

NOXICID[®] CAPS

Esomeprazole (as magnesium)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions about NOXICID CAPS. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking NOXICID CAPS 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 NOXICID CAPS is used for

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.

How NOXICID CAPS works

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 allow healing to take place. This does not stop food being digested in the normal way.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

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.

There is no evidence that NOXICID CAPS is addictive.

This medicine is only available with a prescription.

Before you take NOXICID CAPS

When you must not take it

Do not take NOXICID CAPS if you have an allergy 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 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.

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.

Do not take NOXICID CAPS 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.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

You must tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- any problems with your liver
- severe kidney problems
- 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 that reduces stomach acid

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.

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.

Taking other medicines

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

Tell your 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. 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 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 - medicines used to assist in organ transplants
- erlotinib or related medicines used to treat cancer

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. Your 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 NOXICID CAPS.

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

How to take NOXICID CAPS

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

They may differ from the information contained in this leaflet.

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

How to take it:

NOXICID CAPS is available as enteric capsules.

NOXICID CAPS Enteric capsules

Take one NOXICID CAPS capsule each day, unless your doctor has told you otherwise.

The dose of NOXICID CAPS enteric capsules is usually 20 mg or 40 mg a day depending on what condition you

are being treated for and how severe it is.

Swallow NOXICID CAPS enteric capsules whole with a glass of water. Do not crush or chew the capsules.

Take NOXICID CAPS at about the same time each day.

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

Keep taking 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.

NOXICID CAPS 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.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too many NOXICID CAPS. Do this even if there are no signs of discomfort or poisoning.

While you are taking NOXICID CAPS

Things you must do

Take NOXICID CAPS exactly as your doctor has prescribed.

If you are about to be started 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.

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

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

Tell your doctor if your symptoms return.

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

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

Things you must not do

Do not use it to treat any other conditions 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 NOXICID CAPS.

NOXICID CAPS helps most people with

peptic ulcers or 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.

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

Ask your doctor or pharmacist to answer any questions you may have.

Tell your 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 doctor as soon as possible 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 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, 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 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.

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
- you begin to vomit blood or food
- you pass black (blood-stained) motions.

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

After taking NOXICID CAPS

Storage

Keep NOXICID CAPS 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 in the bottle, with the lid firmly closed, until it is time to take them.

If you take NOXICID CAPS out of the bottle, 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 or any other medicine in the bathroom or near a sink.

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

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking NOXICID CAPS 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 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.

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.

Each bottle contains 30 capsules.

Ingredients

NOXICID CAPS contain 20 mg or 40 mg of esomeprazole (as magnesium) as the active ingredient.

The capsules also contain the following inactive ingredients:

- Sugar spheres (ARTG PI No: 2535)
- Crospovidone
- Hypromellose
- 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]

NOXICID CAPS contains sugars and trace quantities of sulfites.

Distributor

NOXICID CAPS is distributed 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

This leaflet was prepared in March 2023.

Australian registration numbers:

NOXICID CAPS 20 mg - AUST R
246914

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246915

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