PRESCRIBING INFORMATION

Pr ALCON ATROPINE

Atropine Sulfate Ophthalmic Solution, BP

1% w/v

Sterile

Cycloplegic - Mydriatic

Alcon Canada Inc.
2665 Meadowpine Blvd.
Mississauga, ON, Canada L5N 8C7
www.alcon.ca

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Pr ALCON ATROPINE

atropine sulfate ophthalmic solution, BP

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Topical (ophthalmic)	Solution/ 1% w/v	Benzalkonium chloride as preservative. *For a complete listing see Dosage Forms, Composition and Packaging section.*

INDICATIONS AND CLINICAL USE

ALCON ATROPINE (atropine sulfate ophthalmic solution, BP) is a cycloplegic and mydriatic agent indicated for uveitis and refraction.

Geriatrics (> 65 years of age):
Elderly patients may be at a higher risk for undiagnosed glaucoma as well as atropine-induced psychotic reactions and behavioural disturbances.

Pediatrics (< 12 years of age):
ALCON ATROPINE is contraindicated in pediatric patients <12 years of age because of the risk of serious systemic side effects.

CONTRAINDICATIONS

ALCON ATROPINE is contraindicated in:

- Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see the Dosage Forms, Composition and Packaging section of the Prescribing Information.
- Patients with known or suspected angle-closure glaucoma.
- Children less than 12 years of age.
- Children with Down's syndrome, spastic paralysis or brain damage.

WARNINGS AND PRECAUTIONS

General
FOR TOPICAL OPHTHALMIC USE ONLY.

ALCON ATROPINE may provoke hyperthermia and should be used with caution in patients, especially children, who may be exposed to elevated environmental temperatures or who are febrile.

Atropine may cause drowsiness, blurred vision and sensitivity to light. Patients receiving ALCON ATROPINE should be advised not to drive or use machinery until their vision clears.

Nasolacrimal occlusion or gently closing the eyelid after administration is recommended. This may reduce the systemic absorption of medicinal ingredients administered via the ocular route and result in a decrease in systemic adverse reactions.

Ophthalmologic
ALCON ATROPINE may cause increased intraocular pressure (IOP) and provoke glaucoma attacks in patients predisposed to acute angle closure. The possibility of undiagnosed glaucoma should be considered in some patients, in particular geriatric patients. To avoid glaucoma attacks, IOP and an estimation of the depth of the angle of the anterior chamber should be determined prior to initiation of therapy.

Patients may experience sensitivity to light and should be advised to protect their eyes in bright illumination.

ALCON ATROPINE contains the preservative benzalkonium chloride, which may cause eye irritation and is known to discolour soft contact lenses. Contact with soft contact lenses is to be avoided. Patients should be instructed to remove contact lenses prior to applying ALCON ATROPINE and to wait at least 15 minutes before re-inserting contact lenses.

Psychiatric
ALCON ATROPINE may induce psychotic reactions and behavioural disturbances in patients with increased susceptibility to anticholinergic drugs. Reactions may occur at any age. Caution is advised when treating pediatric and elderly patients.

Sexual Function/Reproduction
Studies have not been performed to evaluate the effects of topical ocular administration of atropine in fertility.

Special Populations

Pregnant Women: There are no or limited amount of data from the use of ALCON ATROPINE in pregnant women. There are documented systemic effects stemming from ophthalmic atropine use. ALCON ATROPINE should only be used to treat pregnant women

when the benefit to the mother outweighs the potential risk to the fetus.

Nursing Women: It is unknown whether ALCON ATROPINE is excreted in human breast milk. However, atropine and antimuscarinic agents have been shown to adversely affect lactation in preclinical and in clinical studies. Because many drugs are excreted in human milk, caution should be exercised when ALCON ATROPINE is administered to nursing women.

Pediatrics (< 12 years of age): ALCON ATROPINE is contraindicated in pediatric patients < 12 years of age.

