

Nizatidine 150 mg & 300 mg Capsules **RelonChem**

(Nizatidine)

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Nizatidine Capsules are and what they are used for
2. What you need to know before you take Nizatidine Capsules
3. How to take Nizatidine Capsules
4. Possible side effects
5. How to store Nizatidine Capsules
6. Contents of the pack and other information

1. What Nizatidine Capsules are and what they are used for

Nizatidine belongs to a group of medicines called histamine H₂-receptor antagonists, which reduce acidity in your stomach. Nizatidine Capsules are used to

- **treat non cancerous stomach and duodenal ulcers** (ulcers at the top of the small intestine)
- **protect healed ulcers** in the intestines
- **treat a type of heartburn** called 'reflux oesophagitis' (irritation of the oesophagus, the tube that takes food and liquids into your stomach)
- **prevent ulcers** which may be caused by **NSAID (non-steroidal anti-inflammatory drug)** treatment i.e. ibuprofen, diclofenac - often used to treat arthritis.

2. What you need to know before you take Nizatidine Capsules

Do not take this medicine and speak to your doctor if you have ever had an allergic reaction to:

- Nizatidine, or any of the other ingredients of this medicine (listed under Section 6)
- have taken a similar anti-ulcer medicine before and you suffered an unusual or allergic reaction. An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

Warning and precautions

Talk to your doctor or pharmacist before taking Nizatidine Capsules

- if you have liver or kidney problems.

Other medicines and Nizatidine Capsules

Tell your doctor or pharmacist if you are taking and have recently taken or might take any other medicines, including medicines obtained without a prescription.

Especially aspirin in high doses and other medicines containing salicylate,

as Nizatidine may increase the absorption of these medicines in your blood. You **can take antacids** whilst taking Nizatidine.

Pregnancy and 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

You should have no problems with driving or using machines when taking this medicine.

Nizatidine contains sunset yellow and propylene glycol

Nizatidine 150 mg capsules contain colour sunset yellow (E110), which may cause allergic reactions.

Nizatidine 150 mg capsules contain 0.82 mg propylene glycol in each dosage unit, which is equivalent to 1.64 mg/kg/day.

Nizatidine 300 mg capsules contain 0.98 mg propylene glycol in each dosage unit, which is equivalent to 1.96 mg/kg/day.

3. How to take Nizatidine Capsules

Always take Nizatidine Capsules exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Swallow the capsules with water. You can take the capsules **with or without food**.

Usual doses

- **Duodenal or benign stomach ulcer:** The usual dose is 150 mg in the morning and 150 mg in the evening or 300 mg taken as a single dose in the evening for 4 weeks. If your ulcer has not fully healed your doctor will treat you for a further 4 weeks.
- **Protecting a healed duodenal or stomach ulcer:** One 150 mg capsule in the evening.
- **To treat indigestion, acid reflux, heartburn:** One 150 mg capsule twice a day for up to 3 months. Your doctor may increase this dose to 300 mg twice daily.
- **If you have a stomach/duodenal ulcer** and are also taking medicines known as **non-steroidal anti-inflammatory drugs (NSAIDs):** 300 mg daily for up to 8 weeks.

Use in children and adolescents

Nizatidine Capsules should not be given to children or adolescents.

Length of treatment

Keep taking the capsules for as long as your doctor has told you to, even if you start to feel better.

If you take more Nizatidine Capsules than you should

Contact your doctor or nearest hospital emergency department immediately. Signs of an overdose may include watery eyes, increased saliva, being sick, narrowing of the pupils of the eyes and diarrhoea.

Take the container and any remaining capsules with you.

If you forget to take Nizatidine Capsules

Take the next dose as soon as you remember unless it is almost time for your next dose. **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, pharmacist or nurse.

4. Possible side effects

Like all medicines Nizatidine Capsules can cause side effects, although not everybody gets them. The side effects below may sometimes happen.

If you notice any of these while taking this medicine, stop taking this medicine and see your doctor straight away or go to your nearest hospital emergency department immediately:

Rare: may affect up to 1 in 1,000 people

- any kind of skin rash or 'hives' (small itchy spots), boils or sore lips, swelling of the face, lips, tongue, throat or other parts of the body, fever, sudden wheezing and coughing, uttering or tightness of the chest, chest pain, feeling faint and difficulty breathing due to allergic reaction
- yellowing of the whites of the eyes or skin, dark urine, pale coloured bowel movements, itching due to problems with your liver
- bruising more easily, bleeding, particularly of the mouth and nose, or bruising under the skin. In severe cases, blood in the urine or faeces and headaches due to low platelets in your blood
- frequent infections such as fever, severe chills, sore throat or mouth ulcers due to lack of white blood cells.

These side effects are rare but serious. You may need medical attention.

Other possible side effects

Common: may affect up to 1 in 10 people

- sweating
- sleepiness.

Rare side effects include:

- unusual tiredness, shortness of breath when exercising, dizziness and looking pale due to a decrease in red blood cells (anaemia)
- flaking or peeling of the skin
- narrowing or blockage of the blood vessels, causing a general feeling of being unwell, with fever, tiredness and weight loss
- joint pain, aching muscles, muscle tenderness or weakness not caused by exercise
- if you are a man, breast enlargement or an inability to get or maintain an erection
- high uric acid levels in the blood (shown on blood tests), which may cause severe pain and swelling in the joints, reduced kidney stones (gout)
- fever
- nausea (feeling sick)
- increased liver enzymes (which may be seen in blood tests)
- confusion
- increase in some white blood cells which may be seen in a blood test.

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

Very rare: may affect up to 1 in 10,000 people

- headache
- diarrhoea

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to Store Nizatidine Capsules

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

Do not use the capsules after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not store above 25°C.

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 Nizatidine Capsules contain**

Nizatidine Capsules are available in two strengths; 150 mg and 300 mg. The active ingredient which makes the medicine work is Nizatidine. Each capsule contains 150 mg or 300 mg of Nizatidine. The other ingredients are: croscarmellose sodium, povidone, maize starch, dimethicone, talc, quinoline yellow (E104), titanium dioxide (E171), yellow iron oxide (E172), gelatin, shellac, black iron oxide (E172), potassium hydroxide and propylene glycol.

The 150 mg capsules also contain sunset yellow (E110).

The 300 mg capsules also contain erythrosine (E127).

What Nizatidine Capsules look like and the contents of the pack:

Nizatidine 150 mg Capsules are yellow capsules marked B14.

Nizatidine 300 mg Capsules are orange/yellow capsules marked B15.

They are packed in blisters and supplied in packs of 28 and 30 capsules.

Marketing Authorisation Holder and Manufacturer

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Product licence number:

Nizatidine 150 mg Capsules,
PL 20395/0302.

Nizatidine 300 mg Capsules,
PL 20395/0303.

POM

This leaflet was last revised in April 2025.

Code No.: GO/DRUGS/1025