

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using NIZAC?

NIZAC is used to treat the reflux oesophagitis or reflux disease and ulcers.

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

For more information, see Section [1. Why am I using NIZAC?](#) in the full CMI.

### 2. What should I know before I use NIZAC?

Do not use if you have ever had an allergic reaction to nizatidine, other histamine H<sub>2</sub>-receptor antagonists (eg. cimetidine, ranitidine, famotidine) or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use NIZAC?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with NIZAC and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use NIZAC?

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.

More instructions can be found in Section [4. How do I use NIZAC?](#) in the full CMI.

### 5. What should I know while using NIZAC?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using NIZAC.</li><li>• If you become pregnant while taking this medicine, tell your doctor immediately.</li><li>• Keep all of your doctor's appointments so that your progress can be checked.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use this medicine to treat any other conditions unless your doctor tells you to.</li><li>• Do not give it to anyone else, even if they have the same condition as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how NIZAC affects you.</li><li>• NIZAC may cause dizziness or light-headedness in some patients. Make sure you know how you react before driving a car or operating machinery.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Your doctor may advise you to limit your alcohol intake while you are being treated for your condition.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your tablets in a cool dry place where the temperature stays below 25°C.</li><li>• Keep the tablets in their blister pack until it is time to take them.</li></ul>

For more information, see Section [5. What should I know while using NIZAC?](#) in the full CMI.

### 6. Are there any side effects?

All medicines have side effects. Sometimes they are serious, most of the time they are not. Common side effects include 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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# NIZAC

Active ingredient(s): *Nizatidine*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using NIZAC. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NIZAC.**

Where to find information in this leaflet:

- [1. Why am I using NIZAC?](#)
- [2. What should I know before I use NIZAC?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use NIZAC?](#)
- [5. What should I know while using NIZAC?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using NIZAC?

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

NIZAC belongs to a class of medicines called H2-antagonists or H2- 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.

## 2. What should I know before I use NIZAC?

### Warnings

**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.

**Do not use NIZAC if:**

- 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.

**Check with your doctor if you:**

- 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. 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.**

During treatment, you may be at risk of developing certain side effects. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

### Use in children

- There is no information on its use in children.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by NIZAC, or may affect how well it works. 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.

### 4. How do I use NIZAC?

#### How much to take / use

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

#### When to take / use NIZAC

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.

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

#### How long to take it for

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 use NIZAC

**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 use too much NIZAC

If you think that you have used too much NIZAC, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

### 5. What should I know while using NIZAC?

#### Things you should 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 should 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.**

#### Driving or using machines

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

#### Drinking alcohol

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

#### Looking after your medicine

- Keep the capsules in their blister pack until it is time to take them.  
If you take the tablets out of the box or the blister pack they may not keep well.
- **Keep your tablets in a cool dry place where the temperature stays below 25°C.**

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.
- Heat and dampness can destroy some medicines.

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.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

#### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

### 6. Are there any 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.**

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>Sweating</li> <li>Itchy skin</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p>These are the more common side effects of NIZAC. They are usually mild.</p>
<ul style="list-style-type: none"> <li>abnormal liver function, accompanied by jaundice (yellow skin)</li> </ul>	<p><b>Speak to your doctor if you have any of these rare less serious side effects and they worry you.</b></p> <p>This side effect has been reversed when NIZAC is stopped.</p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>swelling of the face, tongue or back of the throat which may cause difficulty in swallowing or breathing</li> <li>difficulty breathing</li> <li>chest pain.</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What NIZAC contains

NIZAC 150mg

Active ingredient (main ingredient)	Nizatidine
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> <li>maize starch</li> <li>pregelatinised maize starch</li> <li>dimeticone 350</li> <li>magnesium stearate</li> <li>iron oxide yellow</li> <li>titanium dioxide</li> <li>sodium lauryl sulfate</li> <li>gelatin</li> <li>printing Ink OPACODE monogramming ink S-1-17823 BLACK (PI 12108).</li> </ul>
Potential allergens	does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes. May contain traces of sulfites.

NIZAC 300mg

Active ingredient (main ingredient)	Nizatidine
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> <li>maize starch</li> <li>pregelatinised maize starch</li> <li>povidone</li> <li>croscarmellose sodium</li> <li>dimeticone 350</li> <li>purified talc</li> <li>iron oxide yellow</li> <li>Iron oxide red</li> <li>titanium dioxide</li> </ul>

	<ul style="list-style-type: none"> <li>• gelatin</li> <li>• printing Ink Tekprint SW-09008 black ink (PI 2328) or ACG PAM BKI004 (PI 139674).</li> </ul>
<b>Potential allergens</b>	does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes. May contain traces of sulfites.

**Do not take this medicine if you are allergic to any of these ingredients.**

### **What NIZAC looks like**

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; a box of NIZAC 300 mg contains 30 capsules.

### **Australian Registration Numbers:**

NIZAC 150 mg - AUST R 284129

NIZAC 300 mg - AUST R 96963

### **Who distributes NIZAC**

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

Australia

[www.arrotex.com.au](http://www.arrotex.com.au)

This leaflet was prepared in July 2024.