Pediatrics (≥ 12 years of age): Children, especially premature and low birth weight, or patients with Down syndrome, spastic paralysis or brain damage are particularly susceptible to central nervous system disturbances, cardiopulmonary and gastrointestinal toxicity from systemic absorption of atropine. ALCON ATROPINE should be used with extreme caution, if at all, in children ≥ 12 years of age with Down syndrome, spastic paralysis or brain damage.

Fair-skinned children with blue eyes may exhibit an increased response and/or increased susceptibility to adverse reactions.

Parents should be warned not to get this preparation in their children's mouth or cheeks and to wash their hands and their child's hand or cheeks following administration.

Geriatrics (> 65 years of age): Elderly patients may be at a higher risk of undiagnosed glaucoma as well as atropine-induced psychotic reactions and behavioural disturbances.

ADVERSE REACTIONS

Adverse Drug Reaction Overview

ALCON ATROPINE produces reactions similar to those of other anticholinergic drugs. Central nervous system manifestations, such as ataxia, incoherent speech, restlessness, hallucinations, hyperactivity, seizures, disorientation as to time and place, and failure to recognize people are possible. Other toxic manifestations of anticholinergic drugs are skin rash, abdominal distension in infants, unusual drowsiness, tachycardia, hyperpyrexia, vasodilation, urinary retention, diminished gastrointestinal motility, and decreased secretion in salivary and sweat glands, pharynx, bronchi and nasal passages. Severe reactions are manifested by hypotension with rapid progressive respiratory depression.

Symptoms of toxicity are usually transient (lasting a few hours), but may last up to 24 hours.

Prolonged use of mydriatics may produce local irritation characterized by conjunctivitis (follicular), ocular hyperemia, eye edema, eye discharge and eczema.

Pediatric Population: Use of ALCON ATROPINE has been associated with psychotic reactions and behavioural changes in pediatric patients (see WARNINGS AND PRECAUTIONS,

Psychiatric). Central nervous system reactions manifest similar to those listed above.

ALCON ATROPINE can cause hyperpyrexia in children (see WARNINGS AND PRECAUTIONS, General).

Increased risk for systemic toxicity has been observed in children, especially premature and low birth weight, or patients with Down syndrome, spastic paralysis or brain damage with this class of drug. Intestinal obstruction, abdominal distension and bradycardia were reported in premature or low birth weight infants.

Post-Market Adverse Drug Reactions

The following adverse reactions have been identified from post-marketing surveillance:
Cardiac disorders: bradycardia, tachycardia
Eye disorders: drug effect prolonged (mydriasis), eyelid edema, photophobia, vision blurred
Gastrointestinal disorders: abdominal distension, intestinal obstruction, vomiting
General disorders and administration site conditions: pyrexia
Immune system disorders: hypersensitivity
Nervous system disorders: dizziness, headache
Psychiatric disorders: confusional state, disorientation, hallucination
Skin and subcutaneous tissue disorders: erythema, rash

DRUG INTERACTIONS

No specific drug interaction studies have been performed with ALCON ATROPINE. The effects of ALCON ATROPINE may be enhanced by concomitant use of other drugs having antimuscarinic properties, such as amantadine, some antihistamines, phenothiazine antipsychotics, and tricyclic antidepressants.

DOSAGE AND ADMINISTRATION

Recommended Dose

For uveitis: Apply one drop in the eye(s) three times daily.

For cycloplegic refraction: Apply one drop in the eye(s) three times daily for three days. Repeat 1 hour prior to examination.

Missed Dose

In the case of a missed dose, the patient should be advised to take the dose as soon as they remember. However, if it is close to the next scheduled dose, the missed dose should be skipped. A double dose should not be taken to make up for the missed dose.

Administration

Nasolacrimal occlusion or gently closing the eyelid after administration is recommended to reduce systemic absorption of ALCON ATROPINE (see **WARNINGS AND PRECAUTIONS**, **General**).

OVERDOSAGE

Systemic toxicity may occur following topical overdose, particularly in children. It is manifested by flushing and dryness of the skin (a rash may be present in children), blurred vision, a rapid and irregular pulse, fever, abdominal distension in infants, convulsions and hallucinations and the loss of neuromuscular coordination. Severe intoxication is characterized by central nervous system depression, coma, circulatory and respiratory failure, and death.

