Patient Information Leaflet

SCHEDULING STATUS

S2

MIGRIL, ergotamine tartrate 2 mg, cyclizine hydrochloride 50 mg, caffeine hydrate 100 mg, Tablets.

CONTAINS SUGAR:

Glucose liquid 1,960 mg, glucose monohydrate 113,0 mg and lactose 113,0 mg.

Read all of this leaflet carefully because it contains important information for you

Migril is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use Migril carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Migril with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after two days.

What is in this leaflet

1. What Migril is and what it is used for

2. What you need to know before you take Migril

3. How to take Migril

4. Possible side effects

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6. Contents of the pack and other information

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1. What Migril is and what it is used for

Migril is used in the treatment of migraines and to relief the symptoms and to stop the attack getting worse.

2. What you need to know before you take Migril

Do not take Migril if:

- you are hypersensitive (allergic) to ergotamine tartrate, cyclizine hydrochloride, caffeine hydrate or any of the other ingredients of Migril (listed in section 6);
- if you are pregnant or breastfeeding;
- if you have a disease of the blood vessels which includes coronary disease, obliterative vascular disease (narrowing of the arterial tree), chest pain, claudication (cramp-like pain and weakness in muscles), peripheral ischemia (deficiency of blood in legs, feet and hands);
- if you have Raynaud's Syndrome;
- if you have severe high blood pressure or heart problems;
- if you recently had, or are planning to have angioplasty (surgical repair or unblocking of a vessel) or surgery to arteries and veins;
- if you have porphyria;
- if you have hyperthyroidism (overactive thyroid gland), sepsis (severe infections), kidney and liver disease, lack of proper nutrition and anaemia (deficiency of red cells in blood);
- if you have conditions such as glaucoma (increased pressure in the eye), bladder neck obstruction, inability to completely empty your bladder, enlarged prostate gland, and intestinal blockage;
- if you suffer from anxiety disorders or sleeplessness;
- if you have a peptic ulcer;

- if you are HIV positive and are being treated with HIV-protease inhibitor medicine which are potent CYP 3A4 inhibitors, such as amprenavir, indinavir, nelfinavir, ritonavir.
- Migril should not be given to children.

Warnings and precautions

Take special care with Migril:

- If you are elderly, as you may be more susceptible to complications associated with sudden constriction of a blood vessel (vasospasm) and a dangerously low body temperature (hypothermia);
- if you are a heavy smoker, as it may increase your risk of peripheral ischemia (deficiency of blood in legs, feet and hands);
- if you have an acute infectious disease of the liver, as you may have an increased risk of precipitating peripheral ischaemia (deficiency of blood in legs, feet and hands);
- if you have problems of lactose intolerance, or glucose-galactose malabsorption.

Other medicines and Migril

Always tell your health care provider if you are taking any other medicines. (This includes all complementary or traditional medicines.)

The following medicines can cause interactions with the Migril ingredient, ergotamine tartrate:
Potent CYP3A4 inhibitors such as amprenavir, indinavir, nelfinavir and ritonavir (used in the treatment of HIV).
Ergot alkaloids and beta-blocking agents (high blood pressure medicines)

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Antibiotics such as clarithromycin, erythromycin, tetracycline.

Vasoconstrictors (medicines that narrow blood vessels) and local anaesthetic solutions containing vasoconstrictors.

Nitroglycerine (used to widen blood vessels).

Other antimigraine products such as methysergide, serotonin agonists, sumatriptan, almotriptan, rizatriptan and zolmitriptan.

Products called sympathomimetics. It may cause severe elevation of blood pressure and narrowing of blood vessels.

The following medicines can cause interactions with the Migril ingredient, cyclizine hydrochloride:

Alcohol and other central nervous system depressants, e.g. hypnotics and tranquilisers.

Anticholinergic medicines. This can increase the side effects.

Antidepressants called monoamine-oxidase inhibitors (MAOI). This can increase the sedative effect and other side effects.

The following medicines can cause interactions with the Migril ingredient, caffeine hydrate:

Central nervous system stimulating medicines.

Antidepressants called monoamine-oxidase inhibitors (MAOI).

Antiarrhythmics: mexiletine.

