Package leaflet: Information for the user

ranitidina cinfa 150 mg film-coated tablets

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

1. What ranitidina cinfa is and what it is used for

ranitidina cinfa belongs to the group of medicines called histamine H2 receptors. It is an anti-ulcer drug that reduces the production of acid in the stomach.

ranitidina cinfa 150 mg is indicated in:

Adults

- Acute treatment of duodenal ulcer, benign gastric ulcer, and gastroesophageal reflux.
- Treatment of Zollinger-Ellison syndrome (clinical picture that causes an increase in the secretion of gastric acid).
- Prevention of recurrent bleeding in patients with bleeding ulcer.
- Prevention of gastrointestinal bleeding due to stress ulcer, in seriously ill patients.
- In the pre-operative period, in patients at risk of acid aspiration syndrome (Mendelson's syndrome), above all in pregnant women during birth.

Children and adolescents (3 to 18 years of age):

- Short-term treatment of duodenal and stomach ulcers.
- Treatment of gastroesophageal reflux, including reflux oesophagitis and relief of related symptoms.

This presentation requires medical prescription and must not be taken to treat minor symptoms of acid indigestion such as heartburn and discomfort that arises immediately after eating.

2. What you need to know before you take ranitidina cinfa

Do not take ranitidina cinfa:

- If you are allergic (hypersensitive) to ranitidine or any of the other ingredients of this medicine (included in section 6).
- If you suffer from the condition porphyria.

Warnings and precautions
Talk to your doctor or pharmacist before taking ranitidina cinfa:

- Before starting treatment with ranitidina cinfa 150 mg, your doctor must rule out the presence of a tumour, as ranitidina cinfa 150 mg may relieve the symptoms and thus mask the tumour process.
- Do not use ranitidina cinfa 150 mg to relieve the symptoms of indigestion, or any other type of minor symptoms.
- If you suffer from liver disease.
- In elderly patients, people with chronic pulmonary disease, diabetics and immunocompromised patients, as there may be a risk of developing community-acquired pneumonia.

Other medicines and ranitidina cinfa
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, or if you have treatment for kidney problems or for your current illness, such as antacids, sucralfate. Ranitidine can affect the activity of other medicines, so in some cases it will be necessary to adjust the dose or stop the treatment.

If you are taking formulations containing ketoconazole orally, do not take ranitidine either 2 hours before or 2 hours after the administration of ketoconazole.

If you are going to have any diagnostic tests, you should tell your doctor that you are taking this medicine.

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. In these circumstances, your doctor might decide not to prescribe you this medicine, although there may be cases in which you are advised to take it anyway.

Ask your doctor or pharmacist for advice before using any medicine.

Driving and using machines
Although related side effects are not expected, if you feel dizzy, do not drive or use dangerous machinery.

Important information about some of the ingredients of ranitidina cinfa
This medicine may cause stomach problems and diarrhoea as it contains hydrogenated castor oil.

3. How to take ranitidina cinfa

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
Active duodenal ulcer**:** the recommended dose is 150 mg, two times a day (morning and night). It does not need to be taken with meals. It is also possible to administer two tablets of ranitidina cinfa 150 mg at night.
In general, this regimen will be maintained for 4 to 6 weeks, even if you experience relief from your symptoms more quickly.

In patients with a recurrent ulcer, the maintenance treatment is recommended with one tablet of ranitidina cinfa 150 mg at night.

Benign active gastric ulcer
The recommended dose is one tablet of ranitidina cinfa 150 mg two times a day (one in the morning and another at night). It does not need to be taken with meals. You can also take two tablets of ranitidina cinfa 150 mg at night.
In general, this regimen will be maintained for 6 weeks.

