

FRONT SIDE

DATA MATRIX CODE N° XXXXXXXXX



Nexium®
24HR Once Daily Dosing

Esomeprazole magnesium trihydrate

What is in this leaflet

This leaflet answers some of the common questions people ask about **Nexium® 24HR Once Daily Dosing** (referred as **Nexium 24HR elsewhere in this leaflet**). It does not contain all the information that is known about **Nexium 24HR**.

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

All medicines have risks and benefits. Your pharmacist or doctor will have weighed the risks of you taking **Nexium 24HR** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your pharmacist or doctor.

Keep this leaflet with the medicine. You may need to read it again.

What Nexium 24HR is used for

Nexium 24HR is used for lasting symptomatic relief of frequent heartburn and stomach acid complaints due to gastro-oesophageal reflux.

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.

Frequent heartburn is when you have heartburn for two or more times a week. Heartburn that occurs frequently is a typical symptom of gastro-oesophageal reflux disease (GORD).

Who Should Use Nexium 24HR

Nexium 24HR is recommended for adults over 18 years of age suffering from heartburn for two or more times a week.

Nexium 24HR is not the right medicine for you if you suffer heartburn only occasionally (one episode of heartburn a week or less), or if you want immediate relief of heartburn.

How Nexium 24HR works

Nexium 24HR is a type of medicine called a proton-pump inhibitor (PPI). It works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allows healing to take place. This does not stop food being digested in the normal way.

Nexium 24HR will start to suppress acid within a few hours, however it will not give instant symptom relief. You may need to take **Nexium 24HR** for a few days before experiencing the full effect.

There is no evidence that **Nexium 24HR** is addictive.

Before you take Nexium 24HR

When you must not take it

Do not take Nexium 24HR 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 24HR if you are also taking atazanavir or ciltostazol.

Please check with your pharmacist or doctor if you are taking these medicines. These medicines will be affected by **Nexium 24HR**.

Nexium 24HR is not intended for use in children under 18 years of age.

Do not use Nexium 24HR if you are experiencing unexplained weight loss, difficulty swallowing, persistent regurgitation of food or vomiting or vomiting of blood, severe or persistent diarrhoea, blood in the stools or symptoms of gastro-intestinal bleeding, except on medical advice.

Do not take Nexium 24HR 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.

If you are not sure whether you should start taking **Nexium 24HR** alone or **Nexium 24HR** in combination with any other medications talk to your pharmacist or doctor.

Before you start to take it

You must tell your pharmacist or doctor if you:

- have allergies to any other medicines, foods, dyes or preservatives
- have or have ever had any problems with your liver
- have or have ever had severe kidney problems

- have anaemia, previous gastric ulcer or gastrointestinal surgery, difficulty swallowing, persistent vomiting or vomiting of blood, blood in the stools, unexplained weight loss or some other significant medical condition
- have any other medical conditions
- have previously taken heartburn / indigestion medications continuously for 4 or more weeks to control your heartburn
- you are pregnant or plan to become pregnant.

Do not take Nexium 24HR if you are pregnant 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 24HR** while you are pregnant. It may affect your baby.

Do not take Nexium 24HR if you are breastfeeding. Ask your doctor for more information.

It is not known if **Nexium 24HR** is excreted in breast-milk if you are breastfeeding.

Taking other medicines

Do not take Nexium 24HR if you are taking the following medicines:

atazanavir - medicine used to treat viral infections such as HIV
ciltostazol - a medicine used to treat pain and/or cramping in the lower leg (or arms) due to inadequate blood flow to the muscles.

Tell your pharmacist or 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 24HR**. 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 or 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 - a medicine used in organ transplants
- erlotinib or related medicines used to treat cancer.

These medicines may be affected by **Nexium 24HR** or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your pharmacist or doctor can tell you what to do if you are taking any other medicines.

Your pharmacist or doctor has more information on medicines to be careful with or avoid while taking **Nexium 24HR**.

If you have not told your pharmacist or doctor about any of these things, tell them before you take Nexium 24HR.

How to take Nexium 24HR

Follow all directions given to you by your pharmacist or doctor carefully. These instructions may differ from the information contained in this leaflet.

