

NOXICID® CAPS

contains the active ingredient *Esomeprazole (as magnesium)*

Consumer Medicine Information

What is in this leaflet

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

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

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking Noxicid 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 is used for

Reflux Oesophagitis

Noxicid 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 helicoknown as heartburn.

Noxicid 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 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 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 with antibiotics. When Noxicid 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 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.

How Noxicid works

Noxicid 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 want more information. Your doctor may have prescribed Noxicid for another reason.

There is no evidence that Noxicid is addictive.

This medicine is only available with a prescription.

Before you take Noxicid

When you must not take it

Do not take Noxicid 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 Noxicid 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.

Noxicid 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, so Noxicid is not recommended in these patients.

Do not take Noxicid 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 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

Do not take Noxicid if you are 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 while you are pregnant. It may affect your baby.

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

Taking other medicines

Do not take Noxicid if you are taking the following medicines:

- atazanavir, a medicine used to treat 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. 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
- 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 Noxicid 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.

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

How to take Noxicid

Follow all directions given to you by your doctor and 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

Noxicid is available as enteric capsules.

Noxicid Enteric capsules

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

The dose of Noxicid 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 enteric capsules whole with a glass of water.

Take Noxicid at about the same time each day. Keeping a regular time for taking Noxicid will help to remind you to take it.

Keep taking Noxicid for as long as your doctor recommends.

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

Noxicid 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 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. Do this even if there are no signs of discomfort or poisoning.

While you are taking Noxicid

Things you must do

Take Noxicid 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.

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

Tell your doctor if you become pregnant while you are taking Noxicid.

Tell your doctor if your symptoms return.

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

If you need to have any medical tests while you are taking Noxicid, 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 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.

Noxicid 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.

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 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
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite.

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 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

These are very serious side effects.

You may need urgent medical treatment or hospitalisation. These side effects are rare.

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.

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

After taking Noxicid

Storage

Keep Noxicid 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 in the blister pack until it is time to take them.

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

If you take Noxicid out of the blister or 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 or any other medicine in the bathroom or near a sink.

Do not leave Noxicid in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Noxicid 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 looks like

Noxicid Enteric capsules

Noxicid Caps 20 mg:

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, 30 enteric capsules

Each bottle contains 30*, 100, 500 capsules.

Noxicid Caps 40 mg:

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 blister pack contains, 30 enteric capsules

Each bottle contains 30*, 100 and 500 capsules.

*Marketed Pack size

Ingredients

The active ingredient in Noxicid is esomeprazole (as magnesium). Each Noxicid 20 mg and 40 mg capsule contains 20mg or 40 mg of esomeprazole respectively.

The capsules also contain:

- Sugar spheres (maize starch and sucrose)
- Crospovidone
- Hydroxypropylcellulose
- Mannitol
- Methacrylic acid:-ethyl acrylate polymer(1:1)
- Triethyl citrate
- Glycerol monostearate
- Polysorbate 80
- Purified talc
- Empty Hard Gelatin Capsule Shell Size "3" [20 mg capsule only].
- Empty Hard Gelatin Capsule Shell Size "1" [40 mg capsule only].
- Tek Print Ink SW-9008.

Sponsor

Noxicid is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.alphapharm.com.au

Australian registration numbers:

Noxicid 20 mg Enteric capsules (blister) - AUST R 246912

Noxicid 40 mg Enteric capsules (blister) - AUST R 246913

Noxicid 20 mg Enteric capsules (bottle) - AUST R 246914

Noxicid 40 mg (bottle) Enteric capsules - AUST R 246915

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