PACKAGE LEAFLET : INFORMATION FOR THE USER

ranitidina cinfa® 150 mg

Ranitidine(INN)(hydrochloride)

COMPOSITION

Each tablet contains:

Ranitidine (INN) (hydrochloride) ..... 150 mg
Excipients: colloidal anhydrous silica, microcrystalline cellulose, talc, magnesium stearate, hydrogenated castor oil, sodium starch glycollate, titanium dioxide, hypromellose, glycerol triacetate.

INDICATIONS

This medicinal product is indicated for gastric or duodenal ulcer.

CONTRAINDICATIONS

Ranitidine is contraindicated in patients with known hypersensitive to the drug or to any of its ingredients.

PRECAUTIONS

This medicinal product should always be administered under medical supervision.
Patients with kidney diseases should reduce the dose as indicated in the Posology section.
Inform your physician or pharmacist if you have ever had to stop taking a medicinal product for treatment of this disease because of allergy or any other problem.

INTERACTIONS

Inform your physician if you are taking medication for a kidney disease or for the current illness.

WARNINGS

Pregnancy and lactation:
Administration should be avoided during pregnancy (particularly in the first three months) and lactation, unless considered essential by the physician.

Effects on the ability to drive:
None reported.

Use in the elderly:
The indications and dosage are the same as in younger adults.

Use in children:
The recommended dose in children is indicated in the POSOLOGY section.

DOSAGE

Follow the instructions given by your doctor. If you have any question, consult your doctor or pharmacist.

Adults:
The usual dose in stomach and duodenal ulcers or heartburn (a feeling of acid in the esophagus) is 150 mg (1 tablet) twice daily or 300 mg (2 tablets) in the evening for 4 to 6 weeks.

In some cases, up to 150 mg (1 tablet) four times daily may be administered for a maximum period of 12 weeks.

Continue taking the tablets until the end of the treatment period indicated by your doctor.

If you miss a dose, take another as soon as possible, then continue as before.

Do not stop taking the tablets until treatment has been completed even if you notice an improvement after a few days, since the ulcer may not have healed, and the pain and discomfort would recur.

If a marked improvement occurs, your doctor may prescribe you another treatment period with **ranitidina cinfa® 150 mg** tablets in order to prevent the recurrence of pain and discomfort. Depending on the disease for which you are receiving treatment, the usual dose for the maintenance treatment is 150 mg (1 tablet) after dinner.

Children:
The dose depends on the weight of the child. The usual dose ranges from 2 to 4 mg per kilogram body weight. Make sure that the child takes the dose prescribed by the physician.

Patients with renal failure.
Ranitidine plasma levels may be increased in patients with advanced renal failure. In these patients, 150 mg in the evening for 4 to 8 weeks are initially recommended. If after this time the ulcer process has not healed and the patient is considered to require continued treatment, the dose should be increased with caution to 150 mg twice daily, following the instructions given by your doctor.

Each tablet should be taken with a little water. Inform your physician or pharmacist if you have problems swallowing the tablets.

OVERDOSE

The risk of intoxication or poisoning is very small, unless many tablets are taken at once. In the event of overdose, immediately consult your doctor or report to the closest hospital emergency service, taking this package insert with you.

ADVERSE REACTIONS

No adverse reactions have occurred in most patients. However, as with most medicinal products, some people may experience side effects.

Consult your doctor immediately if you hear buzzing or ringing sounds (tinnitus), feel chest pain or tightness, swelling of the eyelids, face or lips, or if you notice urticaria or lumps on the skin.

If you notice a yellow color of the skin (jaundice), a skin rash (red spots), severe stomach pain, changes in the type of pain or feel dizzy, you must contact your doctor as soon as possible.

Inform the physician of any of the following side effects: headache, dizziness, muscle or joint pain, or depression.

Consult your physician or pharmacist if you notice any other adverse reaction not previously described.

If you take all tablets as recommended and do not feel better, inform your doctor as soon as possible.

STORAGE

Keep medicinal products out of sight and reach of children.

Please store below 25°C.

SHELF-LIFE

This medicinal product should not be used after the expiry date printed on the package.

