

Package leaflet: Information for the user

Axid 150mg Capsules

Nizatidine

The name of your medicine is Axid 150mg capsules, which will be referred to as Axid 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1 What Axid capsules are and what they are used for

Axid capsules contain the active ingredient nizatidine, which is one of a group of medicines known as H2 receptor antagonists. This medicine is intended for use in adults.

Axid 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
- 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 Axid capsules

Do not take Axid capsules if

- you are allergic (hypersensitive) to nizatidine, H2 receptor antagonists (other similar drugs) or any of the other ingredients of Axid capsules (see list of ingredients 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 Axid capsules if you

- have a liver or kidney disorder
- 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. Tell your doctor urgently, as you may have a more serious condition.

Other medicines and Axid capsules

Please 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 for the following, as they may interact with your Axid capsules:

- aspirin (this can be bought without prescription).

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

Pregnancy and breast-feeding

It is not known if this medicine is safe to use during pregnancy or breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

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

3 How to take Axid 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

For treatment of duodenal ulcer or benign gastric ulcer, the usual daily dose is 300mg taken in the evening for 4 weeks.

If necessary the treatment may be extended to 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 usual daily dose is 150mg in the evening. Your doctor should check regularly whether this medicine is still suitable for you. Treatment should not last for longer than a year without confirmation from your doctor.

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

The elderly

The same dosage is recommended as for adults unless you have a kidney disorder when the dose should be reduced by your doctor.

Use in children

Axid capsules are not recommended for children.

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

If you take more Axid capsules than you should

Tell your doctor straight away.

If you forget to take Axid capsules

If you miss a dose, take one as soon as you can. If you have missed several doses, tell your doctor.

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. All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor immediately if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

The most common side effects reported are:

- sweating
- nettle rash (urticaria)
- sleepiness.

Other side effects:

- raised liver enzymes*
- inflammation of the liver (hepatitis)*
- jaundice (yellow skin and eyes)
- low blood platelets*, which reduces the ability of blood to clot. This usually just causes easy bruising, but in rare cases has been fatal
- feeling tired all the time (caused by anaemia),* becoming unable to fight off infections (caused by a low white cell count)*
- severe peeling skin

- damage to small blood vessels (vasculitis) 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.

* a blood test will be needed to show this.

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:

HPRA Pharmacovigilance, Earlsfort Terrace, IRL Dublin 2,

Tel: +353 1 6764971, www.hpra.ie;

E-mail: medsafety@hpra.ie

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

5 How to store Axid capsules

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

Do not use this medicine after the expiry date stated on the carton. 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 to protect the environment.

6 Contents of the pack and other information

What Axid capsules contain

The capsules contain 150mg of the active substance nizatidine.

The other ingredients are:

gelatin, maize starch, pregelatinised starch, dimethicone, magnesium stearate (E572), yellow iron oxide (E172), titanium dioxide (E171). The capsules are marked with black edible printing ink, which contains shellac (E902), black iron oxide (E172) and propylene glycol (E1520).

What Axid capsules look like and contents of the pack

The capsules are dark yellow and pale yellow with FLYNN 3144 printed on them.

Opaque or transparent PVC/aluminium foil blisters.

The packs contain 15, 28, 30 or 56 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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The logo for Flynn Pharma Ltd features a stylized bird icon above the company name. The name 'FLYNN' is in a large, bold, sans-serif font, with 'PHARMA' in a smaller font below it, and 'LTD' in a large, bold, sans-serif font at the bottom.