# PHOSPHATE PHEBRA®

## (MONOBASIC SODIUM PHOSPHATE) EFFERVESCENT TABLETS

## 1 NAME OF THE MEDICINE

Monobasic sodium phosphate

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Phosphate Phebra effervescent tablet contains 1.936 g monobasic sodium phosphate which is equivalent to 500 mg phosphorus. The solution provides elemental phosphorus 500 mg (16.1 mmol phosphate). In addition each tablet provides sodium 469 mg (20.4 mmol $Na^+$) and potassium 123 mg (3.1 mmol $K^+$).

Excipients with known effect: sodium, potassium, saccharin and sugars.

For the full list of excipients, see Section 6.1 List of Excipients.

## 3 PHARMACEUTICAL FORM

Phosphate Phebra effervescent tablets are large, white, flat, circular uncoated tablets with a slightly rough surface. The tablets effervesce when placed in water and dissolve to give a palatable orange-flavoured solution. Each tablet has a calorific value of 2.5 kcals.

## 4 CLINICAL PARTICULARS

### 4.1 THERAPEUTIC INDICATIONS

Phosphate Phebra tablets are used as an oral phosphate supplement in the treatment of the following conditions:

1. Hypercalcaemia associated with such conditions as:
    - hyperparathyroidism
    - multiple myelomatosis, and
    - metastatic bone disease.
2. Hypophosphataemia associated with Vitamin D-resistant rickets.

### 4.2 DOSE AND METHOD OF ADMINISTRATION

Phosphate Phebra effervescent tablets should be dissolved in ⅓ to ½ glass of water and taken orally.

The dosage should be adjusted to suit the requirements of individual patients.

**Adults**

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

*Vitamin D-resistant rickets:* 4-6 tablets daily.

**Children**

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

*Vitamin D-resistant rickets:* 2-3 tablets daily.

## 4.3 CONTRAINDICATIONS

Phosphate Phebra tablets are contraindicated in patients with a known hypersensitivity to monobasic sodium phosphate or any of the components of the tablets.

## 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Consideration should be given to the sodium and potassium content of Phosphate Phebra tablets (see Section 2 Qualitative and Quantitative Composition) before administration to patients suffering from conditions associated with significant electrolyte imbalance, or impaired renal function. In cases where restricted sodium intake is indicated, e.g. in the treatment of congestive cardiac failure, hypertension, pre-eclamptic toxaemia, etc., the sodium and potassium content of Phosphate Phebra tablets should be taken into consideration.

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 following treatment with oral phosphates, careful surveillance of patients is recommended.

### Use in renal impairment

Consideration should be given to the sodium and potassium content of Phosphate Phebra tablets before administration to patients suffering from impaired renal function.

### Use in the elderly

As an excessive dosage has been reported to produce hypocalcaemia in isolated cases, particular care should be taken to ensure appropriate dosage in the elderly.

### Paediatric use

See Section 4.2 Dose and method of administration, Children.

### Effects on laboratory tests

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

## 4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Concurrent administrations of Phosphate Phebra tablets with antacids, containing agents such as aluminium hydroxide, calcium or magnesium salts, may result in the displacement of calcium from binding to oral phosphate, thus reducing the efficacy of this medication.

Parathyroid hormone (PTH) increases the urinary excretion of phosphate by blocking tubular reabsorption.

The risk of ectopic calcification may be increased by concurrent use of calcium supplements.

Vitamin D increases the gastrointestinal absorption of phosphates and therefore increases the potential for hyperphosphataemia.

## 4.6 FERTILITY, PREGNANCY AND LACTATION

### Effects on fertility

The effects of Phosphate Phebra tablets in fertility have not been formally studied.

### Use in pregnancy

The safety of Phosphate Phebra tablets in human pregnancy has not been formally studied.

### Use in lactation

The safety of Phosphate Phebra tablets in breastfeeding mothers and their infants has not been formally studied however both sodium and phosphate are found in human milk.

## 4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

## 4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Adverse drug reactions are listed according to system organ classes in MedDRA. Within each system organ class, the adverse drug reactions are ranked by frequency, with the most frequent reactions first. Within each frequency grouping, adverse drug reactions are presented in order of decreasing seriousness. In addition, the corresponding frequency category, using the following convention (CIOMS III) is also provided for each adverse drug reaction: Very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1,000, < 1/100); rare (≥ 1/10,000, < 1/1,000); very rare (< 1/10,000); not known (cannot be estimated from the available data), including isolated reports.

