#### **NOXICID® CAPS HEARTBURN RELIEF**

Esomeprazole (as magnesium)

#### **Consumer Medicine Information**

#### What is in this leaflet

This leaflet answers some of the common questions people ask about NOXICID CAPS HEARTBURN RELIEF. It does not contain all the information that is known about NOXICID CAPS HEARTBURN RELIEF.

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

All medicines have risks and benefits. Your pharmacist or doctor will have weighed the risks of you taking NOXICID CAPS HEARTBURN RELIEF 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 NOXICID CAPS HEARTBURN RELIEF is used for

NOXICID CAPS HEARTBURN RELIEF is used for the relief of frequent heartburn and stomach acid complaints due to gastrooesophageal 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.

### How NOXICID CAPS HEARTBURN RELIEF works

NOXICID CAPS 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.

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

They may differ from the information contained in this leaflet.

### Ask your pharmacist or doctor if you want more information.

There is no evidence that NOXICID CAPS HEARTBURN RELIEF is addictive.

This medicine can be purchased directly from your pharmacy without a doctor's prescription.

### Before you take NOXICID CAPS HEARTBURN RELIEF

### When you must not take it Do not take NOXICID CAPS HEARTBURN RELIEF if you have allergies to:

- esomeprazole or any ingredient listed at the end of this leaflet.
- any medicines containing a protonpump inhibitor (omeprazole, rabeprazole, lansoprazole, pantoprazole).

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 NOXICID CAPS HEARTBURN RELIEF if you are also taking atazanavir or cilostazol.

Please check with your pharmacist or doctor if you are taking these medicines. These medicines will be affected by NOXICID CAPS HEARTBURN RELIEF.

NOXICID CAPS HEARTBURN RELIEF is not approved for use in children younger than 18 years of age.

Do not take NOXICID CAPS 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
- · severe kidney problems
- difficulty swallowing, persistent vomiting or vomiting of blood, blood in stools, unexplained weight loss or some other significant medical conditions
- have previously taken heartburn/ indigestion medications continuously for 4 or more weeks to control your heartburn
- recently finished a course of NOXICID CAPS HEARTBURN RELIEF or a similar medicine in the last 2 weeks
- · any other medical conditions
- · been diagnosed with osteoporosis
- if you have ever had a skin reaction after treatment with a medicine similar to NOXICID CAPS HEARTBURN RELIEF that reduces stomach acid

Ask your pharmacist or doctor before use if you are or may become pregnant. Do not use if you are breastfeeding or wish to start breastfeeding. Ask your pharmacist or doctor about the risks and benefits involved.

It is not known if it is safe for you to take NOXICID CAPS HEARTBURN RELIEF while you are pregnant. It may affect your baby.

It is not known if your baby can take in NOXICID CAPS HEARTBURN RELIEF from breast milk if you are breastfeeding.

#### Taking other medicines

### Do not take NOXICID CAPS HEARTBURN RELIEF if you are taking the following medicines:

- atazanavir and nelfinavir, medicines used to treat Human Immunodeficiency Virus (HIV)
- cilostazol, a medicine used to treat pain and/or cramping in the lower legs (or arms) due to inadequate blood flow to the muscles
- warfarin or clopidogrel- medicines used to prevent blood clots
- methotrexate, a medicine used to treat arthritis and some types of cancer

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 NOXICID CAPS HEARTBURN RELIEF. These include:

- medicines used to treat fungal infections such as ketoconazole, itraconazole and voriconazole
- cisapride
- 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
- St John's wort, a herbal remedy used to treat mood disorders
- medicines used to treat bacterial infections such as clarithromycin and rifampicin
- warfarin, a medicine used to prevent blood clots
- medicines for HIV treatment such as atazanavir and nelfinavir
- digoxin, a medicine used to treat heart conditions
- tacrolimus and mycophenolate mofetil, medicines used to assist organ transplants
- erlotinib or related medicines used to treat cancer

These medicines may be affected by NOXICID CAPS 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 pharmacist and doctor have more information on medicines to be careful with or avoid while taking NOXICID CAPS HEARTBURN RELIEF.

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

### How to take NOXICID CAPS HEARTBURN RELIEF

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

They may differ from the information contained in this leaflet.

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

How to take it

NOXICID CAPS HEARTBURN RELIEF is available as enteric capsules

NOXICID CAPS HEARTBURN RELIEF Enteric capsules

Take one NOXICID CAPS HEARTBURN RELIEF capsule each day.

Swallow NOXICID CAPS HEARTBURN RELIEF enteric capsules whole with a

glass of water. Do not crush or chew the capsules.

