

PATIENT INFORMATION LEAFLET
CALCIUM ACETATE 500 MG TABLETS
Calcium acetate

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Calcium acetate tablets are and what they are used for
2. Before you take Calcium acetate tablets
3. How to take Calcium acetate tablets
4. Possible side effects
5. How to store Calcium acetate tablets
6. Further information

1. WHAT CALCIUM ACETATE TABLETS ARE AND WHAT THEY ARE USED FOR

Calcium acetate tablets are ‘phosphate binding agents’ and are prescribed as part of the management of kidney failure in patients on regular haemodialysis or continuous ambulatory peritoneal dialysis (CAPD). In kidney failure the phosphate levels in the blood can be high. These tablets control the phosphate levels by removing phosphate from the food in your stomach before it gets into the bloodstream.

2. BEFORE YOU TAKE CALCIUM ACETATE TABLETS

Do NOT take the tablets if you:

- are allergic (hypersensitive) to calcium acetate or any of the other ingredients in the tablets (*see Section 6 and end of Section 2*),
- have high levels of calcium in your blood or urine,
- have low levels of phosphate in your blood.

Take special care

Your doctor will monitor your blood-calcium levels regularly. If your levels are too high, your dose will be reduced or treatment stopped immediately.

Long-term high calcium levels in your blood may lead to a build-up of calcium in your blood vessels or soft tissues.

Tell your doctor if you have heart problems or are taking medication for heart problems.

Taking other medicines

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

- enoxacin, norfloxacin, ciprofloxacin or tetracyclines (antibiotics used to treat bacterial infections) as the tablets may interact with them. Take your calcium acetate tablets either 3 hours before or 3 hours after these antibiotics.
- thiazides (diuretics which increase the amount of urine produced) as the tablets may cause an excess of calcium in your bloodstream.
- bisphosphonates (used to treat bone diseases), as these tablets reduce their absorption.

Taking with food and drink

Take the tablets with food.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, think you may be pregnant or planning to become pregnant, or if you are breast-feeding. Your doctor will advise you if you can take these tablets. Ask your doctor or pharmacist for advice before taking any medicine during pregnancy, or if you are breast-feeding.

Driving and using machinery

These tablets should not affect your ability to drive or operate machinery.

Important information about some of the ingredients of this medicine

Calcium acetate tablets contain:

- **Lactose:** 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 CALCIUM ACETATE TABLETS

Always take the tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure about the dose you should take.

Dose

Your doctor will decide your dose based on the levels of phosphate in your blood, but the usual dose is: 1-2 tablets three times a day. In special cases up to 4 tablets can be taken three times a day. Take this medicine by mouth, with food.

If you are taking **antibiotics**, be sure to take your calcium acetate tablets either 3 hours before or 3 hours after the antibiotic.

If you take more tablets than you should

If you have taken more tablets than you should, contact your doctor immediately or go to your nearest hospital accident and emergency department. Take this leaflet and/or the bottle with you.

If you forget to take a dose

If you forget to take a dose, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a missed dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Calcium acetate tablets can cause side effects, although not everybody gets them.

STOP taking Calcium acetate tablets and **seek medical help immediately** if you have any of the following which may be signs of an allergic reaction:

- difficulty breathing or swallowing,
- swelling of the face, lips, tongue or throat,
- severe itching of the skin, with a red rash or raised bumps.

The following side-effects may occur:

- nausea (feeling sick) or vomiting (being sick),
- constipation,
- diarrhoea.

Calcium acetate tablets may cause **high levels of calcium** in the blood (hypercalcaemia), which can lead to the following symptoms:

- nausea (feeling sick) or vomiting (being sick),
- constipation,
- anorexia (lack of appetite).

In more severe cases this can lead to the following symptoms:

- confusion,
- decline in attention, unresponsiveness,
- lack of consciousness.

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. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CALCIUM ACETATE TABLETS

Keep this medicine out of the sight and reach of children. Do not store above 25°C. Store in the original packaging. Do not use the tablets after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater 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 Calcium acetate tablets contain:

- the **active ingredient:** calcium acetate 500 mg per tablet.
- **other ingredients:** starch, lactose (*see also end of Section 2 for further information on lactose*), magnesium stearate, microcrystalline cellulose.

What Calcium acetate tablets look like and contents of the pack

Calcium acetate 500 mg tablets are white 12.5 mm round tablets with bevelled edges and a breakline on one side. The breakline is only to help with breaking the tablet for ease of

swallowing and not to divide into equal doses. They are available in packs of 50, 100, 250, 500 or 1000 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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