Treatment should be symptomatic and supportive.

In case of accidental use/overdose in infants and small children, the body surface must be kept moist.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

STORAGE AND STABILITY

Keep tightly closed. Store at room temperature. Avoid excessive heat. Keep out of the reach and sight of children.

DOSAGE FORMS, COMPOSITION AND PACKAGING

ALCON ATROPINE is a sterile, topical ophthalmic solution containing the following:
Medicinal ingredient: atropine sulfate, 1% w/v
Preservative: benzalkonium chloride
Non-medicinal ingredients: boric acid, hydroxypropyl methylcellulose, sodium hydroxide and/or hydrochloric acid (to adjust pH), purified water.

ALCON ATROPINE is supplied in 5 mL DROP-TAINER™ dispensers.

Tamper evidence is provided by a closure with an extended skirt that locks to the bottle finish on application and breaks away from the closure on opening. After cap is removed: if tamper evidence snap collar is loose, remove before using product.

CONSUMER INFORMATION

Pr ALCON ATROPINE
atropine sulfate ophthalmic solution, BP

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

ABOUT THIS MEDICATION

What the medication is used for:
ALCON ATROPINE is used to:
- Treat inflammation of the uvea (*uveitis)*, a structure of the eye.
- Temporarily freeze the muscles of the eye for a test known as cycloplegic refraction.

What it does:
ALCON ATROPINE contains atropine sulfate, which works on two types of muscles in the eye (*sphincter* and *accommodative*). The result is:
- Increasing the pupil size, which may help prevent scar tissue from forming between the lens and the iris, in patients with uveitis.
- Temporary paralysis of some muscles in the eye and increasing the pupil size for cycloplegic refraction.

When it should not be used:
Do NOT use ALCON ATROPINE if you or your child:
- Are allergic to atropine sulfate or any other of the ingredients in ALCON ATROPINE (see What the important nonmedicinal ingredients are).
- Have or think you may have angle-closure glaucoma.
- Are under the age of 12 years.
- Has Down's syndrome, spastic paralysis or brain damage.

What the medicinal ingredient is:
Atropine sulfate, 1% w/v

What the important nonmedicinal ingredients are:
Preservative: benzalkonium chloride
Others: boric acid, hydroxypropyl methylcellulose, sodium hydroxide and/or hydrochloric acid (to adjust pH) and purified water.

What dosage forms it comes in:
Sterile eye drop in 5 mL DROP-TAINER™ bottle.

WARNINGS AND PRECAUTIONS

BEFORE you use ALCON ATROPINE, talk to your doctor or pharmacist if you or your child:
- Have a fever or are exposed to hot temperatures. ALCON ATROPINE may cause your body temperature to rise.
- Have Down syndrome, spastic paralysis, brain damage or fair skin and blue eyes. Your child may be a higher risk of developing serious side effects.
- Are taking any other medicines.
- Are pregnant, may be pregnant, or are planning to become pregnant. Your doctor will only prescribe ALCON ATROPINE if the benefit to you is greater than the possible risk to your fetus.
- Are breastfeeding or planning to breast-feed.

STOP using ALCON ATROPINE and talk to your doctor if you or your child:
- Develop any signs of toxicity, such as flushing, dryness of the skin, a rash in children, blurred vision, rapid and irregular heartbeat, fever, fits (*convulsions*), hallucinations or loss of coordination.

While using ALCON ATROPINE
ALCON ATROPINE may increase the pressure in your eyes (*intraocular pressure)*. Your doctor should check the pressure in your eyes regularly, especially if you are elderly.

ALCON ATROPINE may cause your eyes to become more sensitive to light. Protect your eyes in bright light.

ALCON ATROPINE may cause changes in behaviour, such as restlessness, hyperactivity, troubled speech, confusion and hallucinations. This can happen at any age, but is more likely to happen in children and the elderly. Talk to your doctor or pharmacist if this happens.

