

NEXPRO TABLETS

Esomeprazole Magnesium (20 mg, 40 mg)

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What Nexpro is used for

Gastro-Oesophageal Reflux Disease (GERD):

Nexpro 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).

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. If you have a peptic ulcer, your doctor will prescribe Nexpro with antibiotics. When Nexpro and antibiotics are taken together, they work to kill the bacterium and let your ulcer heal.

Patients requiring continued NSAID therapy:

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

Nexpro is also taken to help heal and prevent ulcers caused by NSAIDs.

Prolonged treatment after IV induced prevention of rebleeding of 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 Nexpro tablets prescribed by your doctor for a longer period of time. This is to help your ulcer/s to heal.

Treatment of Zollinger Ellison Syndrome:

Nexpro 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.

How Nexpro works

Esomeprazole belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

Before you use Nexpro

- When you must not use it

Do not take Nexpro:

- You are allergic (hypersensitive) to esomeprazole or any of the other ingredients of this medicine.
- You are allergic to other proton pump inhibitor medicines.
- You are taking a medicine containing nelfinavir (used to treat HIV).

Pregnancy and lactation

Do not take Nexpro if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking Nexpro, stop taking it immediately and contact your doctor.

Do not take Nexpro if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Check with your doctor or pharmacist before taking Nexpro if:

- You have severe liver problems.
- You have severe kidney problems.
- You are pregnant or trying to get pregnant.

Nexpro may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking Nexpro 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 Nexpro "on demand" you should contact your doctor if your symptoms continue or change in character.
- Tell your doctor before taking this medicine, if you are due to have a specific blood test (Chromogranin A).

- Taking 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 Nexpro can affect the way some medicines work and some medicines can have an effect on Nexpro.

Do not take Nexpro 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).
- 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 Nexpro.
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop taking Nexpro.
- Cisapride (used for indigestion and heartburn).

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

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How to use Nexpro

- How much to use

The recommended dosage is once daily.

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 (GERD):

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 Nexpro 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 Nexpro 20 mg gastro-resistant tablet once a day
- If your gullet has not been damaged, the usual dose is one Nexpro 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 Nexpro 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:

- The usual dose is 20 mg gastro-resistant tablet twice a day for one week.
- Your doctor will also tell you to take antibiotics called amoxicillin and clarithromycin.

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

- The usual dose is one 20 mg gastro-resistant tablet once a day for 4 to 8 weeks.

To prevent stomach ulcers if you are requiring continued NSAID therapy:

- The usual dose is 20 mg gastro-resistant tablet once a day for 4-8 week.

Prolonged treatment after IV induced prevention of rebleeding of peptic ulcers:

- The usual dose is 40 mg tablet once a day for 4 weeks.

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

- The usual dose is 40 mg gastro-resistant 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.

Nexpro gastro-resistant tablets are not recommended for children less than 12 years old.

- When to use it

- 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 long to use it

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.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

If you take more Nexpro than prescribed by your doctor, talk to your doctor or pharmacist straight away. Taking too many tablets may cause gastrointestinal symptoms like nausea, vomiting, pain in stomach area and weakness of body.

While you are using it

- Things you must do

Tell your doctor if:

- 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).

- Things you must not do

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

- Things to be careful of

Pregnancy and breast-feeding

Before taking Nexpro, 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

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whether you can take Nexpro during this time.

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

Taking Nexpro with food and drink.

You can take your tablets with food or on an empty stomach.

Important information about some of the ingredients of Nexpro:

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

Side effects

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

If you notice any of the following serious side effects, stop taking Nexpro 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.
- Diarrhea.
- Stomach pain.
- Constipation.
- Wind (flatulence).
- Feeling sick (nausea).
- 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).
- Itchy skin.

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.
- Depressed.
- Taste changes.
- Eyesight problems such as blurred vision.
- Suddenly feeling wheezy.
- Short of breath (bronchospasm).
- An inflammation of the inside of the mouth.
- 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).
- Muscle pains (myalgia).
- Generally feeling unwell.
- 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.
- Nexpro 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.

Frequency 'not known': Inflammation in the large bowel, that cause persistent watery diarrhea.

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.

When you are taking this medicine, your doctor will want to monitor you (especially if you are taking it for long term). Hence, you should report any new and exceptional symptoms and circumstances whenever you see your doctor. Please tell your doctor promptly if you get any of the symptoms below:

- Rash (especially in areas exposed to the sun), possibly with pain in the joints (Subacute Cutaneous Lupus Erythematosus, SCLE).
- Fever, extreme tiredness, pus/blood in urine.
- Involuntary muscle contraction, disorientation, convulsions, dizziness, increased heart rate.
- Fracture in the hip, wrist or spine.
- Watery stool, stomach pain and fever that do not go away.
- Anemic (pale skin, weakness, tiredness or lightheadedness), shortness of breath, a smooth tongue, nerve problems (numbness or tingling, muscle weakness and problems walking), vision loss and

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mental problems (depression, memory loss or behavioral changes).

Subacute Cutaneous Lupus Erythematosus (SCLE).
Frequency “not known”.

Interstitial Nephritis.
Kidney problems (interstitial nephritis).

Hypomagnesaemia.
Frequency “not known”: Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood.

Fracture.
Frequency “uncommon”. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Clostridium Difficile Diarrhea.
Severe diarrhea which may be caused by an infection (Clostridium difficile) in your intestines.

Fundic Gland Polyps (Benign).
Frequency “Common”. Benign polyps in the stomach.

Vitamin B12 Deficiency.
Proton pump inhibitors may cause vitamin B12 deficiency.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Pantor

- Storage

- Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

NEXPRO 20 MG TABLET

Brick red colored, round shape, biconvex, film coated tablets, imprinted with “20” on one side with black ink and plain on other side.

NEXPRO 40 MG TABLET

Brick red colored, round shape, beveled edge, biconvex, film coated tablets, imprinted with “40” on one side with black ink and plain on other side.

Ingredients

Active ingredient:

- Esomeprazole Magnesium.

Inactive ingredients:

- Sugar spheres.
- Ethyl cellulose.
- Magnesium Stearate .
- Povidon (Plasdone K- 90D). Magnesium Oxide Light.
- Methacrylic acid – Ethyl acrylate copolymer (1: 1) dispersion 30 percent.
- Diethyl Phthalate
- Talc.
- Silicified microcrystalline cellulose.
- Prosolv HD 90.
- Starlac Copovidone Macrogl 8000.
- Crospovidone (kollidone CL).
- Colloidal silicon dioxide.
- Hypromellose 15 cps.
- Titanium Dioxide.
- Ferric oxide Red.

- MAL number(s):

NEXPRO 20 MG TABLET:

MAL15045130AZ.

NEXPRO 40 MG TABLET:

MAL15045129AZ

Manufacturer

Torrent Pharmaceuticals LTD.
Indrad 382 721, District: Mehsana,
India.

Product Registration Holder

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