

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

This medicine is dispensed with a physician's prescription only

**Salagen
Tablets**

Active ingredient:

Each tablet contains pilocarpine hydrochloride 5.0 mg.

For a list of inactive and allergenic ingredients in the preparation, see section 6 "Additional information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, consult your physician or pharmacist.

This medicine has been prescribed for your treatment. 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 this medicine intended for?

- For the treatment of symptoms of xerostomia and salivary gland hypofunction caused by radiotherapy for cancer of the head and neck.
- Sjogren detected by biopsy.

Therapeutic group: Parasympathomimetics

2. Before using the medicine

Do not use this medicine if:

- You are allergic to the active ingredient, pilocarpine hydrochloride, or to any of the additional ingredients that the medicine contains (see section 6 "Additional information").
- You are under the age of 18.
- You have untreated asthma.
- You have untreated heart or kidney disease.
- You have a chronic disease that is being treated with medicines that act like **Salagen**.
- You have an inflammation of the iris of the eye (iritis).

Special warnings regarding the use of Salagen:

Before you take Salagen, tell your physician if you suffer from:

- impaired lung function (e.g., asthma, chronic bronchitis and/or chronic obstructive pulmonary disease).
- heart disease (e.g., heart failure, arrhythmias).
- gallbladder problems (e.g. gallstones).
- stomach problems (e.g., gastric ulcers).
- impaired liver function.
- nervous system problems or mental disorders.
- impaired kidney function (e.g., renal insufficiency or kidney stones).
- eye disorders (e.g., narrow-angle glaucoma).

Eye tests:

Your physician may check your eyes before you start the treatment. If you have not had your eyes checked recently, tell your physician.

Excessive sweating:

If you sweat excessively during **Salagen** treatment, make sure to drink more liquids. If this does not help, consult your physician as you could suffer from dehydration and organ damage if this continues.

Children and adolescents:

Do not use this medicine if you are under the age of 18.

Drug interactions:

If you are taking, or have recently taken, any other medicines, including non-prescription medicines or nutritional supplements, tell your physician or pharmacist. Particularly if you are taking:

- medicines for reducing blood pressure or for the treatment of heart diseases or eye disorders (e.g., beta blockers).
- medicines to treat diarrhoea (e.g., atropine).
- anticholinergic medicines or medicines with anticholinergic activity (e.g., preparations for treating abdominal spasms).
- medicines for treating eye disorders (e.g., atropine).
- medicines for treating respiratory system disorders (e.g., ipratropium inhalers).

Use of the medicine and food:

The medicine may be taken with food.

* **For treatment with radiotherapy for head and neck cancer:**

Make sure that you take your last tablet of the day with your dinner.

* **For patients who have been diagnosed with Sjogren's syndrome:**

Make sure that you take your last tablet of the day just before you go to bed. Take the last daily dose after dinner.

Pregnancy, breastfeeding and fertility:

Pregnancy:

Do not use the medicine during pregnancy unless your physician has recommended its use. If you are pregnant, or think you may be pregnant, tell your physician before taking **Salagen**.

Breastfeeding:

Do not use the medicine if you are breastfeeding. Consult your physician before taking any medicines.

Male Fertility:

If you are planning to have a child, consult your physician before taking this medicine.

Driving and using machinery:

Use of this medicine may cause dizziness or affect your vision. In particular, you may experience vision problems at night. Therefore, when using this medication be careful when driving, especially at night, and when operating dangerous machinery.

3. How should you use the medicine?

Always use **Salagen** according to your physician's instructions. You should check with your physician or pharmacist if you are unsure about the dosage or treatment regimen of the preparation.

The dosage and treatment regimen will be determined by your physician only.

- The usual dosage for treatment of symptoms of xerostomia (lack of saliva) caused by radiotherapy treatment for head and neck cancer:

One 5 mg tablet three times per day.

- The usual dosage for treatment of Sjogren's syndrome:

One 5 mg tablet four times per day.

Do not exceed the recommended dose

If you have accidentally exceeded the dose: If you have taken an overdose or if a child has accidentally swallowed the medicine, immediately consult a physician or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine at the specified time, do not take a double dose. If you are less than 6 hours late taking your medicine, take it with food as soon as you remember. Delay taking your next dose until at least 3-4 hours after the usual time.

If more than 6 hours have passed, and your next dose is due, take only one dose. Do not take a double dose to make up for the forgotten dose and consult your physician.

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

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.

If you have any additional questions regarding use of the medicine, consult your physician or pharmacist.

4. Side effects:

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

Very common side effects - effects that occur in more than one in ten users:

- flu-like symptoms
- excessive sweating
- headaches
- the need to urinate more frequently

Common side effects - effects that occur in 1-10 of 100 users:

- fatigue
- chills
- runny nose
- allergic reactions including rash and itching
- dizziness
- diarrhoea, constipation
- indigestion, abdominal pain, nausea, vomiting
- hypersalivation
- feeling flushed and warm in the face, rise in blood pressure
- heart palpitations
- watery eyes, abnormal vision, red, swollen and painful eyes

Uncommon side effects - effects that occur in 1-10 of 1,000 users:

- urinary urgency
- flatulence (wind)

Side effects whose frequency is not known (effects whose frequency has not yet been determined):

- breathing difficulties
- severe abdominal or stomach pain
- altered heart rate
- low blood pressure, fainting
- tremor
- altered mental state such as memory loss, mood swings and confusion

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult your physician.

Reporting side effects:

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

5. How should the medicine be stored?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your physician.
- Do not use this medicine after the expiry date (exp. Date) which appears on the package. The expiry date refers to the last day of that month.

Storage conditions:

- Store at a temperature below 25°C. Store in the original packaging for protection from light and humidity.
- The medicine may be used for one month after opening.
- Do not throw away medicines in wastewater or household waste. Ask your pharmacist how to dispose of medicines which are no longer needed. These measures will help protect the environment.

6. Additional information

- In addition to the active ingredient pilocarpine hydrochloride, the medicine also contains: microcrystalline cellulose, stearic acid, opadry white OY-7300, carnauba wax

- What the medicine looks like and what the package contains: child-proof plastic packaging, white tablets marked "SAL" on one side and "5" on the other side. The container also contains a capsule with a moisture absorbent substance for protection of the tablets.

- Contains 100 tablets

- Registration holder and address: Megapharm Ltd., P.O.B. 519, Hod Hasharon 4510501, Israel.

- Manufacturer and address: Pantheon Canada, Mississauga, Ontario, Canada.

- Updated in August, 2020.

- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 101-65-28557.