

PACKAGE LEAFLET: INFORMATION FOR THE USER

MIGRIL® TABLETS

Ergotamine Tartrate 2mg, Cyclizine Hydrochloride 50mg and Caffeine Hydrate 100mg

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Migril® Tablets are and what they are used for
2. What you need to know before you take Migril® Tablets
3. How to use Migril® Tablets
4. Possible side effects
5. How to store Migril® Tablets
6. Contents of the pack and other information

1. What Migril® Tablets are and what they are used for

The name of your medicine is Migril® Tablets. Migril® Tablets contain the active substances ergotamine tartrate, cyclizine hydrochloride and caffeine hydrate. These tablets belong to a group of medicines called vasoconstrictors and anti-emetics. Vasoconstrictors cause narrowing of the blood vessels and anti-emetics stop you feeling and being sick.

Migril® Tablets are used in the treatment of migraines to relieve the symptoms and to stop the attack getting worse.

2. What you need to know before you take Migril® Tablets

Do not take Migril® Tablets if:

- you are allergic (hypersensitive) to ergotamine tartrate, cyclizine hydrochloride, caffeine hydrate or to any of the other ingredients in this medicine (see section 6, Contents of the pack and other information)
- you are suffering from kidney or liver disease
- you are suffering from angina, coronary heart disease or high blood pressure
- you are suffering from temporal arteritis
- you are suffering from a condition called porphyria which affects the liver, skin or blood
- you have trouble with your circulation or cramp like pains in the leg caused by bad circulation
- you have an overactive thyroid (hyperthyroidism)
- you are taking medicines used to treat bacterial infections (e.g. quinupristin, dalfopristin, azithromycin, erythromycin or clarithromycin)
- you are taking medicines used to treat viral infections (protease inhibitors e.g. amprenavir, ritonavir, nelfinavir or indinavir)
- you are taking medicines used to treat fungal infections (e.g. ketoconazole or itraconazole)
- you are taking medicines used to treat ulcers (e.g. cimetidine)
- you are pregnant, wish to become pregnant or are breast-feeding.

Migril® Tablets are not recommended for children.

Warnings and precautions

Talk to your doctor or pharmacist before taking Migril® Tablets if:

- you have hepatitis
- you have anaemia
- you have problems with your heart
- you have a blockage of the gut
- you have a swollen prostate gland
- you are suffering from glaucoma (high pressure in the eyeball)
- you are having problems passing water
- you are elderly.

Other medicines and Migril® Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The following medicines can affect or be affected by treatment with Migril® Tablets:

- beta-blockers: medicines used to treat high blood pressure, heart failure or angina and may have been prescribed for treatment of migraines
- other medicines used to treat migraines (e.g. zolmitriptan, almotriptan, sumatriptan, rizatriptan, frovatriptan). It is important not to take these medicines for 24 hours after taking Migril® Tablets and do not take Migril® Tablets for 6 hours after taking any of these medicines
- eletriptan (used to treat migraines). It is important not to take this medicine for 24 hours after taking Migril® Tablets and do not take Migril® Tablets for 24 hours after taking eletriptan
- saquinavir (used in the treatment of HIV and other viral infections)
- metronidazole (used to treat certain types of infection)
- mexiletine (used to treat heart irregularities)
- disulfiram (used to treat alcohol dependence)
- lithium (used to treat manic depressive illness)
- clotrimazole and fluconazole (used to treat fungal infections)
- phenytoin (used in the treatment of epilepsy)
- glyceryl trinitrate (used to relieve angina)
- diazepam (used to treat anxiety or insomnia)
- atropine (used to treat gut spasm or as premedication before an anaesthetic)
- oral contraceptive (The Pill), hormone injections or hormone replacement treatment (HRT)
- medicines used to treat wheezing (e.g. theophylline) and decongestants (e.g. phenylephrine or pseudoephedrine)
- medicines used to treat depression (e.g. nefazodone, fluoxetine and fluvoxamine), tricyclic antidepressants (e.g. dothiepin, amitriptyline) and monoamine oxidase inhibitors (MAOIs e.g. phenelzine)
- other medicines used to treat bacterial infections such as quinolones (e.g. ciprofloxacin) or tetracyclines.

Migril® Tablets with food and drink

- Grapefruit juice should be avoided while taking these tablets as it can increase the risk of side effects
- Do not smoke or drink alcohol while taking this medicine.

Pregnancy and breast-feeding

You should not take Migril® Tablets if you are pregnant, wish to become pregnant or are breast-feeding.

