PART III: CONSUMER INFORMATION
Betoptic® S
Betaxolol Hydrochloride Ophthalmic Suspension

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

ABOUT THIS MEDICATION

What the medication is used for:
Betoptic S (betaxolol hydrochloride ophthalmic suspension lowers eye pressure (intraocular pressure) in the treatment of ocular hyper tension (high pressure) or in chronic open angle glaucoma, used alone or with other medications.

What it does:
Betaxolol is believed to act by reducing the production of aqueous humour in the eye, thereby reducing eye pressure.

When it should not be used:
Do not use Betoptic S (betaxolol hydrochloride ophthalmic suspension) if you have a known hypersensitivity to benzalkonium chloride or any other ingredient in this product (see **What the medicinal ingredient is** and **What the important nonmedicinal ingredients are**).

- If you have now or have had past respiratory problems such as asthma, severe obstructive bronchitis (severe lung condition which may cause wheeziness, difficulty breathing and or/long standing cough) or severe chronic obstructive pulmonary disease (COPD).
- If you have a slow heart beat, heart failure or disorders of heart rhythm (irregular heart beats)

What the medicinal ingredient is:
Betaxolol

What the important nonmedicinal ingredients are:
Betoptic S (betaxolol hydrochloride ophthalmic suspension) contains benzalkonium chloride (as preservative), carbomer 934P, edetate disodium, mannitol, poly (styrene-divinyl benzene) sulfonic acid, purified water, hydrochloric acid and/or sodium hydroxide (to adjust pH).

What dosage forms it comes in:
Betoptic S (betaxolol hydrochloride ophthalmic suspension) is a sterile isotonic aqueous suspension containing betaxolol 0.25% w/v (0.28% w/v betaxolol hydrochloride) and is supplied in 5 mL bottle.

WARNINGS AND PRECAUTIONS

Take special care with Betoptic S.

BEFORE you use Betoptic S (betaxolol hydrochloride ophthalmic suspension) talk to your doctor or pharmacist if you now have or have had in the past:

- Coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, low blood pressure
- Disturbances of heart rate such as slow heart beat
- Breathing problems, asthma or chronic obstructive pulmonary disease
- Poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome)
- Diabetes, as betaxolol may mask signs and symptoms of low blood sugar
- Overactivity of the thyroid gland as betaxolol may mask signs and symptoms
- Corneal disease

Tell your doctor before you have an operation that you are using Betoptic S as betaxolol may change effects of some medicines used during anaesthesia.

Using other medicines
Betoptic S can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. Tell your doctor if you are using or intend to use medicines to lower blood pressure, heart medicine or medicines to treat diabetes. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding
Do not use Betoptic S if you are pregnant unless your doctor considers it necessary. Do not use Betoptic S if you are breast-feeding. Betaxolol gets into your milk. Ask your doctor for advice before taking any medicine during breast-feeding.

Driving and using machines
You may find that your vision is blurred for a time just after you use Betoptic S. Do not drive or use machines until your vision is clear**.**

If you wear contact lenses
Betoptic S (betaxolol hydrochloride ophthalmic suspension) contains benzalkonium chloride which may cause irritation and is known to discolour contact lenses. Avoid contact with soft contact lenses. Remove contact lenses prior to use and wait at least 15 minutes before reinsertion.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with Betoptic S (betaxolol hydrochloride ophthalmic suspension) include: reserpine and guanthedine. Caution should be exercised if you use adrenergic psychotropic drugs concomitantly. There is a potential for additive effects resulting in hypotension and/or marked bradycardia when ophthalmic beta-blocking agents, antiarrhythmics (including amiodarone) or digitalis glycosides.

PROPER USE OF THIS MEDICATION

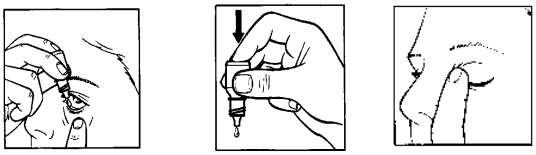
Always use Betoptic S (betaxolol hydrochloride ophthalmic suspension) exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. After using Betoptic S, press a finger into the corner of your eye, by the nose (picture 3) for 2 minutes. This helps to stop betaxolol getting into the

rest of your body.

Usual Adult Dose:
One drop of Betoptic S (betaxolol hydrochloride ophthalmic suspension) in the affected eye(s) twice daily.

Follow these steps to help you use Betoptic S (betaxolol hydrochloride ophthalmic suspension) properly:

How to Use:


1 2 3

- Get the Betoptic S bottle and a mirror.

