PART III: CONSUMER INFORMATION

[Pr]APO-LATANOPROST
Latanoprost Ophthalmic Solution

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

ABOUT THIS MEDICATION

What the medication is used for:
APO-LATANOPROST is used to treat ocular hypertension (high pressure in the eye) in patients with open-angle glaucoma or ocular hypertension. These conditions may eventually affect your eyesight.

What it does:
APO-LATANOPROST is a solution for use only in the eyes. The active ingredient in APO-LATANOPROST is one of a group of medications known as prostaglandins. It helps to lower the pressure within the eye by increasing the natural outflow of fluid from inside the eye.

When it should not be used:
Do not use APO-LATANOPROST 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 nonmedicinal ingredients are)**.

What the medicinal ingredient is:
Latanoprost

What the important nonmedicinal ingredients are:
sodium dihydrogen phosphate monohydrate, disodium phosphate anhydrous, sodium chloride, water for injection, sodium hydroxide and hydrochloric acid and benzalkonium chloride as a preservative.

What dosage forms it comes in:
APO-LATANOPROST is supplied in a 5 mL plastic ophthalmic dispenser bottle. Each bottle contains 2.5 mL of solution, approximately 80 drops. Each millilitre (mL) contains 50 micrograms of latanoprost.

WARNINGS AND PRECAUTIONS

BEFORE you use APO-LATANOPROST talk to your doctor or pharmacist if:

- You are allergic to any of the ingredients in APO-LATANOPROST.
- You are using any other eye drops or taking any other medication.
- You are pregnant, think you might be pregnant or you are planning a pregnancy.
- You are breast feeding or planning to breastfeed.
- You have or have had herpes simplex keratitis (inflammation of the cornea caused by the herpes simplex virus).
- Your eyes are sensitive to light.
- You have liver or kidney problems
- You have or have had eye inflammation (e.g. uveitis, iritis)

APO-LATANOPROST contains a preservative that may be absorbed by contact lenses and stains them a brown colour. Contact lenses can be reinserted 15 minutes after applying the eye drops.

If you are using more than one type of eye drop medication, wait at least 5 minutes between each different eye drop.

INTERACTIONS WITH THIS MEDICATION

*S*tudies have shown that precipitation occurs when eye drops containing thimerosal are mixed with latanoprost ophthalmic solution. If such drugs are used, they should be administered with an interval of at least 5 minutes between applications.

Only on your doctor's advice, APO-LATANOPROST may be used concomitantly with other topical ophthalmic products to further lower intraocular pressure. If more than one topical ophthalmic drug is being used, the drugs should be administered at least 5 minutes apart.

PROPER USE OF THIS MEDICATION

Usual adult dose:
One drop of APO-LATANOPROST should be dropped into the affected eye(s) once daily. The best time to do this is in the evening.

Do not allow the dropper tip of the bottle to touch the eye or other surrounding structures, because this could contaminate the tip with common bacteria known to cause eye infections. Serious damage to the eye with subsequent loss of vision may result if you use eye drop solutions that have become contaminated. If you experience any type of eye condition or have surgery, immediately seek your doctor's advice concerning the continued use of the bottle you are using.

If you forget to use your eye drops at the usual time, wait until it is time for your next dose. If you put too many drops in your eye(s), you may feel some slight irritation.

APO-LATANOPROST is not recommended for use in children.

Follow these steps to help you use APO-LATANOPROST properly:

1. Wash your hands and sit or stand comfortably. If you wear contact lenses, remove them before using your eye

drops.
2. Once the bottle is opened, hold it in one hand and steady your thumb against your brow or the bridge of your nose.
3. Use your index finger to gently pull down the lower eyelid of the affected eye(s) to create a pocket for the drop.
4. Gently press the side of the bottle to allow only a single drop to fall into the pocket. Do not let the tip of the bottle touch your eye.
5. Close your eye for 2 to 3 minutes.
6. If your doctor has told you to use drops in both eyes, repeat the process for the other eye.
   APO-LATANOPROST should be used until your doctor tells you to stop.

