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Firma per approvazione



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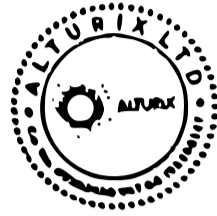
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PACKAGE LEAFLET: INFORMATION FOR THE USER

Phosphate Sandoz Effervescent Tablets

Sodium acid phosphate

The name of your medicine is Phosphate Sandoz Effervescent Tablets and will be referred to as Phosphate Sandoz throughout the rest of this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Phosphate Sandoz is and what it is used for
2. What you need to know before you take Phosphate Sandoz
3. How to take Phosphate Sandoz
4. Possible side effects
5. How to store Phosphate Sandoz
6. Contents of the pack and other information

1. WHAT PHOSPHATE SANDOZ IS AND WHAT IT IS USED FOR

Phosphate Sandoz contains the active substance sodium acid phosphate. Phosphate Sandoz is used for the treatment of high blood calcium caused by conditions such as:

- overactive parathyroid glands (hyperparathyroidism)
- a cancer of the blood (multiple myelomatosis) and in other cancers.

Phosphate Sandoz is also used for the treatment of low blood phosphate caused by a bone disease that does not respond to treatment with vitamin D (vitamin D resistant rickets) and a bone softening condition (vitamin D resistant hypophosphataemic osteomalacia).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PHOSPHATE SANDOZ

Do not take Phosphate Sandoz

- if you are allergic to sodium acid phosphate or any of the other ingredients of Phosphate Sandoz (listed in Section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

Warnings and precautions

Talk to your doctor or pharmacist before taking Phosphate Sandoz.

If you need to take these tablets for a long time it is likely that your doctor will monitor you closely and as part of this may want to monitor the phosphate levels in your blood.

Other medicines and Phosphate Sandoz

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, the following medicines may interact with your Phosphate Sandoz:

- antacids (for indigestion and heartburn) (these can be bought without prescription).

It may still be all right for you to take Phosphate Sandoz and your doctor or pharmacist will be able to decide what is suitable for you.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Phosphate Sandoz should have no effect on your ability to drive or use machines.

Phosphate Sandoz contains:

- **Potassium:** This medicine contains 123mg (3.1mmol) potassium per tablet. To be taken into consideration by patients with reduced kidney function or those on a controlled potassium diet.
- **Sodium:** This medicine contains 469mg (20.4mmol) sodium (main component of cooking / table salt) per tablet. This is equivalent to 23% of the recommended maximum daily dietary intake of sodium for an adult. Talk to your doctor or pharmacist if you need one or more tablets daily for a prolonged period, especially if you have kidney problems associated with high blood calcium or are on a controlled or low salt (sodium) diet e.g. for heart failure, hypertension, or pre-eclamptic toxemia (dangerously high blood pressure during pregnancy).
- **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 PHOSPHATE SANDOZ

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

The recommended dose is:

Adults, adolescents and children 5 years and over

For high blood calcium (hypercalcaemia): Up to 6 tablets daily. Your doctor will adjust your dose.

For low blood potassium due to vitamin D resistant bone disorders: 4-6 tablets daily.

Children under 5 years

For high blood calcium (hypercalcaemia): Up to 3 tablets daily. The doctor will adjust the dose.

For low blood potassium due to vitamin D resistant bone disorders: 2-3 tablets daily. Phosphate Sandoz should be dissolved in 1/3 to 1/2 a glass of water (50-70ml) and taken by mouth.

If you take more Phosphate Sandoz than you should

Go to the nearest casualty department or contact your doctor immediately. Take your tablet container with you.

If you forget to take Phosphate Sandoz

If you miss a dose, take one as soon as you can. If you have missed several doses, tell your doctor. Do not take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are very rare. **Tell your doctor straight away if you get:**

- any sudden wheeziness
- difficulty in breathing
- swelling of the eyelids, face or lips
- rash or itching (especially affecting your whole body)

The following side effects have been reported with this medicine:

- Gastro-intestinal symptoms such as nausea (feeling sick) and diarrhoea

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PHOSPHATE SANDOZ

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and tube after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original tube in order to protect from moisture. Keep the tube tightly closed

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What Phosphate Sandoz contains

The active substance is sodium acid phosphate.

Each tablet contains the equivalent of 1.936g of sodium acid phosphate.

The other ingredients are:

Potassium bicarbonate, sodium bicarbonate, sodium saccharin, orange flavour 52.570 TP, polyethylene glycol 4000, sugar icing, citric acid anhydrous and water.

What Phosphate Sandoz looks like and contents of the pack

The tablets are round, white and effervescent and are available in polypropylene (plastic) tubes of 20 effervescent tablets in cartons of 5 tubes (100 tablets).

Marketing Authorisation Holder

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