

PACKAGE LEAFLET: INFORMATION FOR THE USER

RENNIE

Chewable tablets

CALCIUM CARBONATE, MAGNESIUM SUBCARBONATE, HEAVY

• 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 RENNIE is and what it is used for
2. Before you take RENNIE
3. How to take RENNIE
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1. WHAT RENNIE IS AND WHAT IS IT USED FOR

RENNIE is antacid tablet which relieves stomach upset due to excess acid and heartburn (acid indigestion), and it contains calcium carbonate and magnesium subcarbonate, heavy.

It is used in adults and children over 12 years for short-term alleviation of the symptoms of excess stomach acid such as heartburn, acid reflux, episodic stomach pains and indigestion.

Be sure to consult a doctor if you do not feel better or if you feel worse after 7 days.

2. BEFORE YOU TAKE RENNIE

Do not take RENNIE

- If you are allergic (hypersensitive) to any of the ingredients (listed in Section 6. Further Information)
- If you have severe kidney disease or suffer from kidney stones.
- If you have high calcium levels in the blood, kidneys or urine.
- If you have hypercalciuria (increased calcium excretion in the urine).
- If you have low phosphate levels in the blood.

Take special care with RENNIE

Warnings and precautions

Prolonged use of the medicine should be avoided. The recommended dose should not be exceeded.

This medicine should not be taken continuously for more than 7 days without consulting a doctor.

If symptoms occur from time to time and if there is a need for frequent administration of the medicine, you should seek medical advice.

As with other antacid products, taking these tablets can mask the symptoms of other, more serious, underlying medical conditions. Caution is required if you have impaired kidney function. If the calcium carbonate and magnesium subcarbonate, heavy are used in patients with impaired renal function the level of calcium, phosphate and magnesium in the blood should be regularly monitored.

Prolonged use of high doses of the medicine may cause side effects such as hypercalcemia (increased concentration of calcium in the blood), hypermagnesaemia (increased concentration of magnesium in the blood) and lactic-alkaline syndrome especially in patients with renal failure.

Rennie should not be used in cases of hypercalciuria (increased calcium excretion in the urine).

Prolonged use of the medicine may increase the risk of formation of kidney stones.

Magnesium salts may cause central nervous system depression in patients with renal failure.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

Children and adolescents

Rennie is not recommended for use in children and adolescents under 12 years of age due to insufficient data on safety and efficacy.

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. If you are taking

- antibiotics (tetracyclines, quinolones),
- medication for heart failure (e.g. digoxin),
- thiazide diuretics (water tablets)
- Levothyroxine (for the thyroid gland)
- other prescribed medicines (e.g. fluorides, phosphates, iron containing products, eltrombopag)

Speak to your doctor or pharmacist before taking Rennie because it can affect how these medicines work.

To maximize the benefit of all medicines being used, take Rennie 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 RENNIE.

Taking food and drink with RENNIE film-coated tablets

Avoid concomitant excessive intake of milk and dairy products.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. Rennie can be used during pregnancy if taken as instructed and if prolonged use of high doses is avoided. Rennie can be used while breast-feeding if taken as instructed. As Rennie provides a substantial amount of calcium in addition to dietary calcium intake pregnant women should strictly limit their use of Rennie Chewable tablets to the maximum recommended daily dose and avoid concomitant excessive intake of milk (1 litre contains up to 1.2g elemental calcium) and dairy products.

Driving and using machines

RENNIE should not affect your ability to drive and use machines.

Other warnings

This medicine contains 475 mg of sucrose in one chewable tablet. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE RENNIE

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.

Adults and children over 12 years

The recommended dose is 1-2 chewable tablets as a single dose one hour after meals and before bedtime. In the case of heartburn or stomach pain, this dose may be increased, but to a maximum of 11 tablets per day. Rennie should not be taken continuously for more than 7 days without consulting a doctor.

Children and adolescents

Rennie is not recommended for use in children and adolescents under 12 years of age due to insufficient data on safety and efficacy.

Method of application

Orally. Tablets should be chewed or dissolved in the mouth. The liquid is not required.

If you take more RENNIE than you should

Drink plenty of water and consult your doctor or pharmacist. Prolonged use of high doses of Rennie chewable tablets can lead to kidney failure, hypermagnesaemia, hypercalcemia and alkalosis which can cause symptoms of indigestion (nausea and vomiting, constipation, tiredness, increased urine production, increased thirst, dehydration) and abnormal muscular weakness.

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

4. POSSIBLE SIDE EFFECTS

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

The following side effects have been reported:

- Hypersensitivity reactions including rash, hives, angioedema (symptoms include swelling of the lips, tongue and throat), anaphylaxis (including difficulty breathing, increased heart rate, changes in the state of consciousness)
- Hypermagnesaemia (with antacids containing magnesium) or hypercalcemia and alkalosis that can lead to gastric symptoms and muscle weakness, nausea, vomiting, stomach upset, diarrhea.

Overdose can cause so-called milk-alkali syndrome, followed by the side effects: loss of taste, calcinosis (accumulation of calcium salts in various body tissues), nausea, headache, and increase in the concentration of nitrogen in the blood.

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 RENNIE

Keep out of the reach and sight of children.

Do not store above 25 °C.

Shelf life: 5 years.

Do not use **RENNIE** after the expiry date which is stated on the label, 5 years from the date of manufacture. 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 RENNIE contains

The active substances are calcium carbonate and magnesium subcarbonate, heavy. One chewable tablets contains 680 mg of calcium carbonate (272 mg elemental calcium) and 80 mg of magnesium subcarbonate, heavy.

The other ingredients are: sucrose, maize starch pregelatinised, potato starch, talc, magnesium stearate, paraffin very liquid, peppermint flavor, lemon flavor.

What RENNIEC looks like and contents of the pack

One box contains 4 PVC / Al blisters with 6 chewable tablets.

Regime of dispensing

The medicine is issued without doctor`s prescription.

Manufacturer

Delpharm Gaillard, 33 Rue de l'industrie, 74240 Gaillard, France

Manufacturer of the medicinal product

Bayer Pharma AG, 13342 Berlin, Germany