

Phosex[®]

1000 mg Tablets

CALCIUM ACETATE

PACKAGE LEAFLET: INFORMATION FOR THE USER

Phosex 1000 mg Tablets (Calcium Acetate)

Please read this leaflet carefully before you start taking your medicine. It contains important information about Phosex 1000 mg Tablets.

- Keep this leaflet. You may need to read it again.
- If you have any questions ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. 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 become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1 WHAT PHOSEX TABLETS ARE AND WHAT THEY ARE USED FOR

Phosex Tablets belong to a group of medicines called phosphate binders and are only available on prescription from your doctor.

The tablets are most commonly used to remove phosphate from your body when it has too much.

They must be used together with advice on your diet and in addition to your other kidney treatment.

2 READ THIS BEFORE YOU TAKE PHOSEX TABLETS

Do not take Phosex if:

- you have been given Phosex (calcium acetate) before and had an allergic reaction. (See Section 4 for symptoms.)
- you have had an allergic reaction to any of the other ingredients. (See Section 6 for a list of these.)
- you suffer from high levels of calcium in your blood (hypercalcaemia).

Take special care with Phosex

Before you start taking these tablets, tell your doctor if:

- you are pregnant, or may become pregnant, or you are breast feeding;
- you are taking:
 - any antibiotics,
 - calcium antagonists such as verapamil (for your heart or blood pressure),
 - digitalis glycosides (for your heart);
 - any antacids containing calcium carbonate or other calcium salts.
- you know you suffer from high blood levels of calcium, (detectable through medical tests). Your doctor will inform you of symptoms of this condition.
- you are taking, or going to take products containing vitamin D at the same time as Phosex.

Check with your doctor if you are not sure.

Please note:

- The levels of phosphate and calcium in your blood will be checked regularly.
- As a result of your kidney disease, you may suffer from conditions called ectopic or vascular calcification, or from adynamic bone disease. Your doctor will carry out regular tests for signs of these.

Taking other medicines

- You should tell your doctor if you are taking, or have recently taken, any other medicines, including ones you have bought without a prescription.
- If you are taking Phosex Tablets with **antibiotics**, please see the arrangements described in Section 3, under **Dosage**.
- If you are taking **Vitamin D**, your doctor may need to adjust your dosage.
- Your doctor may take extra precautions with you if you are taking **digitalis, glycosides, verapamil or gallopamil**.
- Before taking any **antacids** or **indigestion medicines** obtained without a prescription, **check** that they do not contain calcium.

Pregnancy and breast-feeding

Before taking Phosex Tablets, tell your doctor if you are pregnant, may become pregnant or are breast feeding.

Driving and using machines

Do not drive if you experience any of these uncommon side effects: feeling confused or delirious or that you may become unconscious.

If in any doubt, consult your doctor or pharmacist.

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3 HOW TO TAKE PHOSEX TABLETS

Dosage

- Take the tablets exactly as directed by your doctor. This is particularly important if you are elderly (aged 65 or over).
- The usual dose of Phosex is one to two tablets with each meal.
- You will start with one tablet with each meal and your doctor will adjust your dose, as necessary, over a few weeks.
- The maximum recommended daily dose is 12 tablets, but exactly how many tablets and how often you must take them, will be written on the label. Please **read the label carefully**.
- Swallow the tablets whole with a little water during your meal. If they cannot be swallowed whole, they may be broken first. Do not chew them. All parts of the broken tablets should be taken.
- Taking Phosex Tablets with **antibiotics**: If you have been prescribed antibiotics, Phosex should be taken with a meal at least three hours before or three hours after the antibiotic. You should discuss the timing of taking these two medicines with your doctor or pharmacist.

If you forget to take Phosex

If you forget to take a dose, do not worry; just take the next dose with the next meal. **Never** take two doses at the same time.

If you take more Phosex than you should

If you swallow too many tablets at one time, or if you think someone else, especially a child, has swallowed any of the tablets, **go immediately** to your nearest hospital emergency department or doctor, taking this leaflet or the tablets with you.

If you stop taking Phosex

You must finish **all** the tablets which your doctor has prescribed. Even if you feel better, you should still take all the tablets you have been given. It could be dangerous to stop taking the medicine without your doctor's advice.

4 POSSIBLE SIDE EFFECTS

Like all medicines, Phosex Tablets can cause side effects (especially when first taken), although not everybody gets them.

Stop taking Phosex immediately and talk to your doctor or pharmacist if you experience allergic reactions such as rash, swelling, welts on the skin or breathing difficulties.

Your doctor will monitor your blood calcium levels as hypercalcaemia (high blood calcium levels) can occur in some patients.

Contact your doctor immediately, or go immediately to your nearest hospital emergency department, if you suffer any of the following **uncommon side effects**, (occurring in less than 1 in every 1000 patients):

- feeling confused,
- feeling delirious,
- feeling you may soon become unconscious (stupor),
- pain in your bones,
- muscle weakness,
- extreme thirst,
- producing abnormally large quantities of urine.

Common side effects (occurring in less than 1 in every 100 patients):

- feeling sick,

- being sick,
- diarrhoea,
- constipation,
- loss of appetite.

If you develop any of these side effects and they are severe or they get worse, or they last for more than two days, **contact your doctor**.

Please remember:

The expected benefits of your medicine will usually be greater than the risk of suffering harmful side effects.

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

5 HOW TO STORE PHOSEX TABLETS

Storage

Keep Phosex Tablets out of the reach and sight of children.

Do not store above 25°C. Store the tablets in their original container and keep the container tightly closed, to protect them from moisture.

Do not take any Phosex Tablets after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Disposal

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 Phosex 1000 mg Tablets contain
The **active** substance is Calcium Acetate 1000 mg, equivalent to 250 mg elemental calcium.

The **other** ingredients are:

- macrogol 8000
- sodium starch glycolate (type A)
- calcium stearate
- lemon meringue flavour containing lemon oil, citral, aldehyde C-9, lime oil, orange oil, vanillin, ethyl vanillin, malto-dextrin and tricalcium phosphate
- yellow iron oxide (E172).

What Phosex Tablets look like and the contents of the pack

The tablets are pale yellow and embossed PHOS-EX on one side with a score-line on the reverse. They are available in bottles of 180 tablets.

Manufacturer and Batch Release Site

Dales Pharmaceuticals
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

Market Authorisation Holder

Pharmacosmos A/S
Roervangsvej 30
DK-4300 Holbaek
Denmark

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