PACKAGE LEAFLET: INFORMATION FOR THE USER

RUPURUT

Chewable tablets

HYDROTALCITE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. WHAT RUPURUT IS AND WHAT IS IT USED FOR

Hydrotalcite is an antacid which is not absorbed into the bloodstream. It can be used to reduce excess stomach acid which causes certain types of digestive disorders (heartburn, feeling of fullness), acute and chronic gastritis, gastric and duodenal ulcer.

2. BEFORE YOU TAKE RUPURUT

Do not take RUPURUT

- If you are allergic to hydrotalcite or any of the other ingredients of this medicine (listed in section 6)
- If you suffer from severe kidney failure
- If you have reduced concentration of phosphate in the blood (hypophosphatemia)
- If you suffer from myasthenia gravis with muscle weakness

Take special care with RUPURUT in

- Child with low phosphate levels
- Renal impairment, especially when undergoing dialysis

• Alzheimer's disease or other forms of dementia (loss of cognitive abilities): Avoid prolonged use or application of high doses medicine
• Constipation
• Suspected bowel obstruction
• Suspected appendicitis

Taking other medicines
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. Rupurut chewable tablets should not be taken with the following medicines, as this may affect their absorption:
• glycosides
• tetracyclines
• derivatives of quinolones, such as ciprofloxacin, ofloxacin
• sodium fluoride
• H2 receptor blockers
• henodeoxycholic acid
• coumarin derivatives

To maximise the benefit of all medicines being used, take Rupurut 1 to 2 hours after taking any other medicines.

If you are not sure if any of the above applies to you, talk to your doctor, pharmacist or nurse before taking RUPURUT.

Taking food and drink with RUPURUT film-coated tablets
In the case of sour foods or beverages (such as wine and fruit juice), take Rupurut chewable tablets 1-2 hours before or after that and avoid taking it simultaneously.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.
Pregnancy:
Animal studies do not indicate harmful effects on the fetus. During pregnancy Rupurut chewable tablets should only be used on a short-term basis.

Breast-feeding:
Medicines containing aluminum, such as Rupurut, pass into breast milk. Information about the passage of medicine Rupurut into breast milk are not available, but the risks to the health of infants are highly unlikely, since only very small amounts of Rupurut are absorbed.

Driving and using machines
RUPURUT should not affect your ability to drive and use machines.

Other warnings
This medicine contains mannitol, which may have a mild laxative effect.

3. HOW TO TAKE RUPURUT

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults is:

In case of indigestion and gastritis:
1-2 chewable tablets (single dose) taken when the symptoms of upset stomach occur.

In case of gastric and duodenal ulcers:

2 chewable tablets 3-4 times a day 1-2 hours after meals and before going to sleep. Treatment should be continued for at least 4 weeks after the symptoms disappear.

Tablets have to be chewed.

A daily dose of 12 chewable tablets should not be exceeded.

If you take more RUPURUT than you should
Contact your doctor. If possible, bring a tablet, this instruction or packaging with you to show the doctor what you have taken.

If you forget to take Rupurut chewable tablets
Do not take a double dose to make up for the forgotten tablet.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **RUPURUT** can cause side effects, although not everybody gets them.

During the application of higher doses (4-5 g per day, that is 8-10 tablets) you may experience infrequent stools, frequent bowel movement (defecation), vomiting and diarrhea, and this can reduce concentration of phosphate. These side effects rarely occur during the application of the recommended dose.

The following side effects may occur:
reduced concentration of phosphate in the serum
increased concentration of magnesium in the serum
allergic reactions
constipation
long term use in patients with renal failure may cause aluminum toxicity with osteomalacia and impaired brain function (encephalopathy).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. 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 RUPURUT

Keep out of the reach and sight of children.

Do not store above 25 ºC.

Do not use **RUPURUT** after the expiry date which is stated on the label.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What RUPURUT contains
The active substance is hydrotalcite in a dose of 500 mg per tablet.

The other ingredients are: banana flavor, sodium saccharin, peppermint flavor, magnesium stearate, corn starch, mannitol.

What RUPURUT looks like and contents of the pack
White, round tablets, with flat surface and slanted edge with typical peppermint aroma, with the Bayer cross embossed on one side and "Rupurut" on the other side. The broken surface is white.
20 chewable tablets (2 blisters of 10 tablets) in a PVC / Al blister, in a cardboard box.

Regime of dispensing
The medicine is issued without doctor`s prescription.

Manufacturer
Bayer Pharma AG, 13342 Berlin, Germany

Manufacturer of the medicinal product
Bayer Bitterfeld GmbH, OT Greppin, Salegaster Chaussee 1, 06803 Bitterfeld-Wolfen, Germany