Reflux oesophagitis
The recommended dose is one tablet of ranitidina cinfa 150 mg two times a day (one in the morning and another at night). It does not need to be taken with meals. You can also take two tablets of ranitidina cinfa 150 mg at night.
In general, this regimen will be maintained for 6-8 weeks, and if necessary up to 12 weeks.
If moderate to severe oesophagitis is presented, you can take up to four tablets of ranitidina cinfa 150 mg for a maximum of 12 weeks.
To treat the related symptoms, take one tablet of ranitidina cinfa 150 mg two times a day for 2 weeks. If the initial response is not as expected, you can continue with the same regimen for another 2 weeks.

Treatment of Zollinger-Ellison syndrome (clinical picture that causes an increase in the secretion of gastric acid)**.**
The initial dose is one tablet of ranitidina cinfa 150 mg, three times a day, increasing if necessary. Patients with this syndrome have received doses up to a maximum of 6 grams/day.

Prevention of Mendelson's syndrome (acid aspiration syndrome).
An oral dose of one tablet of ranitidina cinfa 150 mg will be administered two hours before general anaesthesia and, preferably, another 150 mg dose the previous afternoon.

Prevention of gastrointestinal bleeding due to stress ulcer, in seriously ill patients and recurrent bleeding in patients with bleeding ulcer.
Intravenous administration must be replaced by oral as soon as the patient's condition allows it. The oral dose is 150 mg twice a day.

Children and adolescents
Adolescents aged over 12 years
The recommended dose is the adult dose.

Children weighing over 30 kg, aged from 3 to 11 years
This medicine is not suitable for administration in children aged between 3 and 11 years because the tablets cannot be divided to adapt the dose to their weight.

Neonates
Effectiveness and safety in newborns has not been established.

Patients with kidney failure
Your doctor will indicate the appropriate dose for you. It will not be greater than 150 mg.
Your doctor will indicate the duration of your treatment with ranitidina cinfa 150 mg. Do not discontinue the treatment earlier.

If you do not feel better after having taken all the prescribed tablets, inform your doctor as soon as possible.

How to take ranitidina cinfa
Swallow the tablets whole with a little water. Do not divide or crush the tablets. If you have problems swallowing the tablets, tell your doctor.

If you take more ranitidina cinfa than you should
In case of overdose or accidental ingestion, notify your doctor or pharmacist immediately, specifying the medicine and the amount ingested. Nevertheless, if the quantity ingested is significant, consult a doctor as soon as possible or go to the accident and emergency department of the nearest hospital. Take this leaflet with you.

If you forget to take ranitidina cinfa
If you forget to take a dose, do not worry. Take it as soon as you remember it. Then continue as before. 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.

Uncommon (may affect up to 1 in 100 people):

- abdominal pain, constipation, feeling sick (*nausea*)

Rare (may affect up to 1 out of every 1000 people):

- sudden onset of wheezing and pain or tightness of the chest
- swelling of eyelids, face, lips, mouth or tongue
- skin rash or "wheals" (*lumps*) on any part of the body
- unexplained fever
- feeling of weakness, especially when standing up
- blood tests may show an increase in serum creatinine (renal function test)
- poor liver function (*abnormal liver function)*

Very rare (may affect up to 1 in 10,000 people):

- confusion
- inflammation of the liver (*hepatitis*), which may cause one or more of the following symptoms: nausea (*dizziness*), vomiting, loss of appetite, general discomfort, fever, itching, jaundice (*yellow colour of the skin or of the whites of the eyes*) and dark coloured urine
- light-headedness, tiredness or weakness
- blurred vision
- skin rash, occasionally severe (red/purple spots)
- hair loss
- reversible impotence
- inflammation of the pancreas (pancreatitis)
- diarrhoea
- panting and fatigue
- recurrent infection
- bruising
- headache
- low levels of white cells (*leukopaenia*) and platelets (cells that aid blood coagulation) *thrombocytopaenia.* These are generally reversible.
- muscle or joint pain

- kidney problems (symptoms may include changes in the quantity and colour of the urine, nausea, vomiting, confusion, fever and skin rash)
- sensation of depression
- hallucinations
- abnormal muscle movements or tremors
- swelling, secretion and/or discomfort of the breasts
- severe sudden allergic reaction

Tell your doctor if you are going to have a blood or urine test, or any other test, as the medicine might affect the result.

