

NEXIUM®

Esomeprazole magnesium trihydrate

Consumer Medicine Information

What is in this leaflet

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

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 NEXIUM 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 NEXIUM is used for

Reflux Oesophagitis

NEXIUM 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.

NEXIUM is also taken to help stop reflux oesophagitis coming back or relapsing.

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

NEXIUM is taken to treat the symptoms of pain or discomfort, in the stomach caused by NSAIDs, a type of medicine for pain or inflammation.

NEXIUM 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 NEXIUM with antibiotics. When NEXIUM 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

NEXIUM 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 NEXIUM tablets or granules prescribed by your doctor for a longer period of time. This is to help your ulcer/s to heal.

How NEXIUM works

NEXIUM 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 NEXIUM for another reason.

There is no evidence that NEXIUM is addictive.

Before you take NEXIUM

When you must not take it

Do not take NEXIUM 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 NEXIUM 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 NEXIUM.

NEXIUM is not approved for use in children younger than 1 year of age.

There is no specific information about use in children younger than 1 year of age, so NEXIUM is not recommended in these patients.

Do not take NEXIUM 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
- been diagnosed with osteoporosis

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

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

Taking other medicines

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

- atazanavir and nelfinavir - medicines used to treat viral infections such as 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 NEXIUM. 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 - 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

These medicines may be affected by NEXIUM 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 NEXIUM.

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

How to take NEXIUM

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

NEXIUM is available as tablets and as granules for suspension in sachets.

NEXIUM Tablets

Take one NEXIUM tablet each day, unless your doctor has told you otherwise.

The dose of NEXIUM tablets is usually 20 mg or 40 mg a day depending on what condition you are being treated for and how severe it is.

Swallow NEXIUM tablets whole with a glass of water. Do not crush or chew the tablets.

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

If you have difficulty swallowing the tablets:

1. Place the tablet in half a glass of non-carbonated water. Mineral water or other liquids are not suitable.
2. Gently mix the tablet and water by stirring, taking care not to crush the tablet.
3. Stir until the tablet dissolves into little pellets.
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets.
5. Rinse the glass with half a glass of water and drink.

If you cannot swallow at all, follow steps 1-3 above to disperse the

tablets and administer the liquid and pellets through a gastric tube.

NEXIUM Sachets

NEXIUM sachets are usually used for children or adults who have trouble swallowing tablets. The dose of NEXIUM sachets is 10 to 20 mg a day depending on what condition is being treated and how severe it is.

The granules in NEXIUM sachets should be dispersed as follows in non-carbonated water (mineral water is not suitable) before being taken:

1. For a 10 mg dose empty the contents of a 10 mg sachet into a glass containing 15 mL of water. For a 20 mg dose empty the contents of two 10 mg sachets into a glass containing 30 mL of water.
2. Stir the contents and leave for a few minutes to thicken.
3. Stir again and drink within 30 minutes.
4. If any material remains after drinking, add more water, stir and drink immediately.

For patients who cannot swallow, NEXIUM granules for oral suspension can be administered via a large syringe through a nasogastric or gastric tube:

1. For a 10 mg dose add the contents of a 10 mg sachet to a syringe containing 15 mL of water. For a 20 mg dose add the contents of two 10 mg sachets to a syringe containing 30 mL of water.
2. Immediately shake the syringe and leave for a few minutes to thicken.
3. Shake the syringe and inject through the nasogastric or gastric tube within 30 minutes.
4. Refill the syringe with 15 mL of water, then shake and flush any remaining contents from the nasogastric or gastric tube into the stomach.

Do not crush or chew the pellets in the suspension.

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

Take NEXIUM at about the same time each day.

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

Keep taking NEXIUM for as long as your doctor recommends.

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

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

While you are taking NEXIUM

Things you must do

Take NEXIUM 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 NEXIUM.

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

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

Tell your doctor if your symptoms return.

Although NEXIUM 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 NEXIUM, tell your doctor.

It may affect the results of some tests.

Things you must 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NEXIUM.

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

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, NEXIUM 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 NEXIUM.

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

After taking it

Storage

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

If you take NEXIUM out of the blister pack it will not keep well.

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

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on a window sill.

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.

Disposal

If your doctor tells you to stop taking NEXIUM or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

Product description

What NEXIUM looks like

Tablets

NEXIUM 20 mg are light pink, oblong shaped tablets engraved 20 mg on one side and A / EH on the other.

NEXIUM 40 mg are pink, oblong shaped tablets engraved 40 mg on one side and A / EI on the other.

NEXIUM Granules for oral suspension

NEXIUM 10 mg granules for oral suspension are pale yellow fine granules (brownish granules may be visible) in a unit dose sachet.

Ingredients

Tablets

Each NEXIUM tablet contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 20 mg or 40 mg.

Plus the following inactive ingredients:

- glyceryl monostearate (E 471)
- hydroxypropyl cellulose
- hypromellose
- magnesium stearate (E 572)
- methacrylic acid copolymer
- microcrystalline cellulose (E 460)
- paraffin synthetic
- macrogol 6000
- polysorbate 80 (E 433)
- crospovidone
- sodium stearyl fumarate
- purified talc (E 553(b))
- titanium dioxide (E 171)
- triethyl citrate
- sugar spheres (maize starch and sucrose)

The tablets are coloured with iron oxide red CI77491 and/or iron oxide yellow CI77492.

NEXIUM Granules for oral suspension

Each sachet of NEXIUM granules for oral suspension contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 10 mg.

Plus the following inactive ingredients:

- glyceryl monostearate
- hydroxypropylcellulose
- hypromellose
- magnesium stearate
- methacrylic acid copolymer
- polysorbate 80
- talc
- triethyl citrate
- glucose - anhydrous
- xanthan gum
- crospovidone
- citric acid - anhydrous
- iron oxide yellow
- sugar spheres (maize starch and sucrose)

NEXIUM tablets and granules for oral suspension do not contain gluten.

NEXIUM tablets are available in blister packs of 7 or 30 tablets.

NEXIUM granules are available in packs containing 30 unit dose sachets.

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Sponsor

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Australian Registration Numbers:

NEXIUM 20 mg (blister) - 74133

NEXIUM 40 mg (blister) - 74134

NEXIUM 10 mg (sachet) - 135726

Non-marketed presentations

NEXIUM 20 mg (bottle) - 75726

NEXIUM 40 mg (bottle) - 75727