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

### Take NOXICID CAPS HEARTBURN RELIEF at about the same time each day.

Keeping a regular time for taking NOXICID CAPS HEARTBURN RELIEF will help to remind you to take it.

NOXICID CAPS HEARTBURN RELIEF is not intended for immediate relief. It may take several days to achieve maximum results.

NOXICID CAPS HEARTBURN RELIEF 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.

# NOXICID CAPS HEARTBURN RELIEF can be taken with food or on an empty stomach.

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 NOXICID CAPS HEARTBURN RELIEF. Do this even if there are no signs of discomfort or poisoning.

### While you are taking NOXICID CAPS HEARTBURN RELIEF

Things you must do

Take NOXICID CAPS HEARTBURN RELIEF exactly as pharmacist or doctor has prescribed.

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

Tell all pharmacists, doctors and dentists who are treating you that you are taking NOXICID CAPS HEARTBURN RELIEF.

Tell your pharmacist or doctor if you become pregnant while you are taking NOXICID CAPS HEARTBURN RELIEF.

Tell your doctor if you are not feeling better or your symptoms worsen.

Tell your doctor if your symptoms persist or return within two weeks of completing the course.

If you have suffered from frequent heartburn/indigestion symptoms for some time you should see your doctor.

If you need to have any medical tests while you are taking NOXICID CAPS HEARTBURN RELIEF, tell your doctor It may affect the results of some tests.

Things you must not do

Do not use it to treat any other conditions unless your pharmacist or 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 NOXICID CAPS HEARTBURN RELIEF.

NOXICID CAPS HEARTBURN RELIEF helps most people with reflux disease, but it may have unwanted side effects in a few people.

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 you 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
- skin reaction, especially in sun exposed areas, with joint pain
- · muscle twitching or jerking movements
- · irregular (fast or slow) heartbeat
- · loss of consciousness or awareness

These are all rare or very rare side effects. 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. These side effects are rare.

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 NOXICID CAPS 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 NOXICID CAPS HEARTBURN RELIEF
- you begin to vomit blood or food
- you pass black (blood-stained) motions.

### After taking NOXICID CAPS HEARTBURN RELIEF

#### Storage

### Keep NOXICID CAPS HEARTBURN RELIEF where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

#### Keep your NOXICID CAPS HEARTBURN RELIEF in the blister pack until it is time to take them.

If you take NOXICID CAPS HEARTBURN RELIEF out of the blister it may not keep well.

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

Protect from moisture.

Do not keep NOXICID CAPS HEARTBURN RELIEF or any other medicine in the bathroom or near a sink.

Do not leave NOXICID CAPS HEARTBURN RELIEF in the car or on window sills.

Heat and dampness can destroy some medicines.

### Disposal

If your pharmacist or doctor tells you to stop taking NOXICID CAPS HEARTBURN RELIEF or the enteric capsules have passed their expiry date, ask your pharmacist what to do with any enteric capsules you have left over.

### Product description

# What NOXICID CAPS HEARTBURN RELIEF looks like NOXICID CAPS HEARTBURN RELIEF Enteric 20mg capsules

White to cream coloured pellets filled in hard gelatin capsule with pink cap and pink body, imprinted with 'Mylan' over 'EM 20' in black ink on cap and body.

Each blister pack contains 14 enteric capsules.

#### Ingredients

The active ingredient in NOXICID CAPS HEARTBURN RELIEF is esomeprazole (as magnesium). Each NOXICID CAPS HEARTBURN RELIEF contains 20 mg of esomeprazole.

The capsules also contain the following inactive ingredients:

- Sugar spheres (ARTG PI No: 2535)
- Sucrose
- Crospovidone
- Hyprolose
- Mannitol
- Methacrylic acid ethyl acrylate copolymer (1:1)
- Triethyl citrate
- Glyceryl monostearate
- Polysorbate 80
- Purified talc
- Empty Hard Gelatin Capsule Shells Cap & Body - Pink & Pink Size 3 (ARTG PI No:109606)
- TekPrint SW-9008 Black Ink (ARTG PI No: 2328)
- Sodium hydroxide

NOXICID CAPS HEARTBURN RELIEF contains traces of sulfites.

#### Sponsor

NOXICID CAPS HEARTBURN RELIEF is supplied in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond 30 - 34 Hickson Road Millers Point NSW 2000 www.viatris.com.au

Phone: 1800 274 276

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Australian registration numbers:

NOXICID CAPS HEARTBURN RELIEF esomeprazole 20 mg (as magnesium) enteric capsules blister pack – AUST R 336014

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