

## Package leaflet: Information for the patient

### Nizatidine 150 mg Capsules, Hard Nizatidine 300 mg Capsules, Hard

(nizatidine)

**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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

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

#### **1. What Nizatidine is and what it is used for**

Nizatidine belongs to a group of medicines called H<sub>2</sub>-receptor antagonists (anti-ulcer medicines), which reduce the amount of acid in your stomach.

This medicine is used to:

- heal and stop ulcers in the stomach, or the part where it empties into the small intestine (duodenum)
- heal and stop problems caused by acid in the gullet (oesophagus) or too much acid in the stomach. This can cause pain or discomfort known as indigestion, acid reflux or heartburn
- prevent ulcers which may be caused by NSAID (non-steroidal anti-inflammatory drug) treatment i.e. ibuprofen, diclofenac -often used to treat arthritis
- stop these ulcers from coming back.

#### **2. What you need to know before you take Nizatidine**

##### **Do not take Nizatidine:**

- if you are allergic to nizatidine or any of the other ingredients of this medicine (listed in section 6).
- if you 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.

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Nizatidine

- if you have liver or kidney problems.

##### **Other medicines and Nizatidine**

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

- a medicine called a salicylate (i.e. aspirin), normally used to relieve minor aches and pains.

### **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 Allura red E129 ( 150 mg only)**

May cause allergic reactions.

## **3. How to take Nizatidine**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### **Adults (including older people)**

*For stomach or duodenal ulcers:*

The recommended 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 after 4 weeks, your doctor will treat you for a further 4 weeks. If you are also taking a non-steroidal anti-inflammatory drug (NSAID), the recommended dose is the same as above.

*To treat indigestion, acid reflux, heartburn:*

The recommended dose is 150 mg to 300 mg taken twice a day for up to 12 weeks.

*To prevent ulcers coming back:*

The recommended dose is 150 mg taken in the evening.

*Patients with kidney problems:*

Your doctor may change the dose. If you have kidney problems, your doctor may prescribe a lower or less frequent dose.

### Duration of treatment

It is important that you keep taking the medicine until you finish the full course of treatment.

### **Use in children children and adolescents**

Nizatidine should not be given to children or adolescents.

**If you take more Nizatidine 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 carton or container and any remaining capsules with you.

**If you forget to take Nizatidine**

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 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 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 an 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** (may affect up to 1 in 1,000 people)

- 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, kidney stones (gout)
- increased liver enzymes (which may be seen in blood tests)
- fever
- nausea (feeling sick)
- confusion
- increase in some white blood cells which may be seen in a blood test

### **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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Nizatidine**

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

Do not store above 25°C.

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

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 contains**

The active substance is nizatidine.

Each capsule contains either 150 mg or 300 mg of nizatidine.

The other ingredients are croscarmellose sodium, pregelatinised starch, talc and magnesium stearate.

The capsule is made of gelatin, titanium dioxide (E171), red (300 mg only) and yellow iron oxide (E172) and black printing ink (shellac, macrogol, potassium hydroxide and black iron oxide (E172)).

The 150 mg capsule also contains the colourants Allura red (E129) (see section 2 “Nizatidine contains Allura red (E129)”) and Quinoline yellow (E104).

#### **What Nizatidine looks like and contents of the pack**

Your medicine comes as a hard capsule containing white to off-white powder. The 150 mg capsule has a light yellow body and dark yellow cap, the body has 'NZ 150' and the cap has 'G', both printed in black. The 300 mg capsule has a light brown body and cap, the body has 'NZ 300' and the cap has 'G', both printed in black.

Nizatidine is available in blisters and plastic containers of 28 or 30 capsules.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder**

Mylan, Potters Bar, Herts, EN6 1TL, United Kingdom.

#### **Manufacturer**

Generics [UK] Limited, Potters Bar, Herts, EN6 1TL, United Kingdom.

Gerard, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

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