- Wash your hands.
- Shake well before use.
- Twist off the bottle cap
- After cap is removed: if tamper evident snap collar is loose, remove before using product.
- If you wear contact lenses, remove them before using your eye drops.
- Hold the bottle, pointing down, between your thumb and fingers
- Tilt your head back
- Pull down your lower eyelid with a clean finger until there is a 'pocket' between the eyelid and your eye. The drop will go in here. (picture 1).
- Bring the bottle tip close to the eye. Do this in front of a mirror if it helps.
- Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops.
- Gently press on the base of the bottle to release one drop of Betoptic S (betaxolol hydrochloride ophthalmic suspension) at a time.
- Do not squeeze the bottle: it is designed so that a gentle press on the bottom is all that it needs (picture 2).
- After using Betoptic S (betaxolol hydrochloride ophthalmic suspension), press a finger into the corner of your eye, by the nose (picture 3). This helps to stop Betoptic S getting into the rest of the body. Close your eye for 2 to 3 minutes.
- If you use drops in both eyes, repeat the steps for your other eye.
- Close the bottle cap firmly immediately after use.
- Use up one bottle before opening the next bottle
  If a drop misses your eye, try again.

If you use drops in both eyes, repeat the steps for your other eye. Close the bottle cap firmly immediately after use. If you are using other eye drops wait at least 5 minutes between putting in Betoptic S (betaxolol hydrochloride ophthalmic suspension) and the other drops.

Betoptic S (betaxolol hydrochloride ophthalmic suspension) should be used until your doctor tells you to stop.

Overdose:
In case of accidental ingestion, symptoms of overdose may include slow heartbeat (bradycardia), low blood pressure (hypotension), heart failure (cardiac failure) and bronchospasm (constriction of the airways making breathing difficult). If overdose occurs, treatment should be symptomatic and supportive.

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.

Ocular: flush eye with lukewarm tap water

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, Betoptic S (betaxolol hydrochloride ophthalmic suspension) can cause side effects although not everybody gets them.

You can usually carry on taking the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using Betoptic S (betaxolol hydrochloride ophthalmic suspension) without speaking to your doctor.

You may experience discomfort and occasional tearing for a short time after use. Blurred vision, decreased corneal sensitivity, erythema (eye redness), itching sensation, corneal punctate staining, keratitis (inflammation of the cornea), anisocoria (unequal pupil size) and photophobia (light sensitivity) have also been reported.

- Like other medicines applied into eyes, betaxolol is absorbed into the blood. This may cause similar side effects as seen with intravenous' and/or "oral" as applicable beta-blocking agents. Incidence of side effects after topical ophthalmic administration is lower than when medicines are, for example taken by mouth or injected. Listed side effects include reactions seen within the class of beta-blockers when used for treating eye conditions:

- Generalized allergic reactions including swelling beneath the skin that can occur in areas such as the face and limbs and can obstruct the airway which may cause difficulty swallowing or breathing, hives or itchy rash, localized and generalized rash, itchiness, severe sudden life-threatening allergic reactions.

- Signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness), inflammation of the eyelid, inflammation in the cornea, blurred vision and detachment of the layer below the retina contains blood vessels following filtration surgery which may cause visual disturbances, decreased corneal sensitivity, dry eyes, corneal erosion (damage to the front layer of the eyeball), drooping of the upper eyelid (making the eye stay half closed), double vision.

- Slow heart rate, chest pain, palpitations, edema (fluid build up), changes in the rhythm or speed of the heartbeat, congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid build up) a type of heart rhythm disorder, heart attack, heart failure.

- Low blood pressure, Raynaud's phenomenon, cold hands and feet.

- Constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, cough.
- Taste disturbances, nausea, indigestion, diarrhea, dry mouth, abdominal pain, vomiting.
- Hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, skin rash.
- Muscle pain not caused by exercise.
- Sexual dysfunction, decreased libido.
- Muscle weakness/tiredness.
- Severe respiratory reactions, including bronchospasm and death, have been reported after administration of some ophthalmic beta-blockers like Betoptic S.
- If any of the side effects get serious or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

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

Symptom / effect		**Talk with your doctor or pharmacist**		**Stop taking drug and seek immediate emergency medical attention**
		Only if severe	**In all cases**	
Common	-Severe allergic reactions with symptoms such as swelling of mouth, throat, lips and extremities, trouble breathing, itching and rash.	✓		
Uncommon	-Heart effects including slow or irregular heartbeat, palpitations, and heart failure.			✓
	- Serious eye problems such as keratitis (inflammation of cornea), inflammation of the eyelids (blepharitis), and corneal erosion		✓	

This is not a complete list of side effects. For any unexpected effects while taking BetopticS (betaxolol hydrochloride ophthalmic suspension), contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature (15- 30°C) in the outer container.
Keep out of reach 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 1912C
    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:
www.novartis.ca
or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at: 1-800-363-8883

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