

Consumer Medicine Information

What is in this leaflet

This leaflet is designed to provide you with answers to some common questions about this medicine. It does not contain all the available information and does not take the place of talking with your doctor.

All medicines have risks and benefits. Your doctor has more information about this medicine than is contained in this leaflet. Also, your doctor has had the benefit of taking a full and detailed history from you and is in the best position to make an expert judgement to meet your individual needs.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with this medicine. You may need to read it again.

What NIZAC is used for

The name of your medicine is NIZAC. It contains the active ingredient called nizatidine.

NIZAC belongs to a class of medicines called $\rm H_2$ - antagonists or $\rm H_2$ - blockers. NIZAC works by reducing the amount of acid in your stomach. This helps reduce the pain and allows the ulcer and reflux disease to heal in most people.

NIZAC is used to treat the following conditions:

- Reflux oesophagitis or reflux disease. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe. Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.
- Ulcers. NIZAC is used to treat peptic ulcers. Depending on the position of the ulcer it is called a

gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out of the stomach. Ulcers can be caused in part by too much acid being made in the stomach.

 NIZAC is also used to stop duodenal ulcers from coming back.

Your doctor may have prescribed NIZAC for another reason. Ask your doctor or pharmacist if you have any questions about why NIZAC has been prescribed for you.

There is no evidence that NIZAC is addictive.

Before taking NIZAC

You should tell your doctor if you have any of the following conditions or if you have ever experienced any of these conditions. It is very important that your doctor is aware of these matters when determining whether or not to prescribe NIZAC.

When you must NOT take NIZAC

Do NOT take NIZAC

- if you have had an allergic reaction to NIZAC, other histamine H₂-receptor antagonists (eg. cimetidine, ranitidine, famotidine) or to any of the ingredients listed at the end of this leaflet (see 'Product Description'). Signs of an allergic reaction include itching of the skin, shortness of breath, faintness and hayfever.
- if the packaging is torn or shows signs of tampering.
- if the expiry date on the pack has passed. If you take this medicine

after the expiry date has passed it may not work as well.

Before you start taking NIZAC

You must tell your doctor

- if you are pregnant or intend to become pregnant.
- if you are breast-feeding or plan to breast-feed.
- if you have kidney or liver disease.
- if you have any allergies to any other substances, such as foods, preservatives or dyes.
- if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or health food shop. Some medicines may affect the way other medicines work. Medicines such as ketoconazole and itraconazole used to treat fungal infections may be affected by NIZAC. Your doctor or pharmacist will be able to tell you what to do when taking NIZAC with other medicines.

Tell your doctor about these things before you take NIZAC.

How to take NIZAC

How much to take

Your doctor will tell you how much NIZAC you need to take each day depending on your condition.

When to take it

The 150 mg capsule is usually taken in the morning and in the evening before you go to bed. The 300 mg capsule is usually taken once daily, at bedtime.

How to take it

Both the 150 mg and 300 mg capsules should be swallowed whole with a glass of water or another liquid.

How long do I take it

Your doctor will tell you how long you should continue taking NIZAC capsules. Do not stop taking the capsules just because you feel better. If you stop taking your capsules too early then your condition will not have been properly treated.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking NIZAC as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that you missed.

If you take too much

Immediately telephone your doctor or Poisons Information Centre (13 11 26), or go to casualty at your nearest hospital, if you think you or anyone else has taken too much NIZAC. Do this even if there are no signs of discomfort or poisoning. You made need urgent medical attention.

While you are taking NIZAC

Things you must do

Tell your doctor or pharmacist if you start any new medicine while you are taking NIZAC.

If you are taking NIZAC for an ulcer, you should go to your doctor regularly for checkups to make sure that NIZAC has healed your ulcer.

Things you must NOT do

Do not give NIZAC to anyone else. Your doctor has prescribed it for you and your condition.

Do not take NIZAC to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how NIZAC affects you. NIZAC may cause dizziness or lightheadedness in some people. Make sure you know how you react to NIZAC before you drive a car or operate any machinery.

Your doctor may advise you to limit your alcohol intake while you are being treated for your condition.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NIZAC.

Like other medicines, NIZAC may cause some unwanted side effects. These are likely to vary from patient to patient. It is important that you tell your doctor as soon as possible about any unwanted effects.

Ask your doctor or pharmacist to answer any questions you may have.

While you are taking NIZAC

Tell your doctor if you notice any of the following common side effects and they worry you

- sweating
- · itchy skin

Incidences of abnormal liver function, accompanied by jaundice (yellow skin) have been rarely reported by patients taking NIZAC. This side effect has been reversed when NIZAC is stopped. Tell your doctor if you notice anything unusual or if you are concerned about any aspect of your health, even if you think the problems are not connected with this

medicine and are not referred to in this leaflet.

After using NIZAC

Storage

Keep your capsules in the blister pack until it is time to take them. If you take your capsules out of the blister pack, they may not keep as well.

Keep your capsules in a cool dry place where the temperature stays below 25°C.

All medicines should be kept where young children cannot reach them.

There will be an expiry date (month, year) on your NIZAC container. The medicine should not be taken after this date because it may have lost some of its strength.

Disposal

If your doctor tells you to stop taking NIZAC or you find that the capsules have passed their expiry date, ask your pharmacist what to do with any capsules that are left over.

Product Description

What it looks like

NIZAC comes in two strengths:

- NIZAC 150 mg capsules are coloured light and dark yellow with "Lilly 3144" marked on them.
- NIZAC 300 mg capsules are coloured light yellow and brown with "Lilly 3145" marked on them.

A box of NIZAC 150 mg contains 60 capsules (or 2 capsules as a starter pack); a box of NIZAC 300 mg contains 30 capsules.

Ingredients

NIZAC 150 mg

Active Ingredient - 150 mg nizatidine per capsule.

Inactive Ingredients – starch-maize, starch-pregelatinsed maize, dimeticone 350, magnesium stearate. gelatin, iron oxide yellow CI77492, titanium dioxide, Colorcon black ink S1 8100.

NIZAC 300 mg

Active Ingredient - 300 mg nizatidine per capsule.

Inactive Ingredients – starch-maize, starch-pregelatinsed maize, povidone, carmellose sodium, dimeticone 350, talc-purified, gelatin, red iron oxide CI 77491, iron oxide yellow CI77492, titanium dioxide, Colorcon black ink S1 8100,

NIZAC does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Distributor

Arrow Pharma Pty Ltd 15-17 Chapel Street Cremorne VIC 3121

Australian Registration Numbers:

NIZAC 150 mg - AUST R 96961 NIZAC 300 mg - AUST R 96963

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