Phosphate Sandoz

Summary of Product Characteristics Updated 14-Jan-2022 | Alturix Limited

1. Name of the medicinal product

PHOSPHATE SANDOZ® Effervescent Tablets

2. Qualitative and quantitative composition

Each effervescent tablet contains 1.936g of sodium acid phosphate anhydrous.

Excipients with known effect:

Each tablet contains:

• 123mg potassium

• 469mg sodium

• 136mg sucrose

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Effervescent Tablet

White, round, effervescent tablets

4. Clinical particulars

4.1 Therapeutic indications

Hypercalcaemia associated with such conditions as hyperparathyroidism, multiple myelomatosis and malignancy.

Hypophosphataemia associated with vitamin D resistant rickets and vitamin D resistant hypophosphataemic osteomalacia.

4.2 Posology and method of administration

Posology

Dosage should be adjusted to suit the requirements of individual patients. Excessive dosage has been reported to produce hypocalcaemia in isolated cases. Particular care should therefore be taken to ensure appropriate dosage in the elderly.

Adults, adolescents and children 5 years and over

Hypercalcaemia: Up to 6 tablets daily (adjustment being made according to requirements).

Vitamin D resistant hypophosphateaemic osteomalacia: 4-6 tablets daily.

Children under 5 years

Hypercalcaemia: Up to 3 tablets daily (adjustment being made according to requirements).

Vitamin D resistant rickets: 2-3 tablets daily.

Method of administration

PHOSPHATE SANDOZ should be dissolved in 1/3 to 1/2 a tumblerful of water (50-70ml) and taken orally.

4.3 Contraindications

• Hypersensitivity to sodium acid phosphate anhydrous or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

In cases of impaired renal function associated with hypercalcaemia and in cases where restricted sodium intake is required, e.g. congestive cardiac failure, hypertension or pre-eclamptic toxaemia, the sodium (20.4mmol / 469mg per tablet) and potassium (3.1mmol / 123mg per tablet) content of PHOSPHATE SANDOZ should be taken into consideration. In cases of hypercalcaemia associated with impaired renal function and hyperphosphataemia, the main effect of oral phosphate is to bind calcium in the gut and thus reduce calcium absorption.

The effect of oral phosphate on serum phosphate is likely to be minimal, but close monitoring of serum levels is recommended.

Soft tissue calcification and nephrocalcinosis have been reported in isolated cases following intravenous therapy with phosphate. This is thought to be a function of dosage and rapidity of phosphate administration. While such effects

appear less likely to occur with oral phosphates, careful surveillance of patients is recommended, especially if on long term therapy.

This medicinal product contains 123mg potassium per tablet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

This medicinal product contains 469mg sodium per tablet, equivalent to 23% of the WHO recommended maximum daily intake of 2g sodium for an adult.

The maximum daily dose of this product is equivalent to 141% of the WHO recommended maximum daily intake for sodium. PHOSPHATE SANDOZ is considered high in sodium. This should be particularly taken into account for those on a low salt diet.

This medicinal product contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent administrations of antacids, containing agents such as aluminium hydroxide, may result in displacement of calcium from binding to oral phosphate, thus reducing efficacy.

4.6 Fertility, pregnancy and lactation

The safety of PHOSPHATE SANDOZ in human pregnancy has not been formally studied, but the drug has been widely used for many years without ill-consequence.

4.7 Effects on ability to drive and use machines

PHOSPHATE SANDOZ has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Apart from gastro-intestinal upsets, nausea and diarrhoea, very few side effects have been reported.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system in the United Kingdom: Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Excessive dosage has been reported to produce hypocalcaemia in isolated cases. This has proved reversible when dosage has been adjusted.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other mineral products, ATC code: A12CX

Oral administration of inorganic phosphates produces a fall in serum calcium in patients with hypercalcaemia.

PHOSPHATE SANDOZ Effervescent Tablets also contain sodium ions which aid the correction of the dehydration and sodium depletion seen in hypercalcaemia.

5.2 Pharmacokinetic properties

Absorption

Approximately two thirds of ingested phosphate is absorbed from the gastro-intestinal tract; most of the absorbed phosphate is then filtered by the glomeruli and subsequently undergoes reabsorption. Parathyroid hormone and vitamin D stimulate absorption of phosphate from the small intestine and its reabsorption from the proximal tubule.

Elimination

Virtually all absorbed phosphate is eventually excreted in the urine, the remainder being excreted in the faeces.

5.3 Preclinical safety data

PHOSPHATE SANDOZ Effervescent Tablets contain sodium acid phosphate, anhydrous, sodium bicarbonate and potassium bicarbonate (all of which are subject to pharmacopoeial monographs). The physiological, pharmacological and clinical toxicity of potassium salts are well documented and limited animal data are therefore available.

6. Pharmaceutical particulars

6.1 List of excipients

Potassium bicarbonate

Sodium bicarbonate

Sodium saccharin

Orange flavour 52.570 TP

Polyethylene glycol 4000

Sugar icing CP

Citric acid anhydrous

Water

6.2 Incompatibilities

None.

6.3 Shelf life

3 years

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Polypropylene tubes of 20 effervescent tablets in cartons of 5 tubes (100 tablets).

6.6 Special precautions for disposal and other handling

None.

7. Marketing authorisation holder

Alturix Limited

287 Upper Fourth Street

Milton Keynes

MK9 1EH

8. Marketing authorisation number(s)

PL 44490/0002

9. Date of first authorisation/renewal of the authorisation

28th April 1998

10. Date of revision of the text

December 2021

Company Contact Details

Alturix Limited

Address

287 Upper Fourth Street, Milton Keynes, MK9 1EH, UK

E-mail

info@alturix.com

Medical Information e-mail

medinfo@alturix.com

Telephone

+44 (0)1908 038083

Medical Information Direct Line

+44 (0) 845 5191609