If you consider that any of the side effects you see is serious, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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

5. How to store ranitidina cinfa

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

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

Please store below 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 protect the environment.

6. Contents of the pack and other information

What ranitidina cinfa contains
- The active substance is ranitidine (hydrochloride). Each tablet contains 150 mg.
- The excipients are granular microcrystalline cellulose, talc, hydroxypropylmethylcellulose, hydrogenated castor oil, sodium carboxymethyl starch, titanium dioxide, magnesium stearate, colloidal silica, triacetin.

What ranitidina cinfa looks like and contents of the pack

ranitidina cinfa 150 mg are white, cylindrical, biconvex, coated tablets, marked with the code RC.

Each package contains 28 coated tablets.

Marketing Authorisation Holder and Manufacturer:

LABORATORIOS CINFA, S.A.
C/ Olaz-Chipi, 10 - Polígono Industrial Areta
31620 Huarte - Pamplona (Navarra). Spain

DISTRIBUTOR

Reich Pharm Limited
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18 Whitfield Road,
Hong Kong

Tel.: 2470 1927
Fax: 2470 3448

HK Reg. No. : HK-51065

This leaflet was last reviewed in June 2018

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ranitidina cinfa 300 mg film-coated tablets

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Adults
- Acute treatment of duodenal ulcer, benign gastric ulcer, and gastroesophageal reflux.
- Treatment of Zollinger-Ellison syndrome (clinical picture that causes an increase in the secretion of gastric acid).

Children and adolescents (3 to 18 years of age):
- Short-term treatment of duodenal and stomach ulcers.
- Treatment of gastroesophageal reflux, including reflux oesophagitis and relief of related symptoms.

This presentation requires medical prescription and must not be taken to treat minor symptoms of acid indigestion such as heartburn and discomfort that arises immediately after eating.

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- If you suffer from the condition porphyria.

Warnings and precautions
Talk to your doctor or pharmacist before taking ranitidina cinfa:

- Before starting treatment with ranitidina cinfa 300 mg, your doctor must rule out the presence of a tumour, as ranitidina cinfa 300 mg may relieve the symptoms and thus mask the tumour process.
- Do not use ranitidina cinfa 300 mg to relieve the symptoms of indigestion, or any other type of minor symptoms.
- If you suffer from liver disease.
- In elderly patients, people with chronic pulmonary disease, diabetics and immunocompromised patients, as there may be a risk of developing community-acquired pneumonia.

Other medicines and ranitidina cinfa
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Adults

Active duodenal ulcer
The recommended dose is one tablet of ranitidina cinfa 300 mg at night.
In general, this regimen will be maintained for 4 to 6 weeks, even if you experience relief from your symptoms more quickly.

Benign active gastric ulcer
The recommended dose is one tablet of ranitidine 150 mg two times a day (one in the morning and another at night). It does not need to be taken with meals. You can also take two tablets of ranitidina cinfa 300 mg at night.

In general, this regimen will be maintained for 6 weeks.

Reflux oesophagitis
The recommended dose is one tablet of ranitidina cinfa 150 mg two times a day (one in the morning and another at night). It does not need to be taken with meals. You can also take one tablet of ranitidina cinfa 300 mg at night.
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If moderate to severe oesophagitis is presented, you can take up to two tablets of ranitidina cinfa 300 mg for a maximum of 12 weeks.
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What ranitidina cinfa looks like and contents of the pack

ranitidina cinfa 300 mg are white, oblong, biconvex, coated tablets, grooved and marked with the code R300C.

Each pack contains 28 film-coated tablets.

Marketing Authorisation Holder and Manufacturer:

LABORATORIOS CINFA, S.A.
C/ Olaz-Chipi, 10 - Polígono Industrial Areta
31620 Huarte - Pamplona (Navarra). Spain

DISTRIBUTOR

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HK Reg. No. : HK-51124

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