

ISOPTO® Homatropine 2% Eye Drops

Homatropine hydrobromide

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before you start to use ISOPTO® Homatropine Eye Drops.

This leaflet has been written to answer some common questions about ISOPTO® Homatropine. It does not contain all of the available information and does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. In deciding to prescribe ISOPTO® Homatropine for you, your doctor has weighed the potential risks and benefits of using this medicine.

The information in this leaflet applies to ISOPTO® Homatropine only. This information does not apply to similar products, even if they contain the same ingredients.

If you have any concerns about using ISOPTO® Homatropine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What ISOPTO® Homatropine Eye Drops is used for

ISOPTO® Homatropine contains the active ingredient homatropine hydrobromide, which belongs to a group of medicines known as "anticholinergics".

ISOPTO® Homatropine Eye Drops is used, either alone or in combination with other eye drops/medicines, to enlarge (dilate) the pupil of the eye and to prevent the eyes from focusing. Your doctor may use ISOPTO® Homatropine prior to or after surgical procedure, prior to examining the inside of your eye, or to treat certain eye conditions such as uveitis.

Ask your doctor if you have any questions about why this medicine has been prescribed for you or your child.

Your doctor may have prescribed it for another reason.

Before you use ISOPTO® Homatropine Eye Drops

When you must not use it

Do not use ISOPTO® Homatropine Eye Drops if:

1. You or your child are allergic to homatropine hydrobromide, or to any of the ingredients in ISOPTO® Homatropine (these are listed under **Product Description**) or if you or your child have ever experienced a reaction to any other anticholinergic medicine.
2. You or your child have glaucoma

Do not use ISOPTO® Homatropine Eye Drops if:

- **the packaging is torn or shows signs of tampering.**
- **the date (EXP) printed on the label and carton has passed.** If you use ISOