Esomeprazole 20 mg enteric-coated tablet

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about PHARMACY ACTION 24 Hour Once Daily Heartburn Relief. It does not contain all the information that is known about PHARMACY ACTION 24 Hour Once Daily Heartburn Relief.

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

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking PHARMACY ACTION 24 Hour Once Daily Heartburn Relief 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 PHARMACY ACTION 24 Hour Once Daily Heartburn Relief is used for

PHARMACY ACTION 24 Hour Once Daily Heartburn Relief is used for lasting symptomatic relief of frequent heartburn and stomach acid complaints due to gastrooesophageal reflux.

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 gastro- oesophageal reflux disease (GORD).

Who Should Use PHARMACY ACTION 24 Hour Once Daily Heartburn Relief

PHARMACY ACTION 24 Hour Once Daily Heartburn Relief is recommended for adults over 18 years of age suffering from heartburn for two or more times a week.

PHARMACY ACTION 24 Hour Once Daily Heartburn Relief 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 PHARMACY ACTION 24 Hour Once Daily Heartburn Relief works

PHARMACY ACTION 24 Hour Once Daily Heartburn Relief is a type of medicine called a proton-pump inhibitor (PPI). It works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way. PHARMACY ACTION 24 Hour Once Daily Heartburn Relief will start to suppress acid within a few hours, however it will not give instant symptom relief. You may need to take PHARMACY ACTION 24 Hour Once Daily Heartburn Relief for a few days before experiencing the full effect.

There is no evidence that PHARMACY ACTION 24 Hour Once Daily Heartburn Relief is addictive.

Before you take PHARMACY ACTION 24 Hour Once Daily Heartburn Relief

When you must not take it

Do not take PHARMACY ACTION 24 Hour Once Daily Heartburn Relief if you have allergies to:

- Esomeprazole or any ingredient listed at the end of this leaflet.
- Any medicines containing a protonpump inhibitor.

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 PHARMACY ACTION 24 Hour Once Daily Heartburn Relief if you are also taking atazanavir or cilostazol. Please check with your doctor or pharmacist if you are taking these medicines. These medicines will be affected by PHARMACY ACTION 24 Hour Once Daily Heartburn

Relief. PHARMACY ACTION 24 Hour Once Daily Heartburn Relief is not intended for use in children under 18 year of age. Do not take PHARMACY ACTION 24 Hour Once Daily Heartburn Relief 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

- You must tell your doctor if you have:allergies to any other medicines, foods,
- dyes or preservatives. or have ever had any problems with your liver
- or have ever had severe kidney problems
- have anaemia, previous gastric ulcer or gastrointestinal surgery, difficulty swallowing, persistent vomiting or vomiting of blood, blood in the stools, unexplained weight loss or some other significant medical condition
- any other medical conditions
- have previously taken heartburn / indigestion medications continuously for 4 or more weeks to control your heartburn
- you are pregnant or plan to become pregnant

Do not take PHARMACY ACTION 24 Hour Once Daily Heartburn Relief if you are pregnant or breastfeeding 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 PHARMACY ACTION 24 Hour Once Daily Heartburn Relief while you are pregnant. It may affect your baby.

Do not take PHARMACY ACTION 24 Hour Once Daily Heartburn Relief if you are breastfeeding.

Ask your doctor for more information. It is not known PHARMACY ACTION 24 Hour Once Daily Heartburn Relief is excreted in breast milk if you are breastfeeding.

Taking other medicines

Do not take PHARMACY ACTION 24 Hour Once Daily Heartburn Relief if you are taking the following medicines:

- atazanavir medicines used to treat viral infections such as HIV
- cilostazol a medicine used to treat pain and/ or cramping in the lower leg (or arms) due to inadequate blood flow to the muscles.

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 PHARMACY ACTION 24 Hour Once Daily Heartburn Relief. 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 a medicine used to prevent blood clots
- 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.

These medicines may be affected by PHARMACY ACTION 24 Hour Once Daily Heartburn Relief 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 doctor and pharmacist have more information on medicines to be careful with or avoid while taking PHARMACY ACTION 24 Hour Once Daily Heartburn Relief.

If you have not told your doctor about any of these things, tell them before you take PHARMACY ACTION 24 Hour Once Daily Heartburn Relief.

How to take PHARMACY ACTION 24 Hour Once Daily Heartburn Relief

Follow all directions given to you by your doctor and pharmacist carefully. These instructions may differ from the information contained in this leaflet. If you do not understand the directions on the label, ask your doctor or pharmacist for help.