Overdose:

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 one dose is missed, treatment should continue with the next dose the following day.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

APO-LATANOPROST may change the colour of your eye. It may make your iris (the coloured part of your eye) more brown. This happens most commonly if your iris has mixed colours, i.e., blue-brown, grey-brown, green-brown or yellow-brown. If you use APO-LATANOPROST in one eye only, colour changes in the iris may appear only in the treated eye. These changes may be permanent.

APO-LATANOPROST may also cause your eye lashes to darken, appear thicker and longer than they usually do and increase in number. APO-LATANOPROST might cause eye irritation due to the growth of misdirected eyelashes; tell your doctor if this happens. A very small number of people may notice their eyelids look darker after using APO-LATANOPROST for some time. These changes may be more noticeable if you are only treating one eye. Eyelash changes are reversible after treatment with APO-LATANOPROST is stopped. Eyelid skin darkening may be permanent.

When using APO-LATANOPROST, you might feel as if there is something in your eye(s). Your eye(s) might water and become red. You may also develop a small cyst in your iris. As with other eye drops, if your vision is blurred when you first put your drops in, wait until this wears off before you drive or operate machinery. A few people using latanoprost ophthalmic solution have developed a skin rash.

A few people may experience changes in their vision, sometimes in combination with a red and sore/painful eye. These changes do not always occur right after administering the drops, and if they occur, you may find that reading and seeing fine details is more difficult. Although unlikely, if you experience any of these changes, stop using APO-LATANOPROST and contact your doctor immediately.

Dizziness and headache have also been reported.

APO-LATANOPROST may cause the following side effects as well.

Common Ocular Side Effects: burning and stinging, blurred vision, red eyes, foreign body sensation, itching, increased iris pigmentation, damage of the cornea in a pinpoint pattern, dry eyes, excessive tearing, eye pain, eye lid crusting, red and swollen eyelid, eyelid discomfort/ pain, photophobia (visual sensitivity to light)

Uncommon Ocular Side Effects: discharge from the eye, diplopia (doubled vision), conjunctivitis, iritis/uveitis (inflammation of the interior of the eye), darkening of the palpebral skin (skin related to the eyelid), iris cyst (small cyst appearing in the colored part of the eye), disorder of the conjunctiva.

Common Systemic Side Effects: upper respiratory tract infection/ cold/ flu, pain in muscle/ joint/ back, chest pain/angina pectoris, rash/ allergic skin reaction

Be sure to tell your doctor (or pharmacist) if you notice any other unwanted side effects.

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 call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon ocular adverse events	Macular edema: blurred or wavy vision in the middle of the eye and colors perception changes		✓	
	Herpetic keratitis: Infection and infestations of the eyes (blurred vision, pain, redness, tearing, discharge, sensitivity to lights)		✓	
Uncommon Systemic Adverse Events	Asthma/ Asthma aggravation/ Acute asthma attack/ Difficulty to breath			✓
	Severe skin reactions including rash and skin degradation in different parts of the body			✓

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

HOW TO STORE IT

Before APO-LATANOPROST is first opened, keep it in a fridge (between 2ºC and 8ºC/36ºF and 46ºF), out of direct light. During shipment, the bottle may be maintained at temperatures up to 40ºC (104ºF) for a period not exceeding 8 days. Once the bottle has been opened, APO-LATANOPROST may be kept at room temperature up to 25ºC. APO-LATANOPROST must be used within 6 weeks after opening the bottle. Discard the bottle and/or unused contents after 6 weeks. APO-LATANOPROST should not be used after the expiry date on the bottle. Avoid freezing.

Keep all medicines in a safe place, out of the reach and sight of children.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your doctor, pharmacist or other healthcare professional.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting DISpedia, Apotex's Drug Information Service at: 1-800-667-4708

This leaflet can also be found at:
http://www.apotex.ca/products

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