SCHEDULING STATUS: S3

ATROPINE EYE DROPS, 10 mg/ ml, Sterile eye drops

Atropine sulphate

Contains benzalkonium chloride 0,01 % *m/v* and boric acid 0,40 % *m/v* (as preservatives)

Read all of this leaflet carefully before you start using ATROPINE EYE DROPS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.
- ATROPINE EYE DROPS 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 ATROPINE EYE DROPS is and what it is used for

Atropine sulphate belongs to groups of medicines called mydriatics (medicines that widen the pupil) and cycloplegics (medicines used to relax the muscles which enable the eyes to focus).

This medicine is used to treat inflammation in the eye (uveitis or iritis) and before certain eye examinations.

2. What you need to know before you use ATROPINE EYE DROPS

Do not use ATROPINE EYE DROPS:

- if you are hypersensitive (allergic) to atropine sulphate or any of the other ingredients of ATROPINE EYE DROPS (listed in section 6).
- if you are allergic to a group of medicines called belladonna alkaloids (ATROPINE EYE DROPS belongs to this group).
- if you have or think you may have closed angle glaucoma (increased pressure in the eyes).
- if you are younger than 6 years old.

Warnings and precautions

Take special care with ATROPINE EYE DROPS:

- If you have increased pressure in the eyes, especially if the space between the coloured part of your eye (iris) and clear layer at the front of the eye (cornea) is narrow or if the space between your iris and cornea is narrow angle (more closed). Ask your doctor if you are unsure. The pressure in your eyes should be measured regularly, including before start of treatment.
- Behavioural change, especially in elderly patients, but such a reaction may occur at any age.
- If you have a fever or if you are exposed to high ambient temperatures.
- Sensitivity to light. You have to protect your eyes from light.

Children

ATROPINE EYE DROPS are contraindicated in children younger than 6 years of age “see Do Not use ATROPINE EYE DROPS”.

Other medicines and ATROPINE EYE DROPS

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

Including:

- antihistamines (anti-allergy medicines)
- medicines used to treat depression

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 healthcare provider for advice before using ATROPINE EYE DROPS.

Do not use ATROPINE EYE DROPS if you are pregnant or breastfeeding your baby.

Driving and using machines

ATROPINE EYE DROPS eye drops may cause drowsiness, blurred vision and sensitivity to light.

It is not always possible to predict to what extent ATROPINE EYE DROPS may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which ATROPINE EYE DROPS affects you.

ATROPINE EYE DROPS contains benzalkonium chloride

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15

minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use ATROPINE EYE DROPS

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

Always use ATROPINE EYE DROPS exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Inflammation of the eye (uveitis/iritis):

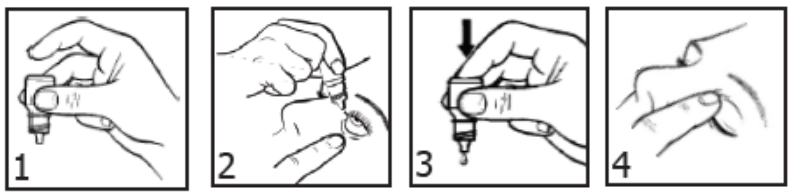
1 drop to be dropped into the eye(s), 3 times daily.

Eye disorder which may cause blurred vision (refraction):

1 drop to be dropped into the eye(s) twice daily for one to two days before examination and one hour before examination.

Method of administration

If you are putting the eye drops in yourself, then follow these instructions carefully:



1. Wash your hands and sit in front of a mirror.
2. Unscrew the bottle cap.

3. Hold the bottle between the thumb and forefinger pointing it downward (Fig.1).
4. Tilt your head back. Pull down the lower eyelid with a clean finger to form a "pocket" between the lower eyelid and the eye. The drop should fall into this place (Fig.2).
5. Place the tip of the bottle close to the eye. Use a mirror if it helps.
6. Avoid contact between the tip of the bottle and the eye or eyelid, adjacent area, or other surfaces. This can contaminate the solution in the bottle.
7. Do not squeeze the bottle. It is designed such that only a gentle press at the bottom is sufficient (Fig.3).
8. Press the bottom of the bottle gently to release a drop of ATROPINE EYE DROPS.
9. After using ATROPINE EYE DROPS, close the eyelid and gently press the inner corner of your eye with your finger for 2 minutes (Fig.4). This will prevent ATROPINE EYE DROPS from reaching the body.
10. If you need to use ATROPINE EYE DROPS for both eyes, repeat steps 5 to 10 for the other eye.
11. Screw the cap tightly after use.

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

If you use more ATROPINE EYE DROPS than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Possible symptoms of overdose is: fast and irregular pulse, restlessness, confusion, hallucinations and loss of coordination or ventilation of the lungs is inadequate.

If you forget to use ATROPINE EYE DROPS

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

If you stop using ATROPINE EYE DROPS

Do not stop using ATROPINE EYE DROPS without consulting your doctor.

4. Possible side effects

ATROPINE EYE DROPS can have side effects.

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

If any of the following happens, stop using ATROPINE EYE DROPS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to ATROPINE EYE DROPS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- photosensitivity

- eye pain
- visual disturbance

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- increased pressure in the eyes

Side effects with unknown frequency:

- swelling of the eyelid
- blurred vision
- dilation of the pupils (prolonged effect of the medicine)
- conjunctivitis
- redness of the eyes
- swelling of the eyes
- secretion of the eyes
- respiratory depression

Systemic reactions

Frequent side effects:

- hallucinations
- confusion
- agitation
- increased heart rate
- constipation

- flushing
- fever

Side effects with unknown frequency:

- coordination disorders
- dizziness
- headache
- slurred speech
- anxiety
- inability to recognize other people
- unusual drowsiness
- hyperactivity
- convulsions
- slow heart rhythm
- low blood pressure
- dilated blood vessels
- decreased secretion of salivary and sweat glands, pharynx, bronchi and nose
- intestinal obstruction
- bloating
- vomiting
- decreased intestinal motility
- decreased saliva, dry mouth
- inflammation or redness of the skin
- dry skin
- difficulty urinating

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, 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 ATROPINE EYE DROPS.

5. How to store ATROPINE EYE DROPS

Store at or below 25 °C. Protect from light and moisture.

Discard 30 days after opening.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the label / carton / bottle

The expiry date refers to the last day of that month.

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 ATROPINE EYE DROPS contains

The active ingredient is atropine sulphate 10 mg/ml.

The other ingredients are benzalkonium chloride solution 50 % *m/v,* boric acid, disodium edetate, hydrochloric acid 32 % (2N solution), sodium carbonate monohydrate, sodium chloride, sodium hydroxide (2N solution) and water for injection.

What ATROPINE EYE DROPS looks like and contents of the pack

Clear colourless solution.

ATROPINE EYE DROPS are packed in 10 ml white dropper bottle with a natural/clear dropper insert and a maroon screw-on cap.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand ,1685

Customer Care: 0860 ADCOCK / 232625

This leaflet was last revised in

28 October 2022

Registration number

J/15.4/312

Botswana: [S2] B9302845

Namibia: [NS2] 90/15.4/0097