How to take it and how much

Take one PHARMACY ACTION 24 Hour Once Daily Heartburn Relief each day. Swallow PHARMACY ACTION 24 Hour Once Daily Heartburn Relief 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 noncarbonated 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
- 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

PHARMACY ACTION 24 Hour Once Daily Heartburn Relief can be taken with food or on an empty stomach.

When to take it

Take PHARMACY ACTION 24 Hour Once Daily Heartburn Relief at about the same time each day.

Keeping a regular time for taking PHARMACY ACTION 24 Hour Once Daily Heartburn Relief will help to remind you to take it.

How long to take it for

PHARMACY ACTION 24 Hour Once Daily Heartburn Relief should be taken for at least 7 days and up to 14 days.

If you purchased the pack containing 7 days' supply and you need to take for longer than 7 days, ask your pharmacist for advice. Do not take beyond 14 days without consulting your doctor.

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 have trouble remembering when to take your medicine, ask your pharmacist for some hints.

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 PHARMACY ACTION 24 Hour Once Daily Heartburn Relief. Do this even if there are no signs of discomfort or poisoning.

While you are taking PHARMACY ACTION 24 Hour Once Daily Heartburn Relief

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 PHARMACY ACTION 24 Hour Once Daily Heartburn Relief.

Tell all doctors, dentists and pharmacists who are treating you that you are taking PHARMACY ACTION 24 Hour Once Daily Heartburn Relief.

Tell your doctor or pharmacist if you become pregnant while you are taking PHARMACY ACTION 24 Hour Once Daily Heartburn Relief.

Tell your pharmacist or doctor if you do not feel better while taking PHARMACY ACTION 24 Hour Once Daily Heartburn Relief. If symptoms persist or recur within 2 weeks of completing the course, consult a doctor. Further examination may be required.

If you need to have any medical tests while you are taking PHARMACY ACTION 24 Hour Once Daily Heartburn Relief, tell your pharmacist or doctor. It may affect the results of some tests.

Things you must not do

Do not take it 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 doctor or pharmacist as soon as possible if you do not feel well while you are taking PHARMACY ACTION 24 Hour Once Daily Heartburn Relief.

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 doctor or pharmacist 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 pharmacist or 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 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, PHARMACY ACTION 24 Hour Once Daily Heartburn Relief 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 PHARMACY ACTION 24 Hour Once Daily Heartburn Relief.

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 PHARMACY ACTION 24 Hour Once Daily Heartburn Relief
- you begin to vomit blood or food
- you pass black (blood-stained) motions.

After taking it

Storage

Keep your PHARMACY ACTION 24 Hour Once Daily Heartburn Relief in the blister pack until it is time to take them. If you take PHARMACY ACTION 24 Hour Once Daily Heartburn Relief out of the blister/HDPE 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 oneand-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking PHARMACY ACTION 24 Hour Once Daily Heartburn Relief or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

Product Description

What PHARMACY ACTION 24 Hour Once Daily Heartburn Relief looks like

PHARMACY ACTION 24 Hour Once Daily Heartburn Relief 20 mg tablets are light pink coloured, oblog, biconvex, coated

tablets debossed with '20' on one side and 'CE' on the other.

Ingredients

Each PHARMACY ACTION 24 Hour Once Daily Heartburn Relief contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 20mg. They also contain the following inactive ingredients:

- Sugar Spheres (Non Pareil Seeds 40-50 which contains maize starch and sucrose)
- Hyprolose
- Crospovidone
- Sucrose
- Maize starch
- Light magnesium oxide
- Purified talc
- Macrogol 6000
- Methacrylic acid ethyl acrylate copolymer (1:1)
- Glyceryl monostearate
- Macrogol 400
- Polysorbate 80
- Hypromellose phthalate
- Microcrystalline cellulose
- Povidone
- Pregelatinised maize starch
- Silicon dioxide
- Lactose monohydrate
- Titanium dioxide
- Iron oxide red
- Iron oxide yellow

Supplier

PHARMACY ACTION 24 Hour Once Daily Heartburn Relief tablets are supplied in Australia by: Generic Health Pty Ltd Level 1, 1102 Toorak Road, Camberwell VIC 3124 This leaflet was prepared January 2018.

PHARMACY ACTION 24 Hour Once Daily Heartburn Relief 20 mg (blister pack) – AUST R 207580