

## **Package Leaflet: Information for the user**

### **Salagen® 5 mg film-coated tablets**

pilocarpine hydrochloride

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What Salagen is and what it is used for
2. What you need to know before you take Salagen
3. How to take Salagen
4. Possible side effects
5. How to store Salagen
6. Contents of the pack and other information

#### **1. What Salagen is and what it is used for**

Salagen contains the active substance pilocarpine hydrochloride, which belongs to a group of medicines called parasympathomimetic agents or cholinergic agents.

Salagen stimulates certain nerves and glands in your body. After you take Salagen, your body will produce more saliva, tears, sweat, gastric juices and mucus.

#### **Salagen is used**

- if you have been given radiotherapy for cancer of the head or neck, and your mouth feels very dry
- if you have been diagnosed with a condition called Sjögren's syndrome, and your mouth and/or your eyes are dry

If you have any questions about how Salagen works or why this medicine has been prescribed for you, ask your doctor.

#### **2. What you need to know before you take Salagen**

##### **Do not take Salagen**

- if you are allergic to pilocarpine hydrochloride or to any of the other ingredients of this medicine (listed in section 6).
- if you have uncontrolled asthma.
- if you have uncontrolled heart or kidney disease.
- if you have a chronic disease which can worsen because of treatment with a medicinal product that acts like Salagen. Talk to your doctor if you are not sure.
- if you have any disorder in which you are to avoid constriction of the pupil of the eye (e.g., an acute inflammation of the iris of the eye).

If any of these apply to you, tell your doctor before taking Salagen.

## **Warnings and precautions**

Talk to your doctor or pharmacist before taking Salagen.

Tell your doctor before you take Salagen if you have any:

- lung problems (e.g. asthma, chronic bronchitis and/or chronic obstructive pulmonary disease)
- serious heart problems (e.g. heart failure, irregular pulse)
- gallbladder or bile duct problems (e.g. gallstones)
- stomach or intestinal problems (e.g. ulcers)
- cognitive problems (difficulties in learning, memory, perception, and problem solving) or mental problems
- kidney problems (e.g. renal insufficiency or kidney stones)
- eye problems (e.g. narrow-angle glaucoma)

### *Eye tests*

Your doctor may want to check your eyes before you start the therapy. If you have not had your eyes checked recently, tell your doctor.

### *Excessive sweating*

If you sweat excessively during Salagen treatment, drink more liquids. If you cannot drink enough liquids, contact your doctor as you may suffer from dehydration and organ damage if this continues.

## **Children and adolescents**

This medicine should not be given to children or adolescents younger than 18 years of age.

## **Other medicines and Salagen**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is especially important to tell your doctor if you are taking any of the following:

- beta blockers (medicines used to treat high blood pressure, heart problems or eye problems)
- medicines for diarrhoea (e.g. atropine)
- medicines for asthma (e.g. ipratropium inhaler)
- medicines that activate so-called parasympathetic nervous system (e.g. some medicines for glaucoma, nervous system or mental diseases, Alzheimer's disease, or medicines used to speed up gastric or intestinal passage)
- medicines that are broken down by a liver enzyme called CYP2A6, e.g., blood pressure lowering medicine irbesartan or medicines to prevent blood clotting (warfarin, dicoumarol).

If you are not sure if any of your medicines belong to this list, ask your doctor or pharmacist.

## **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

### *Pregnancy*

**Do not** use Salagen during pregnancy unless your doctor has recommended it. If you are a woman of childbearing potential, you should use an effective contraception to prevent pregnancy while taking this medicine. Ask your doctor for advice.

### *Breast-feeding*

It is not known whether pilocarpine passes into human milk. Your doctor will tell you whether you should stop the treatment with Salagen or breast-feeding.

### *Fertility*

This medicine may impair fertility in men and women. If you are planning to father a child, ask your

doctor for advice before taking this medicine.

### **Driving and using machines**

Salagen may cause dizziness or affect your vision, in particular, you may have problems seeing well at night. If this happens to you, do not drive or use any tools or machines.

### **3. How to take Salagen**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

#### **The recommended dose is:**

- **For patients who have been treated with radiotherapy for head and neck cancer:**  
The recommended starting dose for adults is one 5 mg tablet three times a day.  
Make sure you take your last tablet of the day with your evening meal.
- **For patients who have been diagnosed with Sjögren's syndrome:**  
The recommended dose for adults is one 5 mg tablet four times a day.  
Make sure that you take your last tablet of the day just before you go to bed.

