NOXICID® CAPS HEARTBURN RELIEF

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking NOXICID CAPS HEARTBURN RELIEF?

NOXICID CAPS HEARTBURN RELIEF contains the active ingredient esomeprazole (as magnesium). It is used for the relief of frequent heartburn and stomach acid complaints due to gastro-oesophageal reflux disease (GORD).

For more information, see Section <u>1. Why am I taking</u> NOXICID CAPS HEARTBURN RELIEF? in the full CMI.

2. What should I know before I take NOXICID CAPS HEARTBURN RELIEF?

Do not take if you have ever had an allergic reaction to NOXICID CAPS HEARTBURN RELIEF or any of the ingredients listed at the end of the CMI. Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section <u>2. What should I know before I take NOXICID CAPS HEARTBURN RELIEF?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NOXICID CAPS HEARTBURN RELIEF and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take NOXICID CAPS HEARTBURN RELIEF?

- NOXICID CAPS HEARTBURN RELIEF is available as enteric capsules. The dose is usually 20 mg per day, once daily, for 7 - 14 days, depending on the severity of your symptoms.
- Follow all directions given to you by your doctor and/or pharmacist.

More instructions can be found in Section <u>4. How do I</u> take NOXICID CAPS HEARTBURN RELIEF? in the full CMI.

5. What should I know while taking NOXICID CAPS HEARTBURN RELIEF?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are taking NOXICID CAPS HEARTBURN RELIEF. Tell your doctor if you become pregnant. Tell your doctor if your symptoms return.
Things you should not do	 Do not take NOXICID CAPS HEARTBURN RELIEF 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.
Driving or taking machines	 Be careful before you drive or take any machines or tools until you know how NOXICID HEARTBURN RELIEF CAPS affects you.

Looking after your medicine

- Keep your medication in the blister pack until it is time to take it.
- Keep it in a cool, dry place where the temperature stays below 25°C

For more information, see Section <u>5. What should I know while taking NOXICID CAPS HEARTBURN RELIEF?</u> in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. These include nausea or vomiting, constipation, diarrhoea, headache, wind, stomach pain, skin rash, itchy skin, dizziness or dry mouth. However, some serious side effects may need urgent medical attention. These include 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, blood in the urine and increased or decreased urine output.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.



NOXICID® CAPS HEARTBURN RELIEF

Active ingredient(s): Esomeprazole (as magnesium)

Consumer Medicine Information (CMI)

This leaflet provides important information about taking NOXICID CAPS HEARTBURN RELIEF. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking NOXICID CAPS HEARTBURN RELIEF.

Where to find information in this leaflet:

- 1. Why am I taking NOXICID CAPS HEARTBURN RELIEF?
- 2. What should I know before I take NOXICID CAPS HEARTBURN RELIEF?
- 3. What if I am taking other medicines?
- 4. How do I take NOXICID CAPS HEARTBURN RELIEF?
- 5. What should I know while taking NOXICID CAPS HEARTBURN RELIEF?
- 6. Are there any side effects?
- 7. Product details

1. Why am I taking NOXICID CAPS HEARTBURN RELIEF?

NOXICID CAPS HEARTBURN RELIEF contains the active ingredient esomeprazole. 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.

NOXICID CAPS HEARTBURN RELIEF 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.

Your doctor may have prescribed NOXICID CAPS HEARTBURN RELIEF for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

NOXICID CAPS HEARTBURN RELIEF is not addictive.

2. What should I know before I take NOXICID CAPS HEARTBURN RELIEF?

Warnings

Do not take NOXICID CAPS HEARTBURN RELIEF if:

- you are allergic to esomeprazole, or any of the ingredients listed at the end of this leaflet.
- you are allergic to any medicines containing proton-pump inhibitors (omeprazole, rabeprazole, lansoprazole, pantoprazole).
 - Symptoms of an allergic reaction may include:
 - Shortness of breath, wheezing or difficulty breathing
 - Swelling of the face, lips or other parts of the body
 - Rash, itching or hives on the skin

Always check the ingredients to make sure you can take this medicine.

- 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.
- the expiry date printed on the pack has passed, 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.

Check with your doctor or pharmacist 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
- 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
 two weeks
- any other medical conditions
- been diagnosed with osteoporosis
- ever had a skin reaction after the treatment with a medicine similar to NOXICID CAPS HEARTBURN RELIEF that reduces stomach acid

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant or may become pregnant except on the advice of a doctor or pharmacist.

