

NOXICID[®] CAPS

Consumer Medicine Information (CMI) summary

The [full CMI](#) 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?

NOXICID CAPS contain the active ingredient esomeprazole. NOXICID CAPS is used to treat Reflux Oesophagitis, Upper gastrointestinal symptoms associated with non-steroidal anti-inflammatory drugs (NSAIDs) therapy, Peptic Ulcers Associated with Helicobacter pylori Infection, Zollinger-Ellison Syndrome and Bleeding Peptic Ulcers.

For more information, see Section [1. Why am I taking NOXICID CAPS?](#) in the full CMI.

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

Do not take if you have ever had an allergic reaction to esomeprazole or any of the ingredients listed at the end of the CMI.

Talk to your doctor 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 [2. What should I know before I take NOXICID CAPS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NOXICID CAPS 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?

- NOXICID CAPS is available as enteric capsules. The dose of NOXICID CAPS enteric capsules is usually 20 mg or 40 mg a day. The dose for NOXICID CAPS depends on what condition you are being treated for and how severe it is.
- Swallow NOXICID CAPS enteric capsule with a whole glass of water.
- Follow all directions given to you by your doctor and pharmacist carefully.

More instructions can be found in Section [4. How do I take NOXICID CAPS?](#) in the full CMI.

5. What should I know while taking NOXICID CAPS?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking NOXICID CAPS.• Tell your doctor if you become pregnant while taking NOXICID CAPS.• Tell your doctor if your symptoms return. |
| Things you should not do | <ul style="list-style-type: none">• Do not take NOXICID CAPS to treat any other complaint unless your doctor tells you to.• Do not give this medicine to anyone else, even if their symptoms seem similar to yours. |
| Driving or using machines | <ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how NOXICID CAPS affects you. |
| Looking after your medicine | <ul style="list-style-type: none">• Keep your NOXICID CAPS in the bottle until it is time to take it.• Keep your medicine in a cool dry place where the temperature stays below 25°C. |

For more information, see Section [5. What should I know while taking NOXICID CAPS?](#) 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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

NOXICID CAPS[®]

Active ingredient(s): *Esomeprazole*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking NOXICID CAPS. **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.**

Where to find information in this leaflet:

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

1. Why am I taking NOXICID CAPS?

NOXICID CAPS contains the active ingredient **esomeprazole**. NOXICID CAPS 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 allowing healing to take place. This does not stop food being digested in the normal way.

Reflux Oesophagitis

NOXICID CAPS is taken to treat reflux oesophagitis. 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. NOXICID CAPS is also taken to help stop reflux oesophagitis coming back or relapsing.

Upper gastrointestinal symptoms associated with non-steroidal anti-inflammatory drugs (NSAIDs) therapy

NOXICID CAPS is taken to treat the symptoms of pain or discomfort, in the stomach caused by NSAIDs, a type of medicine for pain or inflammation. NOXICID CAPS is also taken to help heal and prevent ulcers caused by NSAIDs.

Peptic Ulcers Associated with Helicobacter pylori Infection

Most people who have a peptic (gastric and duodenal) ulcer also have a bacterium called *Helicobacter pylori* in their stomach.

Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach. If you have a peptic ulcer, your doctor will prescribe NOXICID CAPS with antibiotics. When NOXICID CAPS and antibiotics are taken together, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

Zollinger-Ellison Syndrome

NOXICID CAPS is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

Bleeding Peptic Ulcers

When peptic ulcers become severe enough, they start to bleed. You may receive treatment injected into your veins initially. This treatment may be followed with NOXICID CAPS prescribed by your doctor for a longer period of time. This is to help your ulcer/s to heal.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed NOXICID CAPS for another reason.

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

Warnings

Do not take NOXICID CAPS if:

- you are allergic to esomeprazole, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can take this medicine.
- you are allergic to any medicines containing proton-pump inhibitors.

Some 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 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 NOXICID CAPS.

Check with your 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
- been diagnosed with osteoporosis
- ever had a skin reaction after treatment with a medicine similar to NOXICID CAPS that reduces stomach acid

There is no evidence that NOXICID CAPS is addictive.

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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

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

Do not take NOXICID CAPS if you are pregnant or plan to become pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

Children younger than 12 years of age

NOXICID CAPS is not approved for use in children younger than 12 years of age. There is no specific information about use in children younger than 12 years of age for NOXICID CAPS, so this medicine is not recommended in these patients.

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 if you are taking the following medicines:

- atazanavir and nelfinavir - medicines used to treat viral infections such as Human Immunodeficiency Virus (HIV)
- cilostazol, a medicine used to treat intermittent claudication

Some medicines may interfere with NOXICID CAPS. 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 (*Hypericum perforatum*) - 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
- digoxin - a medicine used to treat heart conditions
- methotrexate - a medicine used to treat arthritis and some types of cancer
- tacrolimus and mycophenolate mofetil - medicines used to assist in organ transplants
- erlotinib or related medicines used to treat cancer
- cisapride

These medicines may be affected by NOXICID CAPS or may affect how well it works. You may need different amounts

of your medicine or you may need to take different medicines.

