

PHYCISION LEAFLET

1. Name of the medicinal product

CALCILESS TABLETS

2. Qualitative and quantitative composition

Active ingredients

Each tablet contains:

Dibasic sodium phosphate 285 mg

Monobasic potassium phosphate 602 mg

Each tablet contains approximately 90 mg sodium.

3. Pharmaceutical form

Tablets

4. Clinical particulars

4.1 Therapeutic indications

Prevention and treatment of calcium oxalate stone.

4.2 Posology and method of administration

DOSAGE:

Adults 1-2 tablets X 4 times a day

ADMINISTRATION:

The medicine should be taken with water.

During the course of treatment, drinking lots of fluids (a glass of water every hour) is required.

The tablets can be halved or crushed immediately before swallowing.

Not to store halved or crushed tablets.

Tests and follow-up

Careful monitoring of renal function and serum calcium, phosphorus, potassium and sodium may be required at periodic intervals during phosphate therapy.

Other tests may be warranted in some patients, depending on conditions.

4.3 Contraindications

This product is contraindicated in patients with:

Sensitivity (allergy) to the active ingredients or to any of the other ingredients contained in the medicine.

Severely impaired renal function, from hyperphosphatemia, from urolithiasis.

Infected phosphate stones.

4.4 Special warnings and precautions for use

This product contains potassium and sodium and should be used with caution if regulation of these elements is desired.

Occasionally, some individuals may experience a mild laxative effect during the first few days of phosphate therapy.

If laxation persists to an unpleasant degree, reduce the daily dosage until this effect subsides or, if necessary, discontinue the use of this product.

Use of this medication should be carefully considered when the following medical conditions exist:

Cardiac and blood vessels diseases (particularly in digitalized patients), cardiac failure, hypertension,

Addison's disease,

acute dehydration,

extensive tissue breakdown,

myotonia congenita,

cirrhosis of the liver or severe hepatic disease,

peripheral and pulmonary edema,

hypernatremia,

hypoparathyroidism, and acute pancreatitis.

Impaired function of: the kidney, urinary system,

high blood sodium level,

muscle disturbances,

adrenal insufficiency,

severe burns or severe dehydration, or if you are on a low sodium or sodium-free diet.

Rickets may benefit from phosphate therapy, but caution should be observed.

High serum phosphate levels increase the risk of extra skeletal calcification.

Pregnancy and Breast Feeding, toxemia of pregnancy,

Patients with kidney stones may pass old stones when phosphate therapy is started and should be warned of this possibility.

4.5 Interaction with other medicinal products and other forms of interaction

The use of antacids containing magnesium, aluminum, or calcium in conjunction with phosphate preparations may bind the phosphate and prevent its absorption.

Concurrent use of antihypertensives and medicines for the heart, especially diazoxide, guanethidine, hydralazine, methyldopa, or rauwolfia alkaloid; or corticosteroids, especially mineralocorticoids or corticotropin, with sodium phosphate may result in hypernatremia.

Potassium-containing medications or potassium-sparing diuretics may cause hyperkalemia when used with potassium phosphate and salt substitutes.

Plasma levels of salicylates may be increased since salicylate excretion is decreased in acidified urine. Administration of monobasic phosphates to patients stabilized on salicylates may lead to toxic salicylate levels.

Patients should be advised to avoid the use of antacids containing aluminum, magnesium, or calcium which may prevent the absorption of phosphate.

Non-steroidal anti-inflammatory preparations.

Corticosteroids.

Cyclosporine (for transplants).

Heparin.

4.6 Pregnancy and lactation

Teratogenic Effects

Animal reproduction studies have not been conducted. It is also not known whether this product can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. This product should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this product is administered to a nursing woman.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term or reproduction studies in animals or humans have been performed to evaluate its carcinogenic, mutagenic, or impairment of fertility potential.

4.7 Effects on ability to drive and use machines

No information

4.8 Undesirable effects

The medicine should be discontinued and the patient should be examined immediately if any of the following side effects occur:

swollen legs, confusion, a drop in blood pressure, weakness of the limbs, fatigue or increased

weakness, decrease urine output (rare).

Additional side effects:

gastrointestinal upset (diarrhea, nausea, stomach pain and vomiting) may occur with phosphate therapy.

bone and joint pain (possible phosphate-induced osteomalacia) could occur.

The following adverse effects may be observed (primarily from sodium or potassium): headaches;

dizziness;

apathy, mental confusion; seizures;

muscle cramps; numbness, tingling, pain or weakness of hands or feet;

numbness or tingling around lips;

fast or irregular heartbeat;

shortness of breath or troubled breathing;

unusual weight gain; low urine output; unusual thirst.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

4.9 Overdose

In case of an overdose, or if a child accidentally swallowed, immediately to be referred to a doctor or a hospital emergency room with the package of the medicine.

Not to induce vomiting unless explicitly instructed to do so.

5. Pharmacological properties

Phosphorus has a number of important functions in the biochemistry of the body. The bulk of the body's phosphorus is located in the bones, where it plays a key role in osteoblastic and osteoclastic activities.

Enzymatically catalyzed phosphate-transfer reactions are numerous and vital in the metabolism of carbohydrate, lipid and protein, and a proper concentration of the anion is of primary importance in assuring an orderly biochemical sequence. In addition, phosphorus plays an important role in modifying steady-state tissue concentrations of calcium.

Phosphate ions are important buffers of the intracellular fluid and also play a primary role in the renal excretion of hydrogen ion.

Oral administration of inorganic phosphates increases serum phosphate levels.

Phosphates lower urinary calcium levels in idiopathic hypercalciuria.

In general, in adults, about two thirds of the ingested phosphate is absorbed from the bowel, most of which is rapidly excreted into the urine.

5.1 Pharmacodynamic properties

No information

5.2 Pharmacokinetic properties

No information

5.3 Preclinical safety data

No information

6. Pharmaceutical particulars

6.1 List of excipients

In addition to the active ingredient, the medicine also contains:
powder cellulose, povidone, Eudragit, magnesium stearate, silicon dioxide, castor oil, talc.

The preparation contains sodium. Each tablet contains approximately 90 mg sodium.

6.2 Incompatibilities

No information

6.3 Shelf life

Shelf life after opening - one month.

6.4 Special precautions for storage

Store below 25°C

6.5 Nature and contents of container

HDPE jar containing 50 / 200 white tablets.

6.6 Special precautions for disposal and other handling

No information

7. Marketing authorisation holder

Sam-On Ltd.

25 Ehud Kinammon (Haavoda) St.

Bat-Yam 59602

8. Marketing authorisation number

0462923142

9. Date of first authorisation/renewal of the authorization

NA

10. Date of revision of the text

1/2026

Ref: K-PHOS leaflet rev 9/2020

<https://www.drugs.com/pro/k-phos-no-2.html>

