

MEPREZE®

esomeprazole (as magnesium) tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about MEPREZE.

It does not contain all the information that is known about MEPREZE.

It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist will have weighed the risks of you taking MEPREZE against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What MEPREZE is used for

MEPREZE is used for the relief of frequent heartburn and stomach acid complaints due to gastro-oesophageal reflux disease (GORD). This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

Frequent heartburn is when you have heartburn for two or more times a week. Heartburn that occurs frequently is a typical symptom of GORD.

Who should use MEPREZE

MEPREZE is recommended for adults 18 years of age and over, who

suffer from frequent heartburn at least 2 times a week.

MEPREZE is not the right medicine for you if you suffer heartburn only occasionally (one episode of heartburn a week or less), or if you want immediate relief of heartburn.

How MEPREZE works

MEPREZE is a type of medicine called a proton-pump inhibitor. It works by decreasing the amount of acid made by the stomach. This gives relief of symptoms and also allows healing to take place. This does not stop food being digested in the normal way.

MEPREZE is available only from your pharmacist. It can be purchased directly from your local pharmacy without a doctor's prescription.

There is no evidence that this medicine is addictive.

Before you take MEPREZE

When you must not take it

Do not take MEPREZE if you have allergies to:

- esomeprazole or any ingredient listed at the end of this leaflet
- any medicines containing a proton-pump inhibitor such as omeprazole, lansoprazole, pantoprazole and rabeprazole

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips,

tongue or other parts of the body; rash, itching or hives on the skin.

Do not take MEPREZE if you are also taking atazanavir or cilostazol (see Taking other medicines).

Please check with your pharmacist or doctor if you are taking these medicines. These medicines will be affected by MEPREZE.

MEPREZE is not recommended for children and adolescents under 18 years of age.

Do not take MEPREZE after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Tell your pharmacist or doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives
- any problems with your liver
- severe kidney problems
- any other medical conditions
- difficulty swallowing, persistent vomiting or vomiting blood, blood in the stools or unexplained weight loss
- taken other medication for indigestion or heartburn continuously for four or more weeks in order to control your symptoms
- recently finished a course of MEPREZE or similar medicine within the last two weeks
- been diagnosed with osteoporosis

Do not take MEPREZE if you are pregnant unless your doctor says

so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to take this medicine while you are pregnant. It may affect your baby.

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

It is not known if this medicine passes into breast milk if you are breastfeeding.

Ask your doctor for more information.

Taking other medicines

Do not take MEPREZE if you are taking the following medicines:

- atazanavir, a medicine used to treat Human Immunodeficiency Virus (HIV)
- cilostazol, a medicine used to treat muscle pain or cramping caused by reduced blood circulation in the lower legs (intermittent claudication).

Tell your pharmacist or doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with MEPREZE. These include:

- ketoconazole, itraconazole and voriconazole, medicines used to treat fungal infections
- diazepam, a medicine used to treat anxiety and some other conditions
- phenytoin, a medicine used to treat epilepsy or fits
- citalopram, clomipramine and imipramine, medicines used to treat depression
- St John's wort, a herbal remedy used to treat mood disorders
- clarithromycin and rifampicin, medicines used to treat bacterial infections
- warfarin and clopidogrel, medicines used to prevent blood clots

- nelfinavir or medicines for HIV treatment
- digoxin, a medicine used to treat heart conditions
- methotrexate, a medicine used to treat arthritis and some types of cancer
- tacrolimus, a medicine used to assist in organ transplants
- erlotinib or related medicines used to treat cancer
- clopidogrel, a medicine used to treat heart disease and stroke.
- Cyanocobalamin, used for B-12 deficiency.

These medicines may be affected by MEPREZE or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines.

Your pharmacist or doctor can tell you what to do if you are taking any other medicines.

Your pharmacist or doctor has more information on medicines to be careful with or avoid while taking this medicine.

If you have not told your pharmacist or doctor about any of these things, tell them before you take MEPREZE.

How to take MEPREZE

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

These instructions may differ from the information contained in this leaflet.

If you do not understand the directions on the label, ask your pharmacist or doctor for help.

