

Package leaflet: Information for the user

Nizatidine 150mg & 300mg Capsules

Nizatidine

The name of your medicine is Nizatidine 150mg & 300mg Capsules, which will be referred to as Nizatidine capsules throughout this document.

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 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 capsules contain the active ingredient nizatidine, which is one of a group of medicines known as H2 receptor antagonists.

Nizatidine capsules are used to reduce gastric acid (a digestive acid produced by the stomach). This helps to treat the following conditions:

- Duodenal ulcer (the duodenum is the part of the intestine leaving the stomach)
- Non-cancerous (benign) stomach (gastric) ulcer
- To prevent the return of a duodenal or benign gastric ulcer
- Heartburn caused by acid from the stomach leaking up into the oesophagus [gullet] (gastric oesophageal reflux disease)
- Gastric and/or duodenal ulcer caused by a type of painkiller such as ibuprofen (a non-steroidal anti-inflammatory drug).

2 What you need to know before you take Nizatidine capsules

Do not take Nizatidine capsules:

- If you are allergic to nizatidine, H2 receptor antagonists (other similar drugs) or any of the other ingredients of this medicine (listed in section 6). 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 capsules

- If you have a liver or kidney disorder
- If you respond to treatment but have other symptoms such as loss of appetite, weight loss, feeling tired all the time or notice blood in your stool.

Other medicines and Nizatidine capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is especially important of the following, as they may interact with your Nizatidine capsules:

- aspirin (this can be bought without prescription).

It may still be all right for you to be given Nizatidine capsules and your doctor will be able to decide what is suitable for you.

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

Nizatidine capsules should have no effect on your ability to drive or use machines.

3 How to take Nizatidine capsules

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

Dosage

Adults and the elderly

For treatment of duodenal ulcer: the recommended dose is 300mg taken orally in the evening for 4 weeks. The same dose is used for the treatment of benign gastric ulcer, but may continue for 8 weeks. If preferred, the 300mg daily dose may be given as 150mg in the morning and evening.

To prevent a duodenal or benign gastric ulcer recurring, the recommended dose is 150mg in the evening.

For the treatment of heartburn, the recommended dose is 150mg to 300mg twice daily, for up to 12 weeks.

For the treatment of gastric and/or duodenal ulcer caused by non-steroidal anti-inflammatory drugs, the recommended dose is 300mg (either 300mg at bedtime or 150mg in the morning and in the evening) for up to 8 weeks.

Patients with kidney disorders will need a reduced dose depending on their condition.

Use in children and adolescents

Nizatidine capsules are not recommended for children.

If you take more Nizatidine capsules than you should

Tell your doctor straight away - go to the nearest emergency room and bring the packaging with you.

If you forget to take Nizatidine capsules

If you miss a dose, take one as soon as you can. If you have missed several doses, tell your doctor. 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, Nizatidine capsules can cause side effects, although not everybody gets them. All medicines can cause allergic reactions, although serious allergic reactions are very rare.

Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

You should also seek immediate medical attention if you experience any of the following side effects:

- inflammation of the liver (hepatitis)*
- jaundice (yellow skin and eyes)
- Sudden fever, sore throat, mouth ulcers, unexplained bruising or bleeding, tiredness-signs of reduced blood cell numbers*
- Severe skin reactions including peeling e.g exfoliative dermatitis

* a blood test will be needed to show this.

The most common side effects reported are:

- sweating
- nettle rash (urticaria)
- sleepiness

Other side effects:

- raised liver enzymes*
- damage to small blood vessels (vaculitis) which may cause rashes, blistering of the skin, nodules in the skin and, in severe cases, gangrene of hands or feet
- joint pain
- muscle pain
- development of breasts in men
- impotence
- gout
- fever
- nausea
- confusion
- rash with wide spread joint pain and/or stiffness, swollen lymph glands, fever and, possibly, cloudy urine.

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 Website: 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 capsules

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 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 to protect the environment.

6 Contents of the pack and other information

What Nizatidine capsules contain

The active substance is nizatidine

The other ingredients are:

starch flowable powder, starch, silicone fluid 350 cs, magnesium stearate (Nizatidine 150mg), povidone (Nizatidine 300mg), carboxymethyl cellulose sodium cross-linked (Nizatidine 300mg), talc (Nizatidine 300mg), yellow iron oxide, red iron oxide (Nizatidine 300mg), titanium dioxide, gelatin and black ink.

What Nizatidine capsules look like and contents of the pack

Nizatidine 150mg capsules are a Size 2 capsule with an opaque dark yellow cap and opaque pale yellow body, imprinted with 'Flynn 3144' in black ink.

Nizatidine 300mg capsules are a Size 1 capsule with an opaque brown cap and opaque pale yellow body, imprinted with 'Flynn 3145' in black ink.

The capsules come in opaque or transparent PVC/aluminium foil blisters.

Packs contain 28 or 30 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Flynn Pharma Ltd
Alton House, 4 Herbert Street
Dublin, Ireland

Manufacturer

Dales Pharmaceuticals
Snaygill Industrial Estate, Keighley Road
Skipton, North Yorkshire, BD23 2RW, UK

This leaflet was last revised in October 2015



**FLYNN
PHARMA
LTD**

Artwork for:	Flynn Pharma Limited
Product name:	Nizatidine Capsules 150mg & 300mg
PL/PA no:	?
Type:	Leaflet
Artwork dimensions:	160mm x 190mm
Profile supplied:	Yes
Date of first artwork:	December 2010
Reason for request:	Text edits
Version no:	5DB
Date of revision:	26 October 2015
Colours:	As swatch
Font(s):	8pt FF Zwo
Artwork software:	InDesign CS6
Proof software:	PDF
BAC ref:	S803



Black