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Package leaflet: Information for the user

Nexium Control 20 mg

gastro-resistant hard capsules

esomeprazole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist.
  This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

What is in this leaflet

1. What Nexium Control is and what it is used for
2. What you need to know before you take Nexium Control
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1. What Nexium Control is and what it is used for

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

This medicine is used in adults for the short-term treatment of reflux symptoms (for example, heartburn and acid regurgitation).

Reflux is the backflow of acid from the stomach into the gullet ("foodpipe") which may become inflamed and painful. This may cause you symptoms such as a painful sensation in the chest rising up to your throat (heartburn) and a sour taste in the mouth (acid regurgitation).

Nexium Control is not meant to bring immediate relief. You may need to take the capsules for 2-3 days in a row before you feel better. You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

2. What you need to know before you take Nexium Control

Do not take Nexium Control
- If you are allergic to esomeprazole or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to medicines containing other proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole or omeprazole).
- If you are taking a medicine containing nelfinavir or rilpivirine (used to treat HIV infection).
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Nexium Control or other related medicines.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions
Talk to your doctor before taking Nexium Control if:
- You have had a stomach ulcer or stomach surgery in the past.
- You have been taking treatment continuously for reflux or heartburn for 4 or more weeks. This may be a sign of a more serious condition.
- You have frequent wheezing, particularly with heartburn.
- You have jaundice (yellowing of skin or eyes) or severe liver problems.
- You have severe kidney problems.
- You are aged over 55 years and have new or recently changed reflux symptoms or need to take a non-prescription indigestion or heartburn remedy treatment every day.
- You have ever had a skin reaction after treatment with a medicine similar to Nexium Control that reduces stomach acid. Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported in association with Nexium Control treatment. Stop using Nexium Control and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.
- You are due to have an endoscopy or a urea breath test.
- You are due to have a specific blood test (Chromogranin A).

Tell your doctor immediately before or after taking this medicine, if you notice any of the following symptoms, which could be a sign of another, more serious, disease.
- You lose a lot of weight for no reason.
- You have problems or pain when swallowing.
- You get stomach pain or signs of indigestion such as nausea, fullness, bloating especially after food intake.
- You begin to vomit food or blood, which may appear as dark coffee grounds in your vomit.
- You pass black stools (blood-stained faeces).
- You have severe or persistent diarrhoea; esomeprazole has been associated with a small increased risk of infectious diarrhoea.
- You get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with Nexium Control. Remember to also mention any other ill-effects like pain in your joints.

Seek urgent medical attention if you experience chest pain with light-headedness, sweating, dizziness or shoulder pain with shortness of breath.
This could be a sign of a serious condition with your heart.

If any of the above apply to you (or you are not sure), talk to your doctor straight away.

Children and adolescents
This medicine should not be used by children and adolescents under 18 years of age.

Other medicines and Nexium Control
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because this medicine can affect the way some medicines work and some medicines can have an effect on it.

Do not take this medicine if you are also taking a medicine containing nelfinavir or rilpivirine (used to treat HIV infection).

You should specifically tell your doctor or pharmacist if you are taking clopidogrel (used to prevent blood clots).

Do not take this medicine with other medicines that limit the amount of acid produced in your stomach such as proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole or omeprazole) or an H2 antagonist (e.g. ranitidine or famotidine).

You may take this medicine with antacids (e.g. magaldrate, alginic acid, sodium bicarbonate, aluminium hydroxide, magnesium carbonate or combinations of these) if needed.

Tell your doctor or pharmacist if you are taking any of the following medicines:
- Ketoconazole and itraconazole (used to treat infections caused by a fungus).
- Voriconazole (used to treat infections caused by a fungus) and clarithromycin (used to treat infections). Your doctor may adjust your dose of Nexium Control if you also have severe liver problems and are treated for a long period of time.
- Erlotinib (used to treat cancer).
- Levothyroxine (used to treat hypothyroidism).
- Methotrexate (used to treat cancer and rheumatic disorders).
- Digoxin (used for heart problems).
- Atazanavir, saquinavir (used to treat HIV infection).
- Citalopram, imipramine or clomipramine (used to treat depression).
- Diazepam (used to treat anxiety, relax muscles or in epilepsy).
- Phenytoin (used to treat epilepsy).
- 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 Control.
- Cilostazol (used to treat intermittent claudication – a condition where poor blood supply to the leg muscles causes pain and difficulty in walking).
- Cisapride (used for indigestion and heartburn).
- Rifampicin (used to treat tuberculosis).
- Tacrolimus (in cases of organ transplantation).
- St. John's wort (*Hypericum perforatum*) (used to treat depression).

Pregnancy and breast-feeding
As a precautionary measure, you should preferably avoid the use of Nexium Control during pregnancy. You should not use this medicine during breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Nexium Control has a low likelihood of affecting your ability to drive or use machines. However, side effects such as dizziness and visual disturbances may uncommonly occur (see section 4). If affected, you should not drive or use machines.

Nexium Control contains sucrose, sodium and allura red AC (E129)
Nexium Control contains sugar spheres, which contain sucrose, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
Nexium Control contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium free'.
Nexium Control contains azo colouring agent, Allura red AC (E129), which may cause allergic reactions.

3. How to take Nexium Control

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

How much to take
- The recommended dose is one capsule a day.
- Do not take more than this recommended dose of one capsule (20 mg) a day, even if you don't feel an improvement immediately.
- You may need to take the capsules for 2 or 3 days in a row before your reflux symptoms (for example, heartburn and acid regurgitation) get better.
- The treatment length is up to 14 days.
- When your reflux symptoms have completely gone you should stop taking this medicine.
- If your reflux symptoms get worse or do not improve after taking this medicine for 14 days in a row, you should consult a doctor.