How much to take

Take one MEPREZE 20 mg tablet each day.

How to take it

Swallow the tablets whole with a glass of water.

Do not crush or chew the tablets.

If the tablets are chewed or crushed they will not work properly.

If you have difficulty swallowing the tablets:

1. Place the tablet in half a glass of non-carbonated water. Mineral water or other liquids are not suitable.
2. Gently mix the tablet and water by stirring, taking care not to crush the tablet.
3. Stir until the tablet dissolves into little pellets.
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets.
5. Rinse the glass with half a glass of water and drink.

When to take it

Take MEPREZE at about the same time each day.

This medicine can be taken with food or on an empty stomach.

How long to take it

MEPREZE should be taken for at least 7 days, and up to 14 days. You should not take it for more than 14 days unless directed by a doctor.

Tell your pharmacist or doctor if you do not feel better while taking this medicine. If your symptoms persist or recur within two weeks of completing the course, consult a doctor. Your doctor may recommend further examination.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you are not sure what to do, ask your pharmacist or doctor.

Taking too much (overdose)

Telephone your doctor or the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too many MEPREZE.

Do this even if there are no signs of discomfort or poisoning.

While you are taking MEPREZE

Things you must do

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking MEPREZE.

Tell all doctors, dentists and pharmacists who are treating you that you are taking this medicine.

If you become pregnant while you are taking MEPREZE, tell your doctor or pharmacist immediately.

If you need to have any medical tests while you are taking MEPREZE, tell your doctor that you are taking this medicine.

It may affect the results of some tests.

Things you must not do

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel

well while you are taking this medicine.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your pharmacist or doctor to answer any questions you may have.

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

- nausea or vomiting
- constipation
- diarrhoea
- headache
- wind
- stomach pain
- skin rash, itchy skin
- dizziness
- dry mouth

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- blurred vision
- mood changes, confusion or depression
- muscle pain or weakness, joint pain
- increase in breast size (males)
- increased sweating
- changes in sleep patterns
- fever
- increased bruising
- "pins and needles"
- hair loss
- tremor
- blood in the urine

These side effects may require medical attention.

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

- shortness of breath, wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body
- severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite

These are very serious side effects. You may need urgent medical treatment or hospitalisation.

Occasionally, this medicine may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Tell your pharmacist or doctor if you think you have any of these effects or notice anything else that is making you feel unwell.

Some people may get other side effects while taking this medicine.

Other problems are more likely to arise from the condition itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion during treatment with this medicine
- you begin to vomit blood or food
- you pass black (blood-stained) motions

After taking it

Storage

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

If you take this medicine out of the blister pack it will not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C.

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

Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

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.

Disposal

If your pharmacist or doctor tells you to stop taking this medicine or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

Product description

What this medicine looks like

MEPREZE 20 mg are light pink, oblong, biconvex, film coated tablets debossed with '20' on one side and 'CE' on the other side.

Ingredients

Active ingredients: Mepreze 20 mg - 20 mg esomeprazole (as magnesium).

Inactive ingredients:

- Non-pareil seeds 40-50 (ARTG 108808)
- Hyprolose
- Crospovidone
- Confectioner's sugar (sucrose and maize starch)
- Magnesium oxide light
- Purified talc
- Macrogol 6000
- Methacrylic acid - ethyl acrylate copolymer (1:1)
- Glyceryl monostearate
- Macrogol 400
- Polysorbate 80
- Hypromellose phthalate
- Acetone
- Microcrystalline cellulose

- Iron oxide red
- Povidone
- Pregelatinised maize starch
- Silicon dioxide
- Lactose monohydrate
- OPADRY complete film coating system 03B84893 PINK (ARTG 108603)

MEPREZE tablets are available in blister packs of 7 and 14 tablets. The tablets are gluten free.

Supplier/Distributor

Sandoz Pty Ltd

ABN 60 075 449 553

54 Waterloo Road,

Macquarie Park NSW 2113

Australia

Tel: 1800 634 500

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Australian Register Number

20 mg tablets: AUST R 252682 (blisters)