

PACKAGE LEAFLET: INFORMATION FOR THE USER

Renacet 475 mg film-coated tablets

Calcium acetate

Read all of this leaflet carefully since it contains important information for you.

This medicine is available without prescription. However, you still need to take Renacet 475 mg carefully to get the best result from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after eight days.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Content of this leaflet:

1. What Renacet 475 mg is and what it is used for
2. Before you take Renacet 475 mg
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4. Possible side effects
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1. WHAT RENACET 475 mg IS AND WHAT IT IS USED FOR

Use

Renacet 475 mg is used to reduce increased concentrations of phosphate in the blood. Renacet 475 mg is used for treatment of chronically reduced kidney function where dialysis treatment is required.

2. BEFORE YOU TAKE RENACET 475 mg

Do not take Renacet 475 mg

- if you are allergic (hypersensitive) to calcium acetate or any of the excipients of Renacet 475 mg (see section 6),
- if you have reduced phosphate concentrations in the blood,
- if you have increased calcium concentrations in the blood,
- in case of increased calcium excretion with the urine associated with the occurrence of calcium containing kidney stones,
- if you suffer from decalcifying tumours and metastases in the bones (metastases in the bone tissue),
- if you suffer from severe renal failure without dialysis treatment,
- if you have constipation,
- if you have known strictures of the large intestine,
- if you suffer from abnormal bone decalcification as a consequence of long-term immobilisation (bed-ridden, wheelchair).

Take special care with Renacet 475 mg

Therapy with Renacet 475 mg requires regular measurement of the calcium and phosphate levels in the blood. To avoid an increase in calcium level beyond the normal range, a further calcium therapy (e.g. calcium as food supplement) should only be performed in agreement with your doctor.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You must allow a time interval of 1-2 hours between the intake of Renacet 475 mg and other medicines.

Taking Renacet 475 mg at the same time as some other medicines may decrease their absorption in the body:

For example:

- medicines for the treatment of infections (tetracyclines and doxycycline, quinolones),
- medicines against osteoporosis (biphosphonates),
- medicines for caries (tooth decay) prevention (fluorides),
- treatment with medicines belonging to the group of anticholinergics such as atropine,
- treatment with vitamin D preparations.

The effect of heart glycosides, which are used to treat cardiac insufficiency (when the heart is unable to supply sufficient blood flow to the body), may be increased if taken at the same time as Renacet 475 mg. Whereas taking this medicine at the same time as calcium antagonists, which are also used to treat cardiac insufficiency, may reduce their effect.

For patients treated with thiazide diuretics, there is an increased risk of higher calcium concentrations in the blood. Use of adrenaline may lead to severe heart rhythm disturbances when the calcium concentration in the blood is increased.

Intake of larger quantities of calcium salts may cause a precipitation of fatty and bile acids as calcium soaps. This may impair the absorption of ursodeoxycholic acid and chenodeoxycholic acid as well as fats and fat soluble vitamins.

Taking Renacet 475 mg with food and drink

Renacet 475 mg film-coated tablets should be taken during or immediately after a meal. Tablets should be swallowed with some liquid and must not be chewed.

If you are pregnant and breast-feeding

If you are pregnant and breast-feeding, you should ask your doctor or pharmacist for advice before taking this medicine.

The likelihood of hypercalcaemia is increased in pregnant women in whom calcium and vitamin D are co-administered.

Driving and using machines

Renacet 475 mg has no influence on the ability to drive or use machines.

Important information about some of the ingredients of Renacet 475 mg

This medicinal product contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE RENACET 475 mg

Always take Renacet 475 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Unless your doctor has prescribed a different dose, the usual dose is:

Adults:

with breakfast: 1-2 film-coated tablets
with a snack: 1-2 film-coated tablets
with a main meal: 2-6 film-coated tablets
with supper: 2-4 film-coated tablets

Dosage varies from patient to patient. Since Renacet 475 mg binds phosphate from food, the number of film-coated tablets must be adjusted in accordance with the amount of food (serving size) and thus with the amount of phosphate ingested. For example 4 film-coated tablets with breakfast consisting of only one slice of bread with jam would lead to a calcium excess and thus to the risk of an increased calcium concentration in the blood.

On the other hand only 2 film-coated tablets may be insufficient to bind the larger amount of phosphate ingested with a rich main meal (thus insufficiently effective).

Renacet 475 mg film-coated tablets should be taken during or immediately after a meal. The tablets should be swallowed with some liquid and must not be chewed.

If you take more Renacet 475 mg than you should

Contact your doctor or pharmacist if you have taken more Renacet 475 mg than stated in this leaflet or prescribed by your doctor.

If you forget to take Renacet 475 mg

Do not take a double dose if you have missed the previous one. Continue treatment as prescribed by your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Renacet 475 mg can cause side effects although not everybody gets them.

To assess side effects the following frequencies are used:

Very common:	more than 1 patient out of 10
Common:	1 to 10 patients out of 100
Uncommon:	1 to 10 patients out of 1,000
Rare:	1 to 10 patients out of 10,000
Very rare:	fewer than 1 patient out of 10,000
Not known:	frequency cannot be estimated from the available data

General disorders:

Uncommon: Soft tissue calcification (e. g. in the fatty tissue under the skin) usually occurring only after many years of intake and frequently associated with increased calcium levels in the blood.

Cardiac/vascular disorders:

Uncommon: Increased calcium levels in the blood, especially after overdosage.

Gastrointestinal disorders:

Rare: Gastrointestinal disorders such as nausea and constipation, especially in case of too high dosages.

If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE RENACET 475 mg

- Keep out of the reach and sight of children.
- This medicinal product does not require any special storage conditions.
- Do not use Renacet 475 mg after the expiry date (EXP) which is stated on the carton and blister. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION

What Renacet 475 mg contains

The active substance is: 475 mg Calcium acetate (anhydrous) equivalent to 120.25 mg calcium. The excipients are:

Tablet core: Maize starch, sucrose, gelatin, sodium starch glycolate (Type A), croscarmellose sodium, magnesium stearate.

Film coat: Hypromellose, refined castor oil, saccharin sodium, talc, orange flavour.

What Renacet 475 mg looks like and contents of the pack

Appearance:

White, round, convex film-coated tablet.

Pack sizes:

100 film-coated tablets

200 film-coated tablets

This medical product is authorised in the Member States of the EEA under the following names:

Germany: Renacet 475 mg
United Kingdom: Renacet 475 mg
Portugal: Acetato de cálcio RenaCare 475 mg
Spain: Acetato de calcio RenaCare 475 mg

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