Driving and using machines

It is possible that these tablets may make you feel drowsy. Do not drive or operate machinery if affected.

Migril® Tablets contain lactose and glucose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to use Migril® Tablets

Always take Migril® Tablets exactly as your doctor has told you. Check with your doctor if you are not sure. Your doctor will decide the right dose for you; this will be on the pharmacist's label. Check this carefully, it will tell you how many tablets to take and how often to take them.

It is important that you do not take more than the dose agreed with your doctor.

- The recommended dose for adults is one tablet as soon as possible after the first signs of a migraine.
- Extra doses of a half to one tablet at half-hourly intervals may be required in some cases.
- Do not take more than 4 tablets during any one attack and no more than 3 tablets in a 24-hour period, you must leave a gap of at least 4 days before taking any more tablets.
- Do not take more than 6 tablets in a week.
- Do not take more than two courses of Migril® Tablets in a month.

Do not take Migril® Tablets on a regular basis or to prevent a migraine attack. Regular use can lead to dependence and 'rebound headaches' which in turn may lead you to take tablets more often.

If you take more Migril® Tablets than you should

If you (anybody else or a child), takes more tablets than you should, contact your nearest hospital casualty department or your doctor immediately. Always take the container with you even if empty.

If you forget to take Migril® Tablets

If you forget a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. NEVER take a double dose to make up for the one missed.

4. Possible side effects

Like all medicines, Migril® Tablets can cause side effects, although not everybody gets them. Do not exceed the maximum dose or take the tablets more often than as stated in this leaflet, this could lead to dependence on this medicine as well as other serious side effects.

As can happen with any medicine, a few people may develop an allergic reaction. If you experience any of the following, seek medical help immediately:

- rash, itching, difficulty breathing.

You should also seek medical help immediately if you:

- develop blueness, coldness, numbness or tingling in your hands or feet
- have a headache most days and it is only relieved by taking more of this medicine.

You should tell your doctor or pharmacist if you have any of the following side effects:

- headaches, nausea, vomiting, dry mouth
- constipation, stomach pains, diarrhoea
- drowsiness, dizziness, (including vertigo)
- confusion, anxiousness or depression
- experiencing hallucinations
- sleep disturbances including insomnia
- difficulty in passing water
- muscle cramps, joint pains or pain in the legs
- pain in abdomen and swelling in one leg
- swelling of the skin or itching
- coldness and whiteness of the hands and feet or pins and needles
- a prickling feeling over your skin or numbness
- yellowing of the skin and general weak feeling
- blurred vision or any other visual disturbances (that you don't think are connected to your migraine).
- unpleasant sensation or an overwhelming urge to move the legs (also called Restless Leg Syndrome)

Other side effects that have been reported include:

- an increase or decrease in blood pressure, fainting
- rapid and weak pulse, slow or irregular heart beat, or heightened sense of your heart beating
- angle-closure glaucoma
- reduced blood supply or clotting in the arteries of the body or the brain
- blockage of the arteries in the heart
- pain in your chest or shortness of breath
- thickening of the tissues in the lungs
- tremors and convulsions
- gangrene
- blueness of the skin
- fever
- changes in the blood causing a tendency to bleed or bruise easily
- involuntary rolling of the eyes

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 or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Migril®Tablets

Keep out the sight and reach of children.

- Do not take this medicine after the expiry date on the label or if they show signs of deterioration such as discolouration. The expiry date refers to the last day of the month.
- Do not store above 25°C. Store in the original container do not transfer your tablets to another container.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Migril® Tablets contain

The active ingredients are: ergotamine tartrate 2mg, cyclizine hydrochloride 50mg and caffeine hydrate 100mg.

The other ingredients are: lactose, maize starch, liquid glucose and glucose, amaranth, dioctyl sodium sulfosuccinate, gelatin, sodium metabisulfate and magnesium stearate.

What Migril® Tablets look like and the contents of the pack

Each white round tablet is marked with a score line, CP and 'A4A' on the same side. These are available in bottles of 100 tablets.

Other formats

To listen to or request a copy of this information in Braille, large print or audio please call, free charge: 0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	Reference number
Migril Tablets	29831/0090

This is a service provided by the Royal National Institute for Blind People.

Marketing Authorisation Holder:

Wockhardt UK Ltd., Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer:

CP Pharmaceuticals Ltd., Ash Road North, Wrexham, LL13 9UF, UK.

Product License Number: PL 29831/0090

This leaflet was last revised in 04/2021

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