or any of the ingredients (see section 6 for more details)
- severe problems with your kidneys, liver or heart
- severe high blood pressure
- glaucoma (increased pressure inside the eye)
- medicines for depression, known as Monoamine Oxidase Inhibitors (MAOIs) within the last 14 days
- porphyria - genetic blood disorder.

If you are allergic to paracetamol or have other problems when taking paracetamol you must tell your doctor or pharmacist before taking Midrid. See also section 4 for more details.

Take special care with Midrid and tell your doctor if you suffer with:

- diabetes
- cardiovascular diseases
- an overactive thyroid
- spinal cord injury
- liver damage caused by alcoholism
- an eating disorder.

During treatment with Midrid, 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).

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You must tell your doctor or pharmacist if you are taking any of the following medicines:

- medicines used to thin the blood such as warfarin
- medicines to treat high blood pressure
- cardiac glycosides such as digoxin used to treat heart failure and irregular heart beats or heart rhythm
- quinidine which may be used to treat heart or blood problems
- colestyramine to treat hyperlipidaemia (high levels of fats in the blood, for example, cholesterol)
- medicines to treat the symptoms of depression such as tricyclic antidepressants and monoamine oxidase inhibitors
- metoclopramide or domperidone to treat nausea and vomiting
- bromocriptine to treat Parkinson's disease
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2)
- chloramphenicol which is used to treat bacterial infections
- long term use of carbamazepine, phenobarbitone, phenytoin and primidone (for epilepsy), rifampicin (an antibiotic), St John's Wort (for depression) or other medicines that affect liver enzymes. These medicines may increase the chance of liver damage in case of paracetamol overdose
- another migraine medicine.

Taking Midrid with food and drink

You should avoid alcohol on the same day that you take Midrid.

Pregnancy and breast-feeding

Do not take this medication:

- if you are pregnant or might be pregnant
- if you are breast-feeding
- in the first few weeks after childbirth.

(continued overleaf)

Driving and operating machinery

No information available regarding the effect of this medication on your ability to drive or use machinery. You must not drive if you feel tired or drowsy.

Important information about some of the ingredients in Midrid

Midrid contains **paracetamol**. **Do not take any other medicine containing paracetamol on the same day** that you take Midrid.

3. How to take Midrid

Always take Midrid exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults

If you have any signs that you are going to get a migraine, take the initial dose of Midrid as soon as you get these warning signs. You may be able to prevent it getting to the headache stage.

Swallow two capsules of Midrid with a drink of water as soon as you know you are getting a migraine. If you still have your migraine an hour later, take another capsule. Continue taking a capsule every hour until your migraine has gone, up to a maximum of five capsules in 12 hours. If you still have a migraine 12 hours after you started taking Midrid, you can take one more course of treatment. That is, two capsules to start with followed by one capsule every hour, if needed, up to a maximum of five capsules. After this, you should ask your doctor or pharmacist for advice.

Remember, you must not take more than five capsules in 12 hours.

Children

Midrid is not recommended for use in children.

If you take more Midrid than you should

If you take more than the correct number of capsules (an overdose) it is very important that you go to the nearest casualty department **immediately**, even if you feel well because of the risk of delayed serious liver damage. Take the carton of Midrid with you even if it is empty.

Remember, you must not take more than five capsules in 12 hours.

If you forget to take Midrid

If you still have a migraine and you forget to take a capsule at the correct time (i.e. later than one hour after the previous dose), take it as soon as you remember. You must then wait another hour before taking a further dose, if your migraine has not gone. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Some people may have side-effects when taking this medicine.

If you experience any of the following side effects contact your doctor or pharmacist **immediately**:

- you may get a rash or similar allergic reaction if you are allergic to paracetamol (see section 2)
- dizziness
- tingling/cold fingers or toes.

If you notice any of the following side effects speak to your

doctor or pharmacist. Blood related problems are extremely rare but may result in:

- bruising
- blue tinge to skin
- dizziness
- tiredness
- problems breathing
- severe sore throat.

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).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Midrid

Keep out of sight and reach of children.
Your medicine will be marked on the box with an expiry date. Never take any capsules after this date. If you have any capsules left after this date, return them to your pharmacist.
Medicines should never be thrown away in the bin.
Do not store above 25°C.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Midrid contains

Each capsule contains 325mg paracetamol and 65mg isometheptene mucate. Midrid also contains microcrystalline cellulose, talc and colloidal silicon dioxide. The capsule shell contains gelatin, water, titanium dioxide (E171), erythrosine (E127), quinoline yellow (E104), indigotine (E132) and a very small amount of printing ink.

What Midrid looks like and contents of the pack

Midrid is in the form of a scarlet coloured capsule. Midrid is available in blister packs of 15 and 30 capsules and a bottle of 100 capsules.

Marketing Authorisation Holder

DHP Healthcare Limited, 13 Hanover Square, London W1S 1HN, United Kingdom.

Manufacturer

Medinfar Manufacturing, S.A., Parque Industrial Armando Martins Tavares Rua Outeiro da Armada, 5, Condeixa-a-Nova 3150-194 Sebal, Portugal

Other Formats

To request a copy of this leaflet in Braille, large print or audio please call 0330 1359 454.

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