Contact lens wearers
ALCON ATROPINE contains the preservative benzalkonium chloride, which is known to affect soft contact lenses. Remove your contact lenses before using ALCON ATROPINE and wait at least 15 minutes before putting your contact lenses back in.

Driving and Using Machines
ALCON ATROPINE may cause drowsiness, blurry vision or sensitivity to light. If any of these effects happen to you, wait until they clear before driving or using machines.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist about all the medicines you take, recently took or are planning to take, including those without a prescription.

Drug interaction studies have not been done for ALCON ATROPINE.

Drugs that may interact with ALCON ATROPINE include:
- Amantadine (a medicine used to treat Parkinson's disease and influenza A infections).
- Antihistamines.
- Antipsychotics.
- Antidepressants.

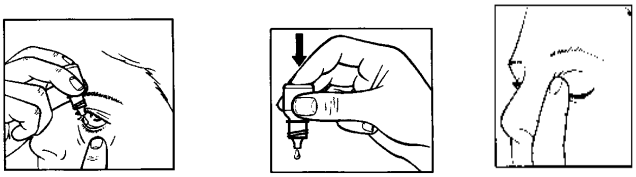
PROPER USE OF THIS MEDICATION

Always use ALCON ATROPINE exactly as your doctor has told you.

Usual dose – adults and children over 12 years of age:
Uveitis: apply 1 drop in the affected eye(s) 3 times a day.

Cycloplegic refraction: apply 1 drop in the affected eye(s) 3 times a day for 3 days. Apply 1 drop in the affected eye(s) 1 hour before your scheduled eye examination.

How to use:



1 2 3

- Get the ALCON ATROPINE bottle and a mirror.
- Wash your hands.
- Twist off the bottle cap.
- After cap is removed: if security snap collar is loose, remove before using product.
- 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.
- Gently press on the base of the bottle to release one drop of ALCON ATROPINE 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).
- If you miss a drop, try again. If you accidentally get a drop on your skin, wipe it off.
- After using ALCON ATROPINE, press a finger into the corner of your eye by the nose (picture 3). This helps to stop ALCON ATROPINE getting into the rest of the body and may lower the chances of getting side effects in the body.
- If you use drops in both eyes, repeat the steps for your other eye.
- Close the bottle cap firmly immediately after use.
- Wash your hands after use.

If you are using other eye drops, wait at least 5 to 10 minutes before between applying ALCON ATROPINE and the other drops. Eye ointments should be added last.

Instructions for parents:
Do NOT get ALCON ATROPINE in your child's mouth or cheeks. Wash your hands and your child's mouth and cheeks after using ALCON ATROPINE.

Overdose:
If you use more ALCON ATROPINE than you should, rinse it out with warm water. Do not apply any more drops until it is time for your next regular dose.

Signs of an overdose may include: flushing and dryness of the skin, rash in children, blurred vision, rapid and irregular heart rate, fever, convulsions, hallucinations or loss of coordination.

If you think you, or a person you are caring for, have taken too much ALCON ATROPINE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:
If you forget to use ALCON ATROPINE, use a single dose as soon as you remember. If it is almost time for the next dose, leave out the missed dose and continue with the next dose of your regular routine. Do not use a double dose to make up for a missed dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

Side effects observed with ALCON ATROPINE include eyelid swelling, sensitivity to light, increase in pupil size, dizziness, headache, allergy, intestinal blockage, abdominal swelling, vomiting, skin inflammation or redness and rash.

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	
Unknown	Toxic effects (may include) flushing and dryness of the skin, a rash in children, blurred vision, rapid and irregular heartbeat, fever, fits, hallucination, loss of coordination, state of confusion or disorientation			✓

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**
Unknown	Allergic reaction (symptoms include swelling of mouth or tongue, shortness or breath, hives, severe itching or rash)			✓

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

HOW TO STORE IT

Store at room temperature. Avoid excessive heat. Keep tightly closed. Keep 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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) 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

This document plus the full prescribing information, prepared for health professionals can be found at:
www.alcon.ca
or by contacting the sponsor,
Alcon Canada Inc., at:
1-800-613-2245.

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