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.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Do not take this medicine if you are breastfeeding or wish to start breastfeeding.

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

Tell your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

Children younger than 1 year

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

3. What if I am taking other medicines?

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

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

Some medicines may interfere with NOXICID CAPS HEARTBURN RELIEF and affect how it works. 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.

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

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NOXICID CAPS HEARTBURN RELIEF.

4. How do I take NOXICID CAPS HEARTBURN RELIEF?

How much to take

- NOXICID CAPS HEARTBURN RELIEF is available as enteric capsules.
- Take one NOXICID CAPS HEARTBURN RELIEF capsule each day.
- 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.

When to take NOXICID CAPS HEARTBURN RELIEF

- NOXICID CAPS HEARTBURN RELIEF should be taken 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.

How to take NOXICID CAPS HEARTBURN RELIEF

- Follow all directions given to you by your pharmacist and doctor carefully.
- Swallow NOXICID CAPS HEARTBURN RELIEF enteric capsules whole with a glass of water.
- NOXICID CAPS HEARTBURN RELIEF can be taken with food or on an empty stomach.
- Do not crush or chew the capsules.
 If the capsules are chewed or crushed, they will not work properly.

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

If you forget to take NOXICID CAPS HEARTBURN RELIEF

- 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.

If you take too much NOXICID CAPS HEARTBURN RELIEF

If you think that you or anyone else has taken too much NOXICID CAPS HEARTBURN RELIEF, urgent medical attention maybe needed.

You should immediately:

- phone the Poisons Information Centre
 (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking NOXICID CAPS HEARTBURN RELIEF?

Things you should 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 should 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.

Driving or taking machines

Be careful before you drive or take any machines or tools until you know how NOXICID CAPS HEARTBURN RELIEF affects you.

There is no evidence that esomeprazole impairs the ability to drive a vehicle or operate machinery.

Looking after your medicine

- 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 temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

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.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Less serious side effects

Less serious side effects	What to do
Mouth related:	Speak to your doctor or
dry mouth	pharmacist if you have any of these less serious
Head related:	side effects and they
• headache	worry you.
• dizziness	

Less serious side effects	What to do
Stomach related:	
• stomach pain	
nausea or vomiting	
constipation	
diarrhoea	
• wind	
Skin related:	
• skin rash	
• itchy skin	

Less serious side effects	What to do
 General: fever hair loss Sight related: blurred vision Hormone related: 	Tell your pharmacist or doctor immediately if you notice any of these symptoms. These are rare or very rare side effects and may require medical attention.
 mood changes, confusion or depression increase in breast size (males) increased sweating Skin and muscle related: tremor 	

Less serious side effects	What to do
 pins and needles skin reaction, especially in sun exposed areas, with joint pain muscle twitching or jerking movements muscle pain or 	
weakness, joint pain increased bruising Heart related:	
 irregular (fast or slow) heartbeat Alertness and sleep related: 	
loss of consciousness or awarenesschanges in sleep patterns	

Serious side effects

Serious side effects	What to do
 Breathing related: shortness of breath, wheezing or difficulty breathing 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you

Serious side effects	What to do
Swelling related:	notice any of these very
 swelling of the face, lips, tongue or other parts of the body 	serious side effects.
Skin related:	
 severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin. This may be associated with a high fever and joint pains. 	
Liver related:	
 signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite 	
Kidney related:	
Blood in the urine	
 pain or indigestion during treatment with NOXICID CAPS HEARTBURN RELIEF you begin to vomit blood or food 	Contact your doctor immediately if you notice any of these side effects.

Serious side effects	What to do
 you pass black (blood- stained) motions 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What NOXICID CAPS HEARTBURN RELIEF contains

	esomeprazole (as
(main ingredient)	magnesium)

Other ingredients (inactive ingredients)	 Sugar spheres (ID 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 (ID 109606) TekPrint SW-9008 Black Ink (ID 2328) Sodium hydroxide
Potential allergens	Traces of Sulfites

Do not take this medicine if you are allergic to any of these ingredients.

What NOXICID CAPS HEARTBURN RELIEF looks like

NOXICID CAPS HEARTBURN RELIEF 20 mg (as magnesium) capsules are 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 (AUST R 336014).

Each blister pack contains 14 enteric capsules.

Who distributes NOXICID CAPS HEARTBURN RELIEF

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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