Quinolone antibacterials such as ciprofloxacin.

Antidepressant: fluvoxamine.

Antiepileptics: phenytoin.

Sedatives and sleeping products.

Disulfiram.

Lithium.

Oestrogens and progesterones.

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Phenylpropanolamine.

Theophylline.

Migril with drink and alcohol

Do not drink grapefruit juice with Migril.

Do not smoke or consume alcohol with MIgril as it may increase the effects of alcohol.

Pregnancy, breastfeeding and fertility

Do not take Migril if you are pregnant, want to become pregnant or are breastfeeding.

Driving and using machines

Migril may lead to drowsiness and impaired concentration, which may be made worse by the simultaneous intake of alcohol or other central nervous system depressants.

You should not operate hazardous machinery or drive motor vehicles or perform potentially hazardous tasks where loss of concentration may lead to accidents.

Migril contains glucose liquid, glucose monohydrate and lactose

Migril contains lactose. Patients with the rare hereditary condition of lactose intolerance should not take Migril.

Migril contains glucose liquid and glucose monohydrate which may have an effect on the control of your blood sugar if you have diabetes mellitus.

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3. How to take Migril

Do not share medicines prescribed for you with any other person.

Always take Migril exactly as described in this leaflet or as your doctor or pharmacist have told you.

Check with your doctor or pharmacist is you are not sure.

- Do not take Migril to prevent a migraine. Migril should only be taken when a migraine attack starts.
- The usual dose is one tablet, at the first sign of a migraine attack.
- If symptoms do not get better, take a half to one tablet every half an hour.
- Do not take more than 4 tablets per migraine attack.
- Do not take more than 6 tablets in one week.

If you take more Migril than you should

In the event of overdosage consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

The symptoms are nausea, vomiting, diarrhoea, extreme thirst, coldness, weakness, tingling and itching of the skin, a rapid and weak pulse, low blood pressure, shock, confusion, convulsions and unconsciousness.

It may be difficult to measure blood pressure; there have been reports of fatalities.

The doctor will manage the overdosage in hospital.

If you forget to take Migril

Do not take a double dose to make up for forgotten individual doses.

If you stop taking Migril

Rebound headache can occur. If this happens contact your doctor.

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4. Possible side effects

Migril can have side effects. Not all side effects reported for Migril are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Migril, please consult your health care provider for advice.

If any of the following happens, stop taking Migril and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Migril. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent side effects:

- blurred vision
- swelling of face, fingers, feet and/or lower legs;

Less frequent side effects:

- chest pain;
- fast or slow heartbeat;
- rapid, weak or absent pulse;
- numbness and tingling of fingers, toes or face;
- pain in the arms, legs or lower back, especially pain in the calves and/or heels on exertion;

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- pale, bluish coloured or cold hands or feet;
- weakness in legs, gangrene;
- changes in vision, miosis.

Frequency unknown:

- convulsions

These are all serious side effects. You may need medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache, dizziness, drowsiness;
- diarrhoea, nausea and vomiting, stomach pain or bloating;
- dryness of the mouth, nose and throat;
- difficulty urinating.

Less frequent side effects:

- itching of skin;

Frequency unknown:

- shortness of breath;
- numbness and tremors;
- anxiety, depression, confusion and hallucinations;
- difficulty moving and thinking;
- muscle cramps and joint pains;
- sleep disturbances, including insomnia.

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If you notice any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of Migril.

Alternately you can contact iNova Pharmaceuticals (Pty) Ltd at 011 087 0000 or www.inovapharma.co.za.

5. How to store Migril

Store all medicines out of reach of children.

- Store at or below 25 °C.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Migril contains

The active substances are ergotamine tartrate, cyclizine hydrochloride and caffeine hydrate.

The other ingredients are docusate sodium, Erythrosine E127, gelatin, glucose liquid, glucose monohydrate, lactose, magnesium stearate, maize starch and sulphurous acid.

What Migril looks like and contents of the pack

Migril is a white, biconvex tablet, branded MIGRIL with a break score on one side and unbranded on the other side.

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It comes in blister strips of 10 tablets each packed into a printed cardboard box.

Boxes contain 10, 20 or 100 tablets.

Holder of Certificate of Registration

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