SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

PHOSPHATE SANDOZ® Effervescent Tablet

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 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.

4.3. Contra-Indications

None.

4.4. Special Warnings and Special 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 toxaemia, 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. Interactions 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. Pre-clinical 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 Content of Container

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

6.6. Instruction for Use and Handling

None.

7 MARKETING AUTHORISATION HOLDER

HK Pharma Ltd
PO BOX 845
BEDFORD,
MK45 9EB

8. MARKETING AUTHORISATION NUMBER(S)

PL 16784/0001

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

28th April 1998

10 DATE OF REVISION OF THE TEXT

27/07/2015