If you have not told your doctor about any of these things, tell them before you start taking NOXICID CAPS.

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

4. How do I take NOXICID CAPS?

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

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

How much to take

NOXICID CAPS is available as enteric capsules.

- Take one NOXICID CAPS capsule each day, unless your doctor has told you otherwise.
- The dose of NOXICID CAPS enteric capsule is usually 20 mg or 40 mg a day depending on what condition you are being treated for and how severe it is.

When to take NOXICID CAPS

- NOXICID CAPS should be taken about the same time each day.
- Keeping a regular time for taking NOXICID CAPS will help you to remember to take it.
- NOXICID CAPS can be taken with food or on an empty stomach.
- Keep taking your NOXICID CAPS for as long as your doctor recommends.

In most patients, NOXICID CAPS relieves symptoms rapidly and healing is usually complete within 4 weeks. Continue taking NOXICID CAPS for as long as your doctor tells you to.

How to take NOXICID CAPS

- Swallow NOXICID CAPS enteric capsule with a whole glass of water.
- Do not crush or chew the capsules. If the capsules are chewed or crushed, they will not work properly.

If you forget to take NOXICID CAPS

NOXICID CAPS should be taken regularly at the same time each day. If you miss your dose at the usual time, 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 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

If you think that you or anyone else has taken too much NOXICID CAPS, urgent medical attention may be 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?

Things you should do

Take NOXICID CAPS exactly as your doctor has prescribed.

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

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

Tell your doctor if you become pregnant while you are taking NOXICID CAPS.

Tell your doctor if your symptoms return.

Although NOXICID CAPS can heal ulcers successfully, it may not prevent them from recurring at a later date.

If you need to have any medical tests while you are taking NOXICID CAPS, tell your doctor.

It may affect the results of some tests.

If you are going into surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Keep all your doctor's appointments so that your progress can be checked.

Things you should 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.

Driving or using machines

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

Looking after your medicine

- Keep your NOXICID CAPS in the bottle until it is time to take it. If you take NOXICID CAPS out of the bottle it will not keep well.
- Store 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 or 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 printed on the pack or if the packaging is torn or shows signs of tampering.

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 about side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Less serious side effects

| Less serious side effects | What to do |
|---|--|
| <ul style="list-style-type: none">• nausea or vomiting• constipation• diarrhoea• headache• wind• stomach pain• skin rash, itchy skin• dizziness• dry mouth | Speak to your doctor if you have any of these less serious side effects and they worry you. |
| <ul style="list-style-type: none">• 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 | Speak to your doctor immediately if you have any of these side effects. These side effects may require medical attention. |

| Less serious side effects | What to do |
|---|------------|
| <ul style="list-style-type: none"> loss of consciousness or awareness. | |

Serious side effects

| Serious side effects | What to do |
|---|--|
| <ul style="list-style-type: none"> 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 over liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |
| <ul style="list-style-type: none"> pain or indigestion during treatment with NOXICID CAPS you begin to vomit blood or food you pass black (blood-stained) motions | <p>Contact your doctor immediately if you notice any of these side effects.</p> |

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NOXICID CAPS even if you do not think that it is connected with the medicine.

NOXICID CAPS help most people with peptic ulcers or reflux disease, but it may have unwanted side effects in a few people.

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

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.

Tell your doctor if you reflux symptoms return after you stop taking NOXICID CAPS.

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.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What NOXICID CAPS contains

| Active ingredient (main ingredient) | Esomeprazole |
|--|--|
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none"> Sugar spheres (ARTG PI No: 2535) Crospovidone Hyprolose Mannitol Methacrylic acid - ethyl acrylate copolymer (1:1) Triethyl citrate Glyceryl monostearate Polysorbate 80 Purified talc Sodium hydroxide Sucrose TekPrint SW-9008 Black Ink (ARTG PI No: 2328) Empty Hard Gelatin Capsule Shells Cap & Body - Pink & Pink Size 3 (ARTG PI No: 109606) [20 mg capsule only] Empty Hard Gelatin Capsule Shells Cap & Body - Brown & Brown Size 1 (ARTG PI No: 109616) [40 mg capsule only] |
| Potential allergens | <ul style="list-style-type: none"> Sugars Trace quantities of sulfites |

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

What NOXICID CAPS looks like

NOXICID CAPS 20 mg 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 246914).

Each bottle contains 30 capsules.

NOXICID CAPS 40 mg are white to cream coloured pellets filled in hard gelatin capsule with brown cap and brown body, imprinted with 'MYLAN' over 'EM 40' in black ink on cap and body (AUST R 246915).

Each bottle contains 30 capsules.

Who distributes NOXICID CAPS

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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NOXICID® is a Viatris company trade mark

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