

**PROPOSED CLEAN PATIENT INFORMATION LEAFLET**

**MODULE 1.3.2**

**ISOPTO ATROPINE 1 % Eye Drops**

## **PROPOSED CLEAN PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:**

**S3**

### **ISOPTO® ATROPINE 1 % Eye Drops, Solution**

#### **Atropine**

**Read all of this leaflet carefully before you start taking ISOPTO®**

#### **ATROPINE**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider
- ISOPTO ATROPINE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

#### **What is in this leaflet**

1. What ISOPTO ATROPINE is and what it is used for
2. What you need to know before you use ISOPTO ATROPINE
3. How to use ISOPTO ATROPINE
4. Possible side effects
5. How to store ISOPTO ATROPINE

## 6. Contents of the pack and other information

### 1. What ISOPTO ATROPINE is and what it is used for

ISOPTO ATROPINE is an eye drops to dilate the pupil of the eye and to relax the iris muscle

### 2. What you need to know before you use ISOPTO ATROPINE

#### **Do not use ISOPTO ATROPINE**

- if you are hypersensitive (allergic) to atropine or any of the other ingredients of ISOPTO ATROPINE (listed in section 6).
- if you have high eye pressure (glaucoma).
- if you are younger than 3 years.

#### **Warnings and precautions**

Special care should be taken with ISOPTO ATROPINE:

- Use extreme caution if ISOPTO ATROPINE is used in children aged 12 years and older and those with Down syndrome, spastic paralysis or brain damage
- have your eye pressure checked regularly and before using the drops if
- you are elderly or at risk of developing glaucoma
  - protect your eyes in bright illumination if your eyes are sensitive to light
  - tell your doctor if you are exposed to a hot environment or have a fever, as your body may overheat

- have regular eye examinations if you have a thin or damaged cornea to prevent further damage

### **Other medicines and ISOPTO ATROPINE**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Especially tell your doctor if you are taking any of the following medicines as they may cause the effects of ISOPTO ATROPINE to become stronger:

- Amantadine for Parkinson's disease
- Anti-histamines for allergies, colds
- Anti-psychotics for nervous disorders
- Anti-depressants for nervous disorders

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using ISOPTO ATROPINE.

### **Driving and using machines**

ISOPTO ATROPINE may cause drowsiness, blurred vision and sensitivity to light. Do not drive or use any tools or machines until your vision clears.

### **ISOPTO ATROPINE contains benzalkonium chloride**

Benzalkonium chloride, a preservative may cause eye irritation and is also known to discolour soft contact lenses.

If you wear contact lenses remove them before using ISOPTO ATROPINE and wait at least 15 minutes before putting them back.

### **3. How to use ISOPTO ATROPINE**

Do not share medicines prescribed for you with any other person.

Always take ISOPTO ATROPINE exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

ISOPTO ATROPINE is only for use as an eye drop.

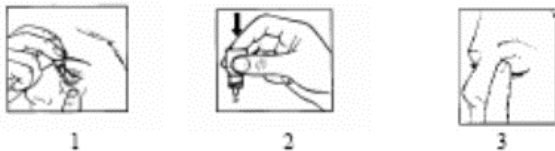
The usual dose for eye examination

- Place one drop in the one eye or both eyes twice daily for 1 to 2 days before examination and 1 drop 1 hour before examination.

The usual dose for inflammation

- Place 1 drop in the one eye or both eyes 3 times daily.

#### **Directions for use**



- a) Wash your hands.
- b) Twist off the bottle cap and remove the snap collar to avoid it falling into the eye.

- c) If you are wearing contact lenses, remove them before instilling ISOPTO ATROPINE. Wait for 15 minutes before reinserting them.
- d) Hold the bottle, pointing down, between your thumb and fingers.
- e) Tilt your head back. Pull down on your eyelid with a finger so that the eyelid forms a 'pocket' with your eye. (picture 1).
- f) Bring the bottle tip close to the eye. Use a mirror if it helps.
- g) Do not touch your eye or eyelid or any surface with the dropper. It could infect the drops.
- h) Gently press on the base of the bottle to release one drop of ISOPTO ATROPINE into the 'pocket'.
- i) Do not squeeze the bottle; a gentle press on the bottom is all that is needed (picture 2).
- j) Close your eyelid and press a finger gently into the corner of your eye, next to your nose (picture 3) and hold for 1 or 2 minutes. This helps to stop ISOPTO ATROPINE getting into the rest of the body and causing side effects.
- k) If you have been instructed to use drops in both eyes, repeat these steps for your other eye.
- l) If a drop misses your eye, try again.
- m) If you use more drops than you should, rinse it all out with warm water. Do not put in any more drops until it is time for your next regular dose.
- n) Close the bottle cap firmly immediately after use.

- o) If you are using other eye drop or eye ointment medicines, leave at least 5 minutes between each medicine. Eye ointments should be administered last.

Your doctor will tell you how long your treatment with ISOPTO ATROPINE will last. If you have the impression that the effect of ISOPTO ATROPINE is too strong or too weak, tell your doctor or Pharmacist.

**If you take more ISOPTO ATROPINE than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre. Symptoms include flushing and dryness of the skin, rash in children, blurred vision, a rapid and irregular pulse, fever, convulsions and hallucinations.

**If you forget to take ISOPTO ATROPINE**

Continue with the next dose as planned and go back to your regular dosing schedule.

Do not use a double dose to make up for forgotten individual doses.

**If you stop taking ISOPTO ATROPINE**

Do not stop treatment early because the inflammation will not be controlled and can lead to blindness.

#### **4. Possible side effects**

ISOPTO ATROPINE can have side effects.

Not all side effects reported for ISOPTO ATROPINE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ISOPTO ATROPINE, please consult your health care provider for advice.

The following reactions have been reported, the frequency is not known:

*Effects in the eye:*

Eyelid swelling, sensitivity to light, blurred vision, increase in pupil size

*General side effects:*

allergy, hallucination, confusion, disorientation, dizziness, headache, increase or decrease in heart rate, intestinal blockage, abdominal distension, vomiting, skin inflammation or redness, rash, fever.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

#### **Reporting of side effects**

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects you can help provide more information on the safety of ISOPTO

ATROPINE.

### **5. How to store ISOPTO ATROPINE**

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep the container tightly closed.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

### **6. Contents of the pack and other information**

#### **What ISOPTO ATROPINE contains**

The active substance is atropine.

The other ingredients are boric acid, methyl hydroxy propyl cellulose, purified water.

Preserved with benzalkonium chloride 0,01 % (m/v).

#### **What ISOPTO ATROPINE looks like and contents of the pack**

A clear, colourless liquid.

Natural low density polyethylene bottle fitted with a natural dispensing tip as plug and a liner-less red polypropylene cap and containing 5 ml.

**Holder of certificate of registration**

ISOPTO Laboratories (SA) (Pty) Ltd

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2090

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