**Table 1: Adverse Drug Reactions**

| System Organ Class | Preferred Terms | Frequency |
|---|---|---|
| ***Renal and urinary disorders*** | Nephrocalcinosis (acute phosphate nephropathy) leading to acute renal failure | Not known |
| ***Gastrointestinal disorders*** | Abdominal pain, nausea, vomiting and diarrhoea | Not known |
| ***Metabolism and nutrition disorders*** | Hyperphosphataemia, hypocalcaemia, hypokalaemia and hypernatraemia | Not known |

### Reporting suspected adverse effects

Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems.

## 4.9 OVERDOSE

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

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 PHARMACODYNAMIC PROPERTIES

Phosphorous is one of the most abundant elements in the human body: nearly 85% is present in the skeleton, with the balance in soft tissues and extracellular fluid. Most phosphorous is complexed as phosphate which is the body's major intercellular anion and an essential component of cell membrane phospholipids, DNA, and RNA. It is also critical to most biochemical processes, including ATP synthesis and metabolic and enzymatic pathways. Phosphorous, as phosphate, also assists in maintaining normal physiological pH balance.

Phosphorous balance is regulated by several hormones, including Parathyroid hormone (PTH), which controls the release of phosphate from bones and inhibits renal reabsorption. Serum phosphate levels are inversely proportional to serum calcium levels and their physiological requirements are the same.

### Mechanism of action

Oral administration of inorganic phosphates produces a fall in serum calcium in patients with hypercalcaemia. The sodium ions in Phosphate Phebra effervescent tablets aid in the correction of the dehydration and sodium depletion which is seen in hypercalcaemia. In cases of hypercalcaemia associated with impaired renal function and hypophosphataemia, the main effect of oral phosphate is to bind calcium in the gut and thus reduce calcium absorption.

### Clinical trials

No data available.

## 5.2 PHARMACOKINETIC PROPERTIES

### Absorption

Phosphates are mainly absorbed from the jejunum and duodenum by passive and active transport. Approximately two thirds of ingested phosphate is absorbed from the gastrointestinal tract and most absorbed phosphate is filtered by the glomeruli and subsequently undergoes reabsorption. PTH and vitamin D stimulate absorption of phosphate from the small intestine and its reabsorption from the proximal tubule. Phosphorous absorption varies linearly with ingestion and diffusion is the primary method of absorption. The presence of large quantities of aluminium, calcium or magnesium may reduce the net absorption due to binding and formation of insoluble salts.

### Distribution

No data available.

### Metabolism

No data available.

### Excretion

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

## 5.3 PRECLINICAL SAFETY DATA

### Genotoxicity

No data available.

**Carcinogenicity**

No data available.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 LIST OF EXCIPIENTS

The excipients are sodium bicarbonate, potassium bicarbonate, macrogol 4000, citric acid, sucrose, Orange 52570 TP0551 and saccharin sodium.

### 6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

### 6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG[1]). The expiry date can be found on the packaging.

### 6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. The tablets must be stored in the tightly closed original container.

Keep out of reach of children.

### 6.5 NATURE AND CONTENTS OF CONTAINER

Phosphate Phebra is available in cartons of 100 tablets. Each carton contains 5 polypropylene tubes, each containing 20 tablets.

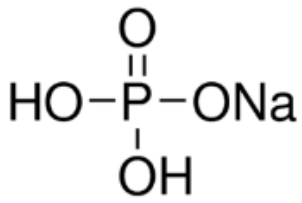
### 6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

### 6.7 PHYSICOCHEMICAL PROPERTIES

The empirical formula of monobasic sodium phosphate is $NaH_2PO_4$. The molecular weight is 119.98.

**Chemical structure**




[1] AUST R 292515

**CAS number**

7558-80-7

## 7 MEDICINE SCHEDULE (POISONS STANDARD)

NOT SCHEDULED

## 8 SPONSOR

Phebra[2] Pty Ltd, 19 Orion Road, Lane Cove West, NSW 2066, Australia.
Telephone: 1800 720 020

## 9 DATE OF FIRST APPROVAL

07 Aug 2017

## 10 DATE OF REVISION

01 Mar 2021

**SUMMARY TABLE OF CHANGES**

| Section Changed | Summary of new information |
|---|---|
| **All** | PI reformatted to align with new form |
| **5.1** | Minor editorial change for better readability |
| **6.1** | Minor editorial change for better readability |

[2] Phebra and the Phi symbol are trademarks of Phebra Pty Ltd, 19 Orion Road, Lane Cove West, NSW 2066, Australia.