

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1996**

The medicine is dispensed with a doctor's prescription only

CALCILESS Tablets

Active ingredients

Each tablet contains:

Dibasic sodium phosphate 285 mg

Monobasic potassium phosphate 602 mg

Inactive ingredients in the preparation - see section 6.

Read this leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Treatment and prophylaxis of renal oxalate calculi.

Therapeutic group: Mineral-based preparation.

2. BEFORE USING THE MEDICINE

X Do not use the medicine if:

- you are sensitive (allergic) to the active ingredients or to any of the other ingredients contained in the medicine.
- you are suffering from severely impaired renal function, from hyperphosphatemia, from urolithiasis.

Special warnings regarding use of the medicine

- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.
- During the course of treatment with this medicine, kidney function, blood calcium and phosphate level tests must be performed.

Before treatment with Calciless, inform the doctor if:

- you are pregnant or breastfeeding.
- you are suffering, or have suffered in the past, from impaired function of: the heart and/or the blood vessels, the liver, the kidney/urinary system, the thyroid gland, from high blood sodium level, muscle disturbances, rickets, pancreatitis, adrenal insufficiency, severe burns or severe dehydration, or if you are on a low-sodium or sodium-free diet.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist.

It is particularly important to inform the doctor or pharmacist if you are taking:

- aspirin and salicylates
- potassium-containing preparations and salt substitutes
- non-steroidal anti-inflammatory preparations
- antihypertensives and medicines for the heart, including diuretics
- corticosteroids
- cyclosporine (for transplants)
- digoxin (for the heart)
- medicines containing sodium or phosphate, calcium, aluminium and magnesium salts such as antacids
- heparin.

Pregnancy and breastfeeding If you are pregnant or breastfeeding, consult a doctor before using medicines.

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

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain.

- The dosage and treatment regimen will be determined by the doctor only.

Do not exceed the recommended dose.

Swallow the medicine with water.

The tablets can be halved or crushed immediately before swallowing.

Do not store halved or crushed tablets.

Tests and follow-up

During the course of treatment, you may be referred for tests of kidney function, blood calcium and phosphate levels.

If you took an overdose, or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Adhere to the treatment regimen as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

- How can you contribute to the success of the treatment? Drink lots of fluids (a glass of water every hour) during the course of treatment.
- Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Calciless may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Discontinue use and refer to the doctor immediately if any of the following side effects occurs: swollen legs, confusion, a drop in blood pressure, weakness of the limbs, fatigue or increased weakness, decrease urine output (rare).

Additional side effects: nausea, dizziness, abdominal pain, apathy.

If any of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants to avoid poisoning.
- Do not use the medicine after the expiry date (exp. date) that appears on the label. The expiry date refers to the last day of that month.
- Storage conditions: Store at a temperature below 25°C. Shelf life after opening - one month.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains: powder cellulose, povidone, Eudragit, magnesium stearate, silicon dioxide, castor oil, talc.
- Each tablet contains approximately 90 mg sodium.
- What the medicine looks like and the contents of the package - a jar containing 200 white tablets.
- Registration holder, manufacturer and address: Sam-On Ltd., 25 Haavoda St., Bat-Yam.
- This leaflet was checked and approved by the Ministry of Health in August 2014.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 0462923142.