

1.6.3 Patient Information leaflet (PIL)

Patient information Leaflet (AUROMIDE PLUS (Tropicamide (0.8% w/v) + Phenylephrine HCl (5% w/v))

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What Tropicamide+PhenylephrineHCl Eye Drops is and what it is used for
2. Before you use Tropicamide+PhenylephrineHCl Eye Drops
3. How to use Tropicamide+PhenylephrineHCl Eye Drops
4. Possible side effects
5. How to store Tropicamide+PhenylephrineHCl Eye Drops
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1. What Tropicamide+PhenylephrineHCl Eye Drops is and what it is used for

AuromidePlus Eye Drop is a combination of two medicines: Phenylephrine HCl and Tropicamide. Phenylephrine HCl is a decongestant while Tropicamide is an anticholinergic. They work by making the pupil of your eye larger and relax the muscles in your eye. This allows proper examination of the inside of your eye.

2. Before you use Tropicamide+PhenylephrineHCl Eye Drops

Do not use these drops if

- You are allergic to the active substance or any of the other ingredients (refer to the end of this leaflet).
- You have history of closed angle glaucoma with your eyes likely to develop sudden increased internal pressure when the pupil is enlarged

Consult your doctor for advice; use of this product may cause: - Increase in the pressure of your eye. You should have your eye pressure checked before initiation of therapy, especially in elderly.

Take special care

Ask yourself the following questions:

- Is this product to be used in a small child?
- Are your eyes red or inflamed?

If the answer to any of these questions is yes, tell your doctor or eye specialist.

If you are pregnant, may be pregnant, or are breastfeeding Tell your doctor or eye specialist, he/she may decide to use these drops or to prescribe you an alternative.

Contact lenses

Your doctor will ask you to remove your contact lenses prior to the administration of the drops. There is no information on the effect of this product on contact lenses. Therefore, do not wear your contact lenses until the effects of the drops have completely worn off.

Driving and using machines

Some people find bright light (such as daylight) uncomfortable for a few hours after receiving Tropicamide eye drops. This may make it difficult for you to drive. As with all eye drops, your vision may be blurred after putting the drops in. Wait until your vision is clear before driving or using machines.

3. How to use Tropicamide + Phenylephrine HCl Eye Drops

The drops are for single use only and provided in single use Tropicamide+PhenylephrineHCl eye drops units, to treat both eyes if necessary. Once opened, use immediately. Discard any unused portion.

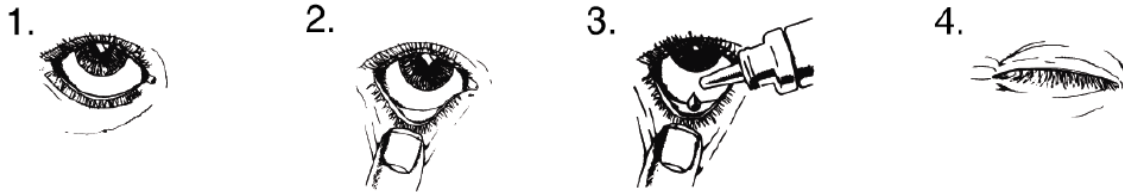
Dosage:

- The normal adult dose is 1 drop followed by a second drop after an interval of 5 minutes. A further 1 drop may be instilled after 30 minutes, if required.
- The dose for children will be decided by the doctor or eye specialist.

Method of administration

Make sure you follow these instructions carefully:

1. Wash your hands.
2. Use a mirror, this will help you to see what you are doing.
3. Carefully dry your eyes using a tissue, and twist off the cap from the Tropicamide + Phenylephrine HCl eye drops body of the unit.
4. Pull your lower eyelid down gently, and then carefully place 1 or 2 drops inside your lower eyelid.
5. Close your eye and blink a few times to make sure your eye is covered by the liquid.
6. Close the eyelids. It is advisable to press gently on the inner corner of your eyelid for 3 minutes. This will help stop the solution draining into your nose and throat. This is especially advisable in children, the elderly and population at risk.
7. Repeat steps 4, 5 and 6 for the other eye if necessary, then throw away the Tropicamide + Phenylephrine HCl eye drops unit, even if some solution remains. If you use more Tropicamide than you should, an overdose is very unlikely to occur. If you suddenly feel unwell after receiving the drops, tell your doctor or eye specialist or contact your nearest emergency department immediately



If a drop misses your eye, try again.

4. Possible side effects

The following side effects may occur:

- Temporary stinging and blurred vision. This will gradually wear off.
- Dry mouth. This is caused by the active substance being absorbed through the tear duct and causing a common effect for this type of medicine. This effect should wear off within a couple of hours.

If any of the side effects gets serious, please seek immediate medical attention. If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

5. How to store Tropicamide+PhenylephrineHCl Eye Drops

Keep out of the reach and sight of children.

Do not use the eye drops after the expiry date which is stated on the overwrap of each unit and on the carton after the letters "EXP". The expiry date refers to the last day of that month.

Do not store above 30°C. Do not freeze. Store in the original package in order to protect from light.

The drops are for single use only and provided in single use Tropicamide + Phenylephrine HCl eye drops units, to treat both eyes if necessary. Once opened, use immediately. Discard any unused portion.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Auromide Plus eye Drops contains

- The active substance is Tropicamide 0.8% w/v and Phenylephrine HCl Hydrochloride 5%w/v.
- The other ingredients are Sodium Metabisulphite, Sodium citrate, Ascorbic Acid, Disodium edetate, HPMC, con. Hydrochloric acid, Chlorobutanol and purified water.

What Tropicamide + Phenylephrine HCl eye Drops looks like and contents of the pack

Tropicamide + Phenylephrine HCl eye Drops is an eye drop solution in a LDPE container. Each carton contains one container with Package insert.

1.6.4 Mock ups and Specimens

*Submitted along with Samples