If you do not understand the directions on the label, ask your pharmacist or doctor for help.

How to take it and how much

Take one Nexium 24HR capsule each day. Do not take more than the recommended dose.

Swallow Nexium 24HR capsules whole with a glass of water. Do not crush, chew or open the capsules. If the capsules are crushed, chewed or opened, they will not work properly.

Nexium 24HR can be taken with food or on an empty stomach.

When to take it

Take Nexium 24HR at about the same time each day. Keeping a regular time for taking Nexium 24HR will help to remind you to take it.

How long to take it for

Nexium 24HR should be taken for at least 7 days and up to 14 days.

Do not take beyond 14 days without consulting your doctor.

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.



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Taking too much (overdose)

Telephone your pharmacist or 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 24HR. Do this even if there are no signs of discomfort or poisoning.

While you are taking Nexium 24HR

Things you must do

If you are about to be started on any new medicine, tell your pharmacist, doctor or dentist that you are taking Nexium 24HR. Tell all pharmacists, doctors and dentists who are treating you that you are taking Nexium 24HR.

Tell your pharmacist or doctor if you become pregnant while you are taking Nexium 24HR.

Tell your pharmacist or doctor if you do not feel better while taking Nexium 24HR. If symptoms persist or recur within 2 weeks of completing the course, consult a doctor. Further examination may be required.

If you need to have any medical tests while you are taking Nexium 24HR, tell your pharmacist or doctor. It may affect the results of some tests.

Side effects such as dizziness and visual disturbances may uncommonly occur. If affected, you should not drive or use machines.

Things you must not do

Do not take it to treat any other complaints unless your pharmacist or doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking Nexium 24HR.

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 pharmacist or doctor to answer any questions you may have.

Tell your pharmacist or 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
- tiredness.

These side effects are usually mild.

Tell your pharmacist or 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
- difficulties urinating.

These side effects may require medical attention.

If you notice any of the following happen, tell your pharmacist or 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, fainting or difficulties in swallowing
- 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
- signs of low magnesium levels, including seizures, dizziness, irregular heartbeat, jitteriness, muscle aches or weakness, and spasms of hand, feet or voice. Low magnesium can lead to low calcium and/or low potassium levels in blood
- 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.

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

Occasionally, Nexium 24HR may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Tell your pharmacist or 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 24HR.

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 24HR
- you begin to vomit blood or food
- you pass black (blood-stained) motions.

After taking it

Storage

Keep your Nexium 24HR in the bottle until it is time to take them.

If you take Nexium 24HR out of the bottle 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 pharmacist or doctor tells you to stop taking Nexium 24HR or the capsules have passed their expiry date, ask your pharmacist what to do with any capsules you have left over.

Product description

What Nexium 24HR looks like

Nexium 24HR are approximately 11 x 5mm capsules, with a clear body, and an amethyst cap imprinted with "NEXIUM 20MG" in white. The capsule has a yellow centre band, and contains yellow and purple enteric coated pellets.

Ingredients

Each Nexium 24HR capsule contains esomeprazole magnesium trihydrate as the active ingredient equivalent to esomeprazole 20 mg.

Plus the following inactive ingredients,

Capsule content

- Glyceryl monostearate
- Hypromellose
- Hypromellose
- Magnesium stearate
- Methacrylic acid copolymer
- Polysorbate 80
- Suglets sugar spheres 250/355 micrometres (sucrose and maize starch)
- Purified talc
- Triethyl citrate
- Titanium dioxide (E171)
- Carmine (E120)
- Indigo carmine aluminium lake (E132)
- Iron oxide yellow (E172)

Capsule shell

- Gelatin
- Erythrosine
- Indigo carmine (E132)
- Allura red AC (E129)

Printing ink

- Povidone
- Propylene glycol
- Shellac
- Sodium hydroxide
- Titanium dioxide (E171)

Band

- Gelatin
- Iron oxide yellow (E172)

Nexium 24HR capsules are available in a bottle of 14 capsules. The bottle contains a sealed container with silica gel dessicant.

Sponsor

Haleon
Sydney, NSW, Australia

📞 AU: 1800 028 533

Australian Registration Number

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AUST R 316501

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