PART III: CONSUMER INFORMATION

SALAGEN
(pilocarpine HCl)
tablets

This leaflet, designed specifically for Consumers is a summary and will not tell you everything about SALAGEN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
SALAGEN tablets are used to treat dry mouth and/or your dry eyes caused by radiotherapy in people with head and neck cancer or by Sjogren's syndrome (a condition that affects the immune system and causes dryness of certain parts of the body such as the eyes and mouth).

What it does:
SALAGEN tablets cause your salivary glands and your tear glands to make more of your natural saliva and tears.

When it should not be used:
SALAGEN should not be taken if you have:
- uncontrolled asthma
- acute inflammation of the iris or narrow-angle (angle closure) glaucoma
- a known sensitivity to pilocarpine, or to any of the tablet's ingredients

What the medicinal ingredient is:
Pilocarpine HCl.

What the nonmedicinal ingredients are:
Stearic acid, microcrystalline cellulose, hypromellose, titanium dioxide, polyethylene glycol, polysorbate 80 and carnauba wax.

What dosage forms it comes in:
Tablets, 5 mg.

WARNINGS AND PRECAUTIONS

BEFORE you use SALAGEN, talk to your doctor or pharmacist if you have:
- an abnormal heart beat or have had heart failure
- either high blood pressure or low blood pressure,
- asthma or difficulty breathing, bronchitis or emphysema
- liver disease such as hepatitis, cirrhosis or other
- blurred vision, difficulty seeing at night, glaucoma or inflammation of the eye (iritis),
- frequent heartburn or indigestion, ulcers
- difficulty urinating, kidney failure or kidney stones
- gall stones,
- confusion, tremors, psychiatric illness

or if you:
- are taking, or begin taking, any other medicines, even medicines you buy without a prescription. Some medicines may interfere with each other in your body. Some people find SALAGEN tablets affect their vision. Make sure you know how this medicine affects you before you do dangerous activities at night or in low light (example: drive a car or use machines).

INTERACTIONS WITH THIS MEDICATION

Check with your doctor before starting any new prescription or over-the-counter medicines, including natural/herbal remedies while on SALAGEN.

Drugs that may interact with SALAGEN include:
- vitamins, nutritional supplements, and herbal products

and medications used to treat:
- Myasthenia Gravis (e.g. ambenonium)
- Common cold or motion sickness (e.g. some antihistamines)
- Hypertension (e.g. beta blockers like propranolol and metoprolol)
- irritable bowel disease,
- Parkinson's disease
- Ulcers
- Urinary problems

PROPER USE OF THIS MEDICATION

Usual adult dose:
Take SALAGEN tablets three or four times a day as directed by your doctor. Your doctor may recommend a reduced dosage if you suffer from liver or kidney problems. Do not take more than six tablets (30mg) per day.

Take SALAGEN tablets with or without food.
Do not chew or bite on the tablet.

Overdose:
Overdose symptoms include salivation, sweating, vomiting, difficulty breathing, changes in blood pressure, diarrhea, nausea and shock. Mental confusion and an irregular heartbeat can also occur.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
If you miss a dose of SALAGEN, take the next dose when you normally would. Do not take more than two tablets at a time.
SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Most side effects that could occur have been generally mild or of moderate intensity. The possible side effects are:

- mild to moderate sweating
- chills
- nausea (feeling sick) and vomiting
- diarrhea
- passing urine more often
- problems with digestion
- dizziness
- runny eyes
- runny nose
- headache
- flushing (redness in face)

Tell your doctor right away if you find the above listed side effects continue, bother you, or are severe.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

<table>
<thead>
<tr>
<th>Symptom / effect</th>
<th>Talk with your doctor or pharmacist</th>
<th>Stop taking drug and seek immediate emergency medical help</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Uncommon</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weakness</td>
<td>Only if severe</td>
<td>✓</td>
</tr>
<tr>
<td>Confusion, agitation, or very depressed</td>
<td>In all cases</td>
<td>✓</td>
</tr>
<tr>
<td>Vision abnormalities</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Chest pain, a rapid heart beat, or your pulse races</td>
<td>Only if severe</td>
<td>✓</td>
</tr>
<tr>
<td>Difficulty breathing</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Severe pain in your stomach or abdomen</td>
<td>Only if severe</td>
<td>✓</td>
</tr>
<tr>
<td>Fainting</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Allergic reaction: skin rash, hives, itching or swelling of the eyes, face, lips, tongue or throat, difficulty swallowing or breathing</td>
<td>Only if severe</td>
<td>✓</td>
</tr>
</tbody>
</table>

This is not a complete list of side effects. For any unexpected effects while taking SALAGEN, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature (15 - 30°C). Do not store in the bathroom where heat and moisture may damage this medicine.

Keep SALAGEN tablets out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: http://www.pfizer.ca
or by contacting the sponsor, Pfizer Canada Inc., at: 1-800-463-6001.

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