PART III: CONSUMER INFORMATION

PrGD®-LATANOPROST/TIMOLOL
latanoprost and timolol ophthalmic solution (latanoprost 50 mcg/mL and timolol 5 mg/mL)

This leaflet is part III of a three-part "Product Monograph" published when GD-LATANOPROST/TIMOLOL was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about GD-LATANOPROST/TIMOLOL. Contact your doctor or pharmacist if you/your child have any questions about the drug. Please read this information carefully.

ABOUT THIS MEDICATION

What GD-LATANOPROST/TIMOLOL is used for:
GD-LATANOPROST/TIMOLOL is used to reduce eye pressure in patients with open angle glaucoma ocular hypertension. Both these conditions are related to an increase in pressure within the eye and eventually they may affect your eyesight.

What GD-LATANOPROST/TIMOLOL does:
GD-LATANOPROST/TIMOLOL is a combination of an ophthalmic prostaglandin drug *(latanoprost)* and an ophthalmic beta-blocking drug *(timolol)*, both of which lower the pressure within the eye in different ways. The prostaglandin drug works by increasing the natural outflow of fluid from inside the eye. The beta-blocking drug works by decreasing the fluid production in the eye.

When GD-LATANOPROST/TIMOLOL should not be used:
- **if you have a reactive airway disease including bronchial asthma, a history of bronchial asthma, or severe chronic obstructive pulmonary disease.**
- **if you have heart problems such as ~~a~~ sinus bradycardia (low heart beat), sick sinus syndrome, sino-atrial block, second or third degree atrioventricular block not controlled with pace-maker, overt cardiac (heart) failure, or cardiogenic shock.**
- **if you have known hypersensitivity to latanoprost, timolol, benzalkonium chloride or any other ingredient in the product. (See What the medicinal ingredients are).**

What the medicinal ingredients are:
Each millilitre (mL) contains 50 micrograms of latanoprost and 5 milligrams of timolol as timolol maleate

What the important nonmedicinal ingredients are:
Benzalkonium chloride (preservative), sodium chloride, sodium dihydrogen phosphate monohydrate, disodium hydrogen phosphate anhydrous, water for injection, hydrochloric acid and sodium hydroxide.

What dosage forms it comes in:
GD-LATANOPROST/TIMOLOL is supplied in a 5 mL plastic ophthalmic dispenser bottle with a dropper tip, screw cap and tamper proof overcap.

WARNINGS AND PRECAUTIONS

Before using GD-LATANOPROST/TIMOLOL, talk to your doctor or pharmacist if:
- You are allergic to any of the ingredients in GD-LATANOPROST/TIMOLOL.
- You have a respiratory disease such as asthma, have a history of asthma, or have chronic obstructive pulmonary disease (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough).
- You have disturbances of heart rate such as slow heart beat (bradycardia).
- You have certain heart diseases or conditions – symptoms can include chest pain or tightness, breathlessness or choking, heart failure, low blood pressure (hypotension).
- You have problems with your blood pressure or thyroid function.
- You have poor blood circulation disease (peripheral arterial disease such as Raynaud's disease or Raynaud's syndrome).
- You have diabetes or have low blood sugar levels.
- You have or have had muscle weakness or have been diagnosed as having myasthenia gravis.
- 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 are planning a surgery
- You have kidney or liver disease

Tell your doctor before you have an operation that you are using GD-LATANOPROST/TIMOLOL as Timolol Maleate may change effects of some medicines used during anaesthesia.

GD-LATANOPROST/TIMOLOL contains a preservative (benzalkonium chloride) that may be absorbed by contact lenses. The preservative may form a precipitate with an ingredient (thimerosal) present in several contact lens soaking solutions. If you wear contact lenses, remove them before using GD-LATANOPROST/TIMOLOL. Wait 15 minutes after applying the eye drops before putting your lenses back in. 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

GD-LATANOPROST/TIMOLOL 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 or other medicines including:
- calcium channel blockers, beta-adrenergic blocking agent
- antiarrhythmics (e.g. amiodarone, quinidine),
- monoamine oxidase inhibitors
- narcotics
- digitalis, fluoxetine, paroxetine

PROPER USE OF THIS MEDICATION

Always use GD-LATANOPROST/TIMOLOL exactly as your doctor has told you.
Usual adult dose:
One drop of GD-LATANOPROST/TIMOLOL should be dropped into the affected eye(s) once daily.

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.

