

Nexium[®] 20mg Tablets

Esomeprazole 20mg Gastro-resistant Tablets

(esomeprazole magnesium)

Your medicine is known by one of the above names, but will be referred to as Nexium throughout this:

Patient Information Leaflet

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- 1) What Nexium is and what it is used for
- 2) Before you take Nexium
- 3) How to take Nexium
- 4) Possible side effects
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- 6) Further information

1) What Nexium is and what it is used for

Nexium contains a medicine called esomeprazole. This belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

Nexium is used to treat the following conditions:

Adults and young people aged 12 years and above

- 'Gastro-oesophageal reflux disease' (GORD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
- Ulcers in the stomach or upper part of the gut (intestine) that are infected with bacteria called '*Helicobacter pylori*'. If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.

Adults

- Stomach ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Nexium can also be used to stop stomach ulcers from forming if you are taking NSAIDs.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).
- Prolonged treatment after prevention of rebleeding of ulcers with intravenous Nexium.

2) Before you take Nexium

Do not take Nexium if:

- You are allergic (hypersensitive) to esomeprazole or any of the other ingredients of this medicine (listed in Section 6: Further information).
- You are allergic to other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, omeprazole).
- You are taking a medicine containing nelfinavir (used to treat HIV).

Do not take Nexium if any of the above apply to you.

If you are not sure, talk to your doctor or pharmacist before taking Nexium.

Take special care with Nexium

Check with your doctor or pharmacist before taking Nexium if:

- You have severe liver problems.
 - You have severe kidney problems.
- Nexium may hide the symptoms of other diseases.

Therefore, if any of the following happen to you before you start taking Nexium or while you are taking it, talk to your doctor straight away:

- You lose a lot of weight for no reason and have problems swallowing.
- You get stomach pain or indigestion.
- You begin to vomit food or blood.
- You pass black stools (blood-stained faeces).

If you have been prescribed Nexium "on demand" you should contact your doctor if your symptoms continue or change in character.

Taking a proton pump inhibitor like Nexium, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Using other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines. This includes medicines that you buy without a prescription. This is because Nexium can affect the way some medicines work and some medicines can have an effect on Nexium.

Do not take Nexium Tablets if you are taking a medicine containing nelfinavir (used to treat HIV).

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Atazanavir (used to treat HIV).
- Ketoconazole, itraconazole or voriconazole (used to treat infections caused by a fungus).
- Erlotinib (used to treat cancer).
- Citalopram, imipramine or clomipramine (used to treat depression).
- Diazepam (used to treat anxiety, relax muscles or in epilepsy).

- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking Nexium.
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop taking Nexium.
- Cilostazol (used to treat intermittent claudication – a pain in your legs when you walk which is caused by an insufficient blood supply).
- Cisapride (used for indigestion and heartburn).
- Digoxin (used for heart problems).
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your Nexium treatment.
- Rifampicin (used for treatment of tuberculosis).
- St. John's wort (*Hypericum perforatum*) (used to treat depression).

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as Nexium to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

Pregnancy and breast-feeding

Before taking Nexium, tell your doctor if you are pregnant or trying to get pregnant. Ask your doctor or pharmacist for advice before taking any medicine. Your doctor will decide whether you can take Nexium during this time.

It is not known if Nexium passes into breast milk. Therefore, you should not take Nexium if you are breastfeeding.

Driving and using machines

Nexium is not likely to affect you being able to drive or use any tools or machines.

Important information about some of the ingredients of Nexium

Nexium gastro-resistant tablets contain sucrose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

3) How to take Nexium

Always take Nexium exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

- Nexium gastro-resistant tablets are not recommended for children less than 12 years old.
- If you are taking this medicine for a long time, your doctor will want to monitor you (particularly if you are taking it for more than a year).
- If your doctor has told you to take this medicine as and when you need it, tell your doctor if your symptoms change.

Taking this medicine

- You can take your tablets at any time of the day.
- You can take your tablets with food or on an empty stomach.
- Swallow your tablets whole with a drink of water.
Do not chew or crush the tablets. This is because the tablets contain coated pellets which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets.

What to do if you have trouble swallowing the tablets

- If you have trouble swallowing the tablets:
 - Put them into a glass of still (non-fizzy) water. Do not use any other liquids.
 - Stir until the tablets break up (the mixture will not be clear). Then drink the mixture straight away or within 30 minutes. Always stir the mixture just before drinking it.
 - To make sure that you have drunk all of the medicine, rinse the glass very well with half a glass of water and drink it. The solid pieces contain the medicine - do not chew or crush them.
- If you cannot swallow at all, the tablet can be mixed with some water and put into a syringe. It can then be given to you through a tube directly into your stomach ('gastric tube').