If you have persistent or longstanding, frequently recurring symptoms even after treatment with this medicine, you should contact your doctor.

Taking this medicine
- You can take your capsule at any time of the day either with food or on an empty stomach.
- Swallow your capsule whole with half a glass of water. Do not chew, crush or open the capsule. This is because the capsule contains coated pellets, which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets.

If you take more Nexium Control than you should
If you take more Nexium Control than recommended, talk to your doctor or pharmacist straight away. You may experience symptoms such as diarrhoea, stomach ache, constipation, feeling or being sick and weakness.

If you forget to take Nexium Control
If you forget to take a dose, take it as soon as you remember it, on the same day. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

If you notice any of the following serious side effects, stop taking Nexium Control and contact a doctor immediately:
- Sudden wheezing, swelling of your lips, tongue and throat, rash, fainting, or difficulties in swallowing (severe allergic reaction, seen rarely).
- 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', seen very rarely.
- Yellow skin, dark urine and tiredness, which can be symptoms of liver problems, seen rarely.
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome), seen very rarely.

Talk to your doctor as soon as possible if you experience any of the following signs of infection:
This medicine 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 medicine at this time.

Other side effects include:

Common (may affect up to 1 in 10 people)
- Headache.
- Effects on your stomach or gut: diarrhoea, stomach ache, constipation, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).
- Benign growths (polyps) in the stomach.

Uncommon (may affect up to 1 in 100 people)
- Swelling of the feet and ankles.
- Disturbed sleep (insomnia), feeling sleepy.
- Dizziness, tingling feelings such as "pins and needles".
- Spinning feeling (vertigo).
- Dry mouth.
- Increased liver enzymes shown in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives), and itchy skin.

Rare (may affect up to 1 in 1,000 people)
- Blood problems such as a reduced number of white blood 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 on the inside of the mouth.
- An infection called "thrush" which can affect the gut and is caused by a fungus.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pain (arthralgia), or muscle pain (myalgia).
- Generally feeling unwell and lacking energy.
- Increased sweating.

Very rare (may affect up to 1 in 10,000 people)
- Low numbers of red blood cells, white blood cells, and platelets (a condition called pancytopenia).
- Aggression.
- Seeing, feeling, or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain.
- Muscle weakness.
- Severe kidney problems.
- Enlarged breasts in men.

Not known (frequency cannot be estimated from the available data)
- Low levels of magnesium in the blood. This may cause weakness, being sick (vomiting), cramps, tremor, and changes in heart rhythm (arrhythmias). If you have very low levels of magnesium, you may also have low levels of calcium and/or potassium in your blood.
- Inflammation of the gut (leading to diarrhoea).
- Rash, possibly with pain in the joints.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via the national reporting system: In Ireland, HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie e-mail: medsafety@hpra.ie. In Malta, ADR Reporting, www.medicinesauthority.gov.mt/adrportal
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nexium Control

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the bottle after EXP.
The expiry date refers to the last day of that month.

Do not store above 30°C.

Keep this medicine in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nexium Control contains
- The active substance is esomeprazole. Each gastro-resistant hard capsule contains 20 mg esomeprazole (as magnesium trihydrate).
- The other ingredients are:
  glycerol monostearate 40-55, hydroxypropylcellulose, hypromellose, magnesium stearate, methacrylic acid - ethyl acrylate copolymer (1:1) dispersion 30 per cent, polysorbate 80, sugar spheres (sucrose and maize starch), talc, triethyl citrate, carmine (E120), indigo carmine (E132), titanium dioxide (E171), yellow iron oxide (E172), erythrosine (E127), allura red AC (E129), povidone K-17, propylene glycol, shellac, sodium hydroxide, and gelatin (see section 2, "Nexium Control contains sucrose, sodium and allura red AC (E129).")

What Nexium Control looks like and contents of the pack
Nexium Control 20 mg gastro-resistant hard capsules are approximately 11 x 5 mm capsules with a clear body, and an amethyst cap imprinted with "NEXIUM 20 MG" in white. The capsule has a yellow centre band, and contains yellow and purple enteric coated pellets.

Nexium Control is available in high-density polyethylene (HDPE) bottles with an induction seal closure and child resistant closure. The bottle also contains a sealed container with silica gel desiccant.
Each pack contains either 1 or 2 bottles, each with 14 gastro-resistant hard capsules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Haleon Ireland Dungarvan Limited, Knockbrack, Dungarvan, County Waterford, Ireland.

Manufacturer
Haleon Germany GmbH, Barthstrasse 4, 80339 Munich, Germany.

This leaflet was last revised in September 2026.
Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

Further helpful information

What are the symptoms of heartburn?
The normal symptoms of reflux are a painful sensation in the chest rising up to your throat (heartburn) and a sour taste in the mouth (acid regurgitation).

Why do you get these symptoms?
Heartburn can be a result of eating too much, eating high fat food, eating too quickly and drinking lots of alcohol.
You may also notice that when you lie down, that your heartburn gets worse. If you are overweight or smoke you increase the probability of suffering from heartburn.

What can I do to help relieve my symptoms?
- Eat healthier food and try to avoid spicy and fatty foods and large meals late before bedtime.
- Avoid fizzy drinks, coffee, chocolate and alcohol.
- Eat slowly and eat smaller portions.
- Try to lose weight.
- Stop smoking.

When should I seek advice or help?
- You should seek urgent medical advice if you experience chest pain with light-headedness, sweating, dizziness or shoulder pain with shortness of breath.
- If you experience any of the symptoms detailed in Section 2 of this leaflet and it advises you to talk to your doctor or pharmacist.
- If you are suffering from any of the side effects detailed in Section 4 which require medical attention.

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