Depending on how you respond to treatment, your doctor may suggest a higher or lower dose. The dose can be increased up to 30 mg (6 tablets) a day.

### **Patients with impaired liver function**

If you have cirrhosis (liver disorder), your doctor will start your treatment at a lower daily dose. Depending on how you respond to treatment, your doctor may gradually increase your dose up to the recommended daily dose.

### **Method of administration**

Salagen should only be taken by mouth. ~~Do not chew or bite the tablets.~~

Take Salagen tablets with a glass of water during or directly after meals.

Try to take your tablets at intervals spread out evenly over the day, e.g. take your first tablet in the morning, one in the afternoon and one in the evening.

### **Duration of treatment**

Your doctor will tell you exactly how long you will need to take the tablets. If no improvement is noted after 2-3 months your doctor may decide to discontinue therapy.

### **If you take more Salagen than you should**

If you have accidentally taken too many Salagen tablets, **talk to a doctor immediately**. You may require medical attention or even urgent hospital admission.

Overdose symptoms may include stomach cramps, diarrhea, nausea and vomiting, unwanted passage of stool and urine, sweating, salivation, increased secretion from the bronchi, shrinking of eye pupil, slow heartbeat, low blood pressure, muscle spasms or twitching, general weakness.

### **If you forget to take Salagen**

Do not take a double dose to make up for a forgotten tablet.

### **If you stop taking Salagen**

Do not stop taking your medicine unless your doctor tells you to.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, Salagen can cause side effects, although not everybody gets them.

##### **Very common side effects**

*(may affect more than 1 in 10 people):*

- flu-like symptoms
- sweating
- headache
- the need to pass urine more frequently

##### **Common side effects**

*(may affect up to 1 in 10 people):*

- weakness
- chills
- runny nose
- allergic reactions including rash and itching
- dizziness (more likely in patients older than 65 years)
- diarrhoea; constipation
- indigestion; abdominal pain; nausea; vomiting
- watering of the mouth
- flushing; rise in blood pressure
- palpitations (feeling your heart beating faster, harder or skipping a beat)
- watery eyes; abnormal or blurred vision; red and swollen eyes (conjunctivitis), painful eyes

##### **Uncommon side effects**

*(may affect up to 1 in 100 people):*

- sudden urge to pass urine
- flatulence (wind)

##### **Other side effects of the active substance pilocarpine hydrochloride:**

- breathing difficulties
- stomach or abdominal spasms
- changes in heartbeat, including slow heartbeat (bradycardia), rapid heartbeat (tachycardia), irregular heartbeat (arrhythmia), heart conduction disturbances which prevent your heart from beating normally (atrioventricular block)
- severe lowering of blood pressure which may lead to unconsciousness (shock)
- low blood pressure;
- tremor
- changes in mental state including memory disorders, hallucinations (seeing or hearing things that are not real), agitation, mood swings and confusion

##### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at:

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Salagen**

Keep this medicine out of the sight and reach of children.

Do not use Salagen after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package and container in order to protect from light and humidity.

Do not use Salagen if you notice that the pack is damaged or shows signs of tampering.

Do not throw any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Salagen contains**

- The active substance is pilocarpine hydrochloride. Each Salagen 5 mg film-coated tablet contains 5 mg of pilocarpine hydrochloride.
- The other ingredients are cellulose microcrystalline and stearic acid. The coating is composed of Opadry white OY-7300 (containing hypromellose, macrogol 400 and titanium dioxide [E171]) and carnauba wax.

### **What Salagen looks like and contents of the pack**

Salagen tablets for oral use are white, round biconvex tablets, marked “SAL” on one side and “5 mg” on the other side.

The tablets are packed in blisters and supplied in cartons containing 14, 21, 28 or 84 tablets. Not all pack sizes may be available in your country.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

Norgine Pharmaceuticals Limited,  
Norgine House, Widewater Place,  
Moorhall Road, Harefield,  
Uxbridge, UB9 6NS, UK.

### **Manufacturer**

Norgine B. V.,  
Antonio Vivaldistraat 150,  
1083 HP Amsterdam,  
The Netherlands

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