How much to take

- Your doctor will tell you how many tablets to take and how long to take them for. This will depend on your condition, how old you are and how well your liver works.
- The usual doses are given below.

To treat heartburn caused by gastro-oesophageal reflux disease (GORD):

Adults and children aged 12 or above:

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the usual dose is one Nexium 40 mg gastro-resistant tablet once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your gullet has not yet healed.
- The usual dose once the gullet has healed is one Nexium 20 mg gastro-resistant tablet once a day
- If your gullet has not been damaged, the usual dose is one Nexium 20 mg gastro-resistant tablet each day. Once the condition has been controlled, your doctor may tell you to take your medicine as and when you need it, up to a maximum of one Nexium 20 mg gastro-resistant tablet each day.
- If you have severe liver problems, your doctor may give you a lower dose.

To treat ulcers caused by *Helicobacter pylori* infection and to stop them coming back:

- Adults and young people aged 12 or above: the usual dose is one Nexium 20 mg gastro-resistant tablet twice a day for one week.
- Your doctor will also tell you to take antibiotics for example amoxicillin and clarithromycin.

To treat stomach ulcers caused by NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):

- Adults aged 18 and above: the usual dose is one Nexium 20 mg gastro-resistant tablet once a day for 4 to 8 weeks.

To prevent stomach ulcers if you are taking NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):

- Adults aged 18 and above: the usual dose is one Nexium 20 mg gastro-resistant tablet once a day.

To treat too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome):

- Adults aged 18 and above: the usual dose is Nexium 40 mg tablet twice a day.
- Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine for. The maximum dose is 80 mg twice a day.

To be used as prolonged treatment after prevention of rebleeding of ulcers with intravenous Nexium:

- Adults aged 18 and above: the usual dose is one Nexium 40 mg tablet once a day for 4 weeks.

If you take more Nexium than you should

If you take more Nexium than prescribed by your doctor, talk to your doctor or pharmacist straight away.

If you forget to take Nexium

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

4) Possible side effects

Like all medicines, Nexium can cause side effects, although not everybody gets them.

If you notice any of the following serious side effects, stop taking Nexium and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis'.
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.

These effects are rare, affecting less than 1 in 1,000 people.

Other side effects include:

Common (affects less than 1 in 10 people)

- Headache.
- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).

Uncommon (affects less than 1 in 100 people)

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feelings such as "pins and needles", feeling sleepy.
- Spinning feeling (vertigo).
- Dry mouth.
- Changes in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Musculoskeletal disorders
- Fracture of the hip, wrist or spine (if Nexium is used in high doses and over long duration).

Rare (affects less than 1 in 1,000 people)

- Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely.
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- Feeling agitated, confused or depressed.
- Taste changes.
- Eyesight problems such as blurred vision.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- An inflammation of the inside of the mouth.
- An infection called "thrush" which can affect the gut and is caused by a fungus.
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Generally feeling unwell and lacking energy.
- Increased sweating.

Very rare (affects less than 1 in 10,000 people)

- Changes in blood count including agranulocytosis (lack of white blood cells)
- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain.
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Muscle weakness.
- Severe kidney problems.
- Enlarged breasts in men.

Not known (frequency cannot be estimated from the available data)

- If you are on Nexium for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.
- Inflammation in the gut (leading to diarrhoea).

Nexium may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a **severely** reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about your medication at this time.

Do not be concerned by this list of possible side effects. You may not get any of them. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5) How to store Nexium

- **Keep all medicines out of the sight and reach of children.**
- Do not take Nexium after the expiry date printed on the carton or blister strip label. The expiry date refers to the last day of the month.
- Do not store above 30°C. Store in the original package.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6) Further information

What Nexium contains:

Each gastro-resistant tablet contains 20mg of the active ingredient esomeprazole (as magnesium trihydrate) as enteric coated pellets.

Each gastro-resistant tablet also contains glycerol monostearate 40-55, hypromellose, hypromellose, magnesium stearate, methacrylic acid ethyl acrylate copolymer (1:1) dispersion 30 per cent, microcrystalline cellulose, synthetic paraffin, macrogol, polysorbate 80, crospovidone, sodium stearyl fumarate, sugar spheres (sucrose and maize starch), talc, titanium dioxide (E171), triethyl citrate, reddish-brown iron oxide (E172) and yellow iron oxide (E172).

What Nexium looks like and contents of the pack

The tablets are pink, oblong gastro-resistant, marked 'A EH' on one side and '20mg' on the other.

Nexium tablets are available as blister packs of 14 tablets in a carton.

PL 10383/1677 **POM**

Who makes and repackages your medicine?

Your medicine is manufactured by AstraZeneca AB, S-15185 Sodertalje, Sweden. Procured from within the EU and repackaged by Product Licence Holder: Primecrown Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

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