Do not throw away any medicines via wastewater or household waste. If you are unsure, ask your pharmacist how to throw away packages and medicines you no longer need. These measures will help to protect the environment.

PHARMACEUTICAL FORM AND CONTAINER CONTENTS

Each package contains 28 coated tablets.

OTHER PRESENTATIONS

ranitidina cinfa® 300 mg coated tablets. Packages containing 28 tablets.

ON MEDICAL PRESCRIPTION

REVISED TEXT: May 1998

HOLDER AND MANUFACTURER

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

DISTRIBUTOR

Reich Pharm Limited
Unit 3001, 30/F, Citicorp Centre,
18 Whitfield Road,
Hong Kong

Tel.: 2470 1927
Fax: 2470 3448

HK Reg. No. : HK-51065

PACKAGE LEAFLET : INFORMATION FOR THE USER

ranitidina cinfa® 300 mg

Ranitidine(INN)(hydrochloride)

COMPOSITION

Each tablet contains:

Ranitidine (INN) (hydrochloride) ..... 300 mg
Excipients: Granulated microcrystalline cellulose, talc, hydroxypropylmethylcellulose, hydrogenated castor oil, sodium carboxymethyl starch, titanium dioxide, magnesium stearate, colloidal silica, triacetin.

INDICATIONS

This medicinal product is indicated for gastric or duodenal ulcer.

CONTRAINDICATIONS

Ranitidine is contraindicated in patients with known hypersensitive to the drug or to any of its ingredients.

PRECAUTIONS

This medicinal product should always be administered under medical supervision.
Patients with kidney diseases should reduce the dose as indicated in the Dosage section.
Inform your physician or pharmacist if you have ever had to stop taking a medicinal product for treatment of this disease because of allergy or any other problem.

INTERACTIONS

Inform your physician if you are taking medication for a kidney disease or for the current illness.

WARNINGS

Pregnancy and lactation:
Administration should be avoided during pregnancy (particularly in the first three months) and lactation, unless considered essential by the physician.

Effects on the ability to drive:
None reported.

Use in the elderly:
The indications and dosage are the same as in younger adults.

Use in children:
The recommended dose in children is indicated in the Dosage section.

DOSAGE

Follow the instructions given by your doctor. If you have any question, consult your doctor or pharmacist.

Adults:
The usual dose in stomach and duodenal ulcers or heartburn (a feeling of acid in the esophagus) is 300 mg (1 tablet) at night for 4 weeks.

Continue taking the tablets until the end of the treatment period indicated by your doctor.

If you miss a dose, take another as soon as possible, then continue as before.

Do not stop taking the tablets until treatment has been completed even if you notice an improvement after a few days, since the ulcer may not have healed, and the pain and discomfort would recur.

If a marked improvement occurs, your doctor may prescribe you another treatment period with **ranitidina cinfa®** tablets at a lower dose, in order to prevent the recurrence of pain and discomfort. The usual dose is 150mg (1 tablet of **ranitidina cinfa®** 150mg) after dinner. In some cases it may be necessary to use 300mg once a day.

Children:
The dose depends on the weight of the child. The usual dose ranges from 2 to 4 mg per kilogram body weight. The maximum dose is 300mg per day.Make sure that the child takes the dose prescribed by the physician.

Patients with renal failure.
Ranitidine plasma levels may be increased in patients with advanced renal failure. In these patients, 150 mg in the evening for 4 to 8 weeks are initially recommended. If after this time the ulcer process has not healed and the patient is considered to require continued treatment, the dose should be increased with caution to 300 mg daily, following the instructions given by your doctor.

Each tablet should be taken with a little water. Inform your physician or pharmacist if you have problems swallowing the tablets.

OVERDOSE

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Inform the physician of any of the following side effects: headache, dizziness, muscle or joint pain, or depression.

Consult your physician or pharmacist if you notice any other adverse reaction not previously described.

If you take all tablets as recommended and do not feel better, inform your doctor as soon as possible.

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Each package contains 28 coated tablets.

OTHER PRESENTATIONS

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ON MEDICAL PRESCRIPTION

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