Follow these steps to help you use GD-LATANOPROST/TIMOLOL properly:

1. Wash your hands and sit or stand comfortably. If you wear contact lenses, remove them before using your eye drops.
2. Twist off the outer protective cap from the bottle.
3. Unscrew the inne  e bottle.
4. Once the bottle i  old it in one hand and steady your thum[illegible] our brow or the bridge of your nose.
5. Use your index finger to gently pull down the lower eyelid of the affected eye(s) to create a pocket for the drop.
6. Gently press, or  he 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.
7. Close your eye for 2 to 3 minutes.
8. If your doctor has told you to use drops in both eyes, repeat the process for the other eye. GD-LATANOPROST/TIMOLOL should be used until your doctor tells you to stop.

GD-LATANOPROST/TIMOLOL is not recommended for use in children.

Overdose:

In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional poison control centre, even if there are no symptoms.

Missed Dose:

If you forget one dose of GD-LATANOPROST/TIMOLOL, continue with the next dose as normal. Do not double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

In some patients, GD-LATANOPROST/TIMOLOL may cause a gradual change in eye color by increasing the amount of brown pigment in the iris (the colored part of the eye). This change may not be noticeable for several months to years. This effect may be more noticeable in patients with eye colors that are mixtures of green and brown, blue/gray and brown, or yellow and brown. The brown pigment may gradually spread outward toward the outside edge of the iris. However, the entire iris or parts of it may become more brownish in appearance. This change may be more noticeable if you are only treating one eye. Therefore, there is the potential for permanent difference in the colour between the treated and the untreated eyes. Your doctor will examine you regularly to make sure that your medication is working and look for changes in eye color. If you should experience any changes in eye color, your doctor can stop treatment. However, any color change that has already occurred may be permanent, even after the medication is stopped.

GD-LATANOPROST/TIMOLOL may also cause your eye lashes to darken, appear thicker and longer than they usually do. A very small number of people may notice their eye lid skin looks darker after using GD-LATANOPROST/TIMOLOL for some time. These changes may be more noticeable if you are only treating one eye. GD-LATANOPROST/TIMOLOL may also cause your eye lashes to become ingrown.

GD-LATANOPROST/TIMOLOL may cause iris cyst (small cyst appearing in the colored part of the eye).

When using GD-LATANOPROST/TIMOLOL, you might feel as if there is something in your eye(s). Your eye(s) might water and become red. 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 GD-LATANOPROST/TIMOLOL 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 more difficult. Although unlikely, if you experience any of these changes, stop using GD-LATANOPROST/TIMOLOL and contact your doctor immediately.

GD-LATANOPROST/TIMOLOL may cause the following side effects as well.

Common side effects: eye irritation, including burning and stinging, inflammation of the eye lid and eye pain, upper respiratory tract infection.

Effects on the body: headache and skin rash, loss of appetite, muscle pain, joint pain, chest pain, heart palpitations, asthma, low blood sugar in diabetics, dry eyes, nervous system effects including anxiety, nervousness, dizziness, confusion, disorientation, insomnia, hallucinations.

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 DO ABOUT THEM

Symptom/Effect		Talk with your doctor or pharmacist		Stop taking the drug and seek emergency medical assistance
		Only if severe	In all cases	
Rare	Heart effects such as irregular heartbeat, high blood pressure and low blood pressure			✓
	Severe respiratory reactions has been reported with administration of timolol			✓

Symptom/Effect		Talk with your doctor or pharmacist		Stop taking the drug and seek emergency medical assistance
		Only if severe	In all cases	
Rare	Allergic reactions with symptoms such as swelling of the mouth, and throat, difficulty breathing, hives, itching, rash.			✓
	Beta adrenergic blockers (e.g. timolol) have been reported to cause muscle weakness in those with myasthenia gravis or similar conditions			✓

HOW TO STORE IT

Always keep medicine well out of the reach of children.

Before GD-LATANOPROST/TIMOLOL is first opened, keep it in a fridge (between 2°C and 8°C), out of direct light.
Once the bottle has been opened, GD-LATANOPROST/TIMOLOL can be kept at normal room temperature up to 25°C, out of direct light. GD-LATANOPROST/TIMOLOL must be used within 10 weeks after opening the bottle. Discard the bottle and/or unused contents after 10 weeks. GD-LATANOPROST/TIMOLOL should not be used after the expiry date on the bottle.

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 1908C
    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

Patients can refer to www.Pfizer.ca for further 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, Upjohn Canada ULC, at: 1-800-463-6001

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Upjohn Canada ULC
Kirkland, Québec H9J 2M5