

# NEXIUM<sup>®</sup>

Esomeprazole magnesium trihydrate

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## Consumer Medicine Information

Name of consumer

Address of consumer

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### 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.

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### What NEXIUM is taken 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 a type of medicine for pain or inflammation called NSAIDs.

#### **Nexium is also taken to help heal and prevent ulcers caused by a medicine (NSAID) for pain or inflammation**

#### *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.

When **Nexium** is taken with antibiotics, it will kill *Helicobacter*

*pylori* and let your peptic ulcer heal. When **Nexium** is taken together with two antibiotics, the combination is more effective than taken one or two at a time. It is possible that the antibiotics may not always kill *Helicobacter pylori*. **You may need treatment with further antibiotics.**

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### How NEXIUM works

**Nexium** is a type of medicine called a proton-pump inhibitor.

**Nexium** 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.

Your doctor will have explained why you are being treated with **Nexium** and told you what dose to take.

#### **Follow all directions given to you by your doctor carefully.**

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

There is no evidence that **Nexium** is addictive.

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## Before you take NEXIUM

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### *When you must not take it*

Do not take Nexium if you have allergies to:

- Nexium or any ingredient listed at the end of this leaflet.
- Any medicines containing a proton-pump inhibitor.

Symptoms of an allergic reaction include skin rash, difficulty in breathing, hayfever or feeling faint.

Do not take Nexium if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

We do not know if it is safe for you to take it 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.

**Nexium is not approved for use in children.**

There is no specific information about use in children, so Nexium is not recommended in children.

**Do not take Nexium after the use by (expiry) date printed on the pack.**

It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

**Do not take Nexium if the packaging is torn or shows signs of tampering.**

**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.**

### *Before you start to take it*

**You must tell your doctor if:**

1. **you have any allergies to**
  - any other medicines, foods, dyes or preservatives.
2. **you have any other medical conditions**

### *Taking other medicines*

**Tell your doctor if you are taking any other medicines, including:**

- ketoconazole, itraconazole
- cisapride
- diazepam
- phenytoin
- citalopram, clomipramine or imipramine
- clarithromycin
- warfarin
- other medicines that you buy at the chemist, supermarket or health food shop.

These medicines may be affected by Nexium or may affect how well it works.

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

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

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## Taking NEXIUM

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### *How to take it*

**Take one Nexium each day, unless your doctor has told you otherwise.**

The dose of Nexium 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 whole with a glass of water. For patients with swallowing difficulties, the tablet can be placed in half a glass of non-carbonated water (mineral water is not suitable). No other**

**liquids should be used. The tablet may be gently mixed and care should be taken not to crush the tablet. Stir until the tablet dissolves into little pellets and drink the liquid with the pellets immediately or within 30 minutes. Rinse the glass with half a glass of fluid and drink. The pellets must not be chewed or crushed.**

**For those who cannot swallow, Nexium tablets may also be administered, dispersed in non-carbonated water, through a gastric tube.**

**If the tablets 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.

In most patients, Nexium relieves symptoms rapidly and healing is usually complete within 4 weeks.

Although Nexium heals ulcers very successfully, it may not prevent them recurring at a later date.

**Tell your doctor if your symptoms return.**

**It does not matter whether you take Nexium 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 even if there are no signs of discomfort or poisoning.

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## **While you are taking NEXIUM**

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### ***Things you must do***

Take Nexium exactly as your doctor has prescribed.

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.

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### **Side effects**

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

Nexium 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 are all mild side effects of Nexium.

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.

In rare cases, severe allergic reactions or muscular pain may occur. Vary rarely, inflammation of the liver has been reported.

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.

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### **After using it**

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#### ***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.

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.

Do not leave it in the car on hot days.

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### **Disposal**

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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.

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### **Product description**

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#### ***What Nexium looks like***

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

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

#### ***Ingredients***

Each Nexium tablet contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 20mg or 40mg; plus,

Glyceryl monostearate (E 471)  
Hydroxypropyl cellulose  
Hypromellose  
Magnesium stearate (E 572)  
Methylacrylic acid copolymer  
Microcrystalline cellulose (E 460)  
Paraffin hard  
Macrogol 6000  
Polysorbate 80 (E 433)  
Crospovidone  
Sodium stearyl fumarate  
Purified talc (E 553(b))  
Titanium dioxide (E 171)  
Triethyl citrate  
Sugar spheres

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

**Nexium** tablets are available in blister packs wallets of 30 tablets.

**Nexium tablets** do not contain gluten.

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## **Sponsor**

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AstraZeneca Pty Ltd  
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Nexium 40 mg (blister) - 74134

Non-marketed presentations  
Nexium 20 mg (bottle) - 75726  
Nexium 40 mg (bottle) - 75727

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