

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

SALVAKAL TABLETS

- **Active ingredient: Pilocarpine HCl 5 mg**
- **Read the 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.
- The medicine is not intended for children under 18 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

- For the treatment of symptoms of xerostomia (saliva deficiency) and salivary gland hypofunction caused by radiotherapy for cancer of the head and neck.
- To treat Sjogren's disease detected by biopsy.
- **Therapeutic group:** Parasympathomimetics.

2. BEFORE USING THE MEDICINE

❗ Do not use the medicine if:

- you are pregnant or breastfeeding
- you have a known sensitivity to any of the medicine's ingredients
- you are below 18 years of age
- you have untreated asthma or chronic obstruction of the respiratory system, eye inflammation or glaucoma
- you suffer from an untreated kidney or heart disease
- you suffer from a chronic disease treated with medicines that act similarly to this medicine

Special warnings regarding use of the medicine

❗ Before treatment with Salvakal, tell the doctor if:

- you suffer, or have suffered in the past, from impaired lung function (e.g., asthma, chronic bronchitis and/or chronic obstructive pulmonary disease)
- you suffer, or have suffered in the past, from a heart disease (e.g., heart failure, heart rate disorders)
- you suffer, or have suffered in the past, from gallbladder problems (e.g., gallstones)
- you suffer, or have suffered in the past, from stomach problems (e.g., ulcer)
- you suffer, or have suffered in the past, from liver function problems
- you suffer, or have suffered in the past, from nervous system problems or mental problems
- you suffer, or have suffered in the past, from kidney function problems (e.g., renal insufficiency or kidney stones)
- you suffer, or have suffered in the past, from eye problems (e.g., narrow-angle glaucoma).

❗ If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is particularly important to inform the doctor or the pharmacist if you are taking:

- medicines to lower blood pressure and to treat heart diseases (e.g., beta-blockers)
- anticholinergics or medicines with anticholinergic activity (e.g., medicines to treat abdominal spasms)
- medicines to treat diarrhea
- Atropine – medicines to treat eye problems
- Ipratropium inhalers – medicines to treat problems with the respiratory system

❗ Use of the medicine and food Take the medicine during or immediately after meals.

❗ Pregnancy and breastfeeding Use of the medicine is prohibited during pregnancy and when breastfeeding.

- **Male fertility** If you and your partner are planning pregnancy, talk to the doctor before using the medicine.

❗ Driving and operating machinery Salvakal may cause dizziness and affect your vision; you may especially experience problems with night vision. If this happens to you, do not drive or operate dangerous machinery.

- This medicine may cause excessive sweating; therefore, drink plenty of fluids to prevent dehydration!

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. Take the medicine during or immediately after meals.

- **If you accidentally took a higher dosage:** If you took an overdose or if a child accidentally swallowed the medicine, immediately refer to the doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

- **If you forgot to take the medicine:** If less than 6 hours have passed from the usual time at which you take the medicine, take it with food as soon as you remember. Take the next dose at least 3-4 hours late.

If more than 6 hours have passed, only take one dose. Do not take a double dose to compensate for a forgotten dose.

- Adhere to the treatment regimen recommended by the doctor.
- Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

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

4. SIDE EFFECTS

- As with any medicine, use of this medicine 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 as soon as possible if you feel weakness and a need to lie down, confusion, depression, nervousness, strong pain in the eyes, chest pain, skin irritation, red, swollen or painful eyes, strong abdominal pain.**

Very common side effects:

- flu-like symptoms
- sweating
- headache
- more frequent need to pass urine

Common side effects:

- fatigue
- chills
- runny nose
- allergic reactions such as rash and itching
- dizziness
- diarrhea, constipation
- indigestion, abdominal pain, nausea, vomiting
- hypersalivation
- flushing, rise in blood pressure
- palpitations
- murky eyes, abnormal vision, red, swollen and painful eyes

Uncommon side effects:

- more frequent urge to pass urine
- flatulence

Other side effects observed with the active substance Pilocarpine:

- breathing difficulties
- severe stomach or abdominal pain
- changes in heart rhythm
- decreased blood pressure, fainting
- tremor
- changes in mental state including memory disorders, mood changes and confusion
- If a side effect occurs, if any side effect worsens or if you suffer from a side effect not mentioned in this leaflet, consult 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 induce vomiting without explicit instruction from the doctor.

- Do not use the medicine after the expiry date (exp. date) indicated on the package/bottle/carton/label. The expiry date refers to the last day of that month.

- Storage conditions: Store at a temperature below 25°C.

- After opening, the medicine can be used for one month.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains: Microcrystalline Cellulose, Colloidal Silicon Dioxide, Stearic Acid.
- What does the medicine look like and what are the contents of the package: white tablets packaged in a plastic jar, 30 tablets per package. Note – the package contains a bag with a desiccant to protect the tablets.
- License holder and address: Sam-On Ltd., 25 Haavoda St., Bat-Yam.
- This leaflet was checked and approved by the Ministry of Health in May 2014.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1519333938.