

Phosphate Sandoz

Summary of Product Characteristics Updated 29-Oct-2015 | HK Pharma Limited

1. Name of the medicinal product

PHOSPHATE SANDOZ® Effervescent Tablets

2. Qualitative and quantitative composition

PHOSPHATE SANDOZ Effervescent Tablets containing 1.936g of sodium acid phosphate anhydrous.

3. Pharmaceutical form

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

PHOSPHATE SANDOZ Effervescent should be dissolved in 1/3 to 1/2 a tumblerful of water and taken orally.

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

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

Vitamin D resistant hypophosphataemic 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.

4.3 Contraindications

None

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, eg. congestive cardiac failure, hypertension or pre-eclamptic toxoemia, the sodium (20.4mmol per tablet) and potassium (3.1mmol 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.

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 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

None

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

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

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

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. 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

36 months

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container. Keep the container tightly closed

6.5 Nature and contents of container

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

6.6 Special precautions for disposal and other handling

None

7. Marketing authorisation holder

HK Pharma Ltd

PO Box 845

Bedford

MK45 93B

8. Marketing authorisation number(s)

PL 16784/0001

9. Date of first authorisation/renewal of the authorisation

28th April 1998

10. Date of revision of the text

July 2015

Company Contact Details

HK Pharma Limited

Address

PO Box 845, BEDFORD, MK45 9EB

Telephone

+44(0)845 5191 609

Fax

+44 (0)844 774 7811