

CONSUMER MEDICINE INFORMATION



ESOMEPRAZOLE 24 HOUR ONCE DAILY HEARTBURN RELIEF

ESOMEPRAZOLE MAGNESIUM

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief. It does not contain all the available information about TerryWhite Chemmart® Esomeprazole 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 pharmacist or doctor has weighed the risks of you taking TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief against the benefits it is expected to 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 TERRYWHITE CHEMMART® ESOMEPRAZOLE 24 HOUR ONCE DAILY HEARTBURN RELIEF IS USED FOR

TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief is used for the symptomatic relief of frequent heartburn, acid regurgitation and other symptoms associated with gastroesophageal 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 two or more times a week. Heartburn that occurs frequently is a typical symptom of gastroesophageal reflux disease (GORD).

Who Should Use TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief TerryWhite Chemmart® Esomeprazole 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. TerryWhite Chemmart® Esomeprazole 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 TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief works TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief is a type of medicine called a proton-pump inhibitor. 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.

TerryWhite Chemmart® Esomeprazole 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 TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief for a few days before experiencing the full effect. There is no evidence that TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief is addictive.

BEFORE YOU TAKE TERRYWHITE CHEMMART® ESOMEPRAZOLE 24 HOUR ONCE DAILY HEARTBURN RELIEF

When you must not take TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief Do not take TerryWhite Chemmart® Esomeprazole 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 proton- pump 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 TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief if you are also taking atazanavir or clobazam. Please check with your pharmacist or doctor if you are taking these medicines. These medicines will be affected by TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief (see Taking other medicines). **TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief is not intended for use in children younger than 18 years of age. Do not take TerryWhite Chemmart® Esomeprazole 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 pharmacist or doctor if you have:

- allergies to any other medicines, foods,
- dyes or preservatives
- any problems with your liver
- experienced any significant weight loss, difficulty in swallowing or dark tarry stools
- severe kidney problems
- any other medical conditions

Do not take TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief 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 TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief while you are pregnant. It may affect your baby. Do not take TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief if you are breastfeeding. Ask your doctor for more information. It is not known if TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief is excreted in breast-milk if you are breastfeeding.

Taking other medicines Do not take TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief if you are taking the following medicines:

- atazanavir - medicine used to treat viral infections such as HIV
- clobazam - 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 TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief. These include:

- medicines used to treat fungal infections such as ketoconazole, itraconazole and voriconazole
- medicines used to treat bacterial infections such as clarithromycin and rifampicin
- diazepam, a medicine used to treat anxiety and some other conditions
- phenytoin, a medicine used to treat epilepsy
- medicines used to treat depression such as citalopram, clomipramine or imipramine

- warfarin and clopidogrel – medicines used to prevent blood clots
- digoxin, a medicine used to treat certain heart problems
- medicines for HIV treatment such as nelfinavir
- St. John's Wort, a herbal remedy used to treat mood disorders
- 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 TerryWhite Chemmart® Esomeprazole 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 TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief.

If you have not told your doctor or pharmacist about any of these things, tell them before you take TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief.

HOW TO TAKE TERRYWHITE CHEMMART® ESOMEPRAZOLE 24 HOUR ONCE DAILY HEARTBURN RELIEF

Follow all directions given to you by your doctor or 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 TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief tablet each day. Swallow TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief 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. Take TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief at about the same time each day.

Keeping a regular time for taking TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief will help to remind you to take it. TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief can be taken with food or on an empty stomach.

How long to take it for TerryWhite Chemmart® Esomeprazole 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 pharmacist or 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 TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief tablets. Do this even if there are no signs of discomfort or poisoning.

WHILE YOU ARE TAKING TERRYWHITE CHEMMART® ESOMEPRAZOLE 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 TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief. Tell all doctors, dentists and pharmacists who are treating you that you are taking TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief. If you need to have any medical tests while you are taking TerryWhite Chemmart® Esomeprazole 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 TerryWhite Chemmart® Esomeprazole 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 doctor or pharmacist if you notice any of the following and they worry you:

- headache
- stomach pain
- constipation
- diarrhoea
- wind
- nausea
- vomiting
- itching
- skin rash
- dizziness
- dry mouth

These side effects are usually mild.

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

- disturbances in vision (blurred vision)
- feeling depressed
- mood changes, agitation, aggression, hallucination
- confusion
- muscle pain or weakness
- joint pain
- increase in breast size (males)
- increased sweating
- changes in sleep patterns
- fever
- increased bruising
- tremor
- blood in the urine
- hair loss
- difficulty in breathing (bronchospasm)
- tingling, prickling or numbness of the hands and feet ("pins and needles")
- taste disturbance, sore mouth, thrush
- increased sensitivity to sunlight
- frequent infections such as fever, severe chills, sore throat or mouth ulcers

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:

- liver problems (often seen as yellowing of your skin or the whites of your eyes, feeling generally unwell, nausea, vomiting, loss of appetite)
- 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. These are very serious side effects.

You may need urgent medical treatment or hospitalisation. Occasionally, TerryWhite Chemmart® Esomeprazole 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 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 TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief.

Sometimes when a person stops taking this medicine after taking it for a long time, they may experience a bounce back in excess stomach acid.

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 TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief
- you begin to vomit blood or food
- you pass black (blood-stained) motions

AFTER TAKING TERRYWHITE CHEMMART ESOMEPRAZOLE 24 HOUR ONCE DAILY HEARTBURN RELIEF

Storage Keep your TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief in the blister pack until it is time to take them. If you take TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief 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 doctor tells you to stop taking TerryWhite Chemmart® Esomeprazole 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 TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief looks like TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief tablets are light brick red to brown, oval, biconvex, enteric-coated tablets with 'E5' debossed on one side and plain on other side.

Ingredients **Active ingredient:** TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief tablets – esomeprazole magnesium equivalent to esomeprazole 20mg

Inactive ingredients:

- crospovidone
- diethyl phthalate
- hydroxypropylcellulose
- hypromellose phthalate
- macrogol 400
- macrogol 4000
- macrogol 6000
- microcrystalline cellulose
- Non Pareil Seeds 40-60 [sugar spheres (sucrose and maize starch); Proprietary ingredient # 108075]
- Opadry Complete Film Coating System 03B86651 Brown (Proprietary ingredient # 106495).
- povidone
- purified talc
- sodium stearyl fumarate

TerryWhite Chemmart® Esomeprazole 24 Hour Once Daily Heartburn Relief tablets do not contain lactose, glucose or gluten.

Sponsor: Soul Pattinson (Manufacturing) Pty Ltd 250 Camberwell Road, Camberwell, VIC 3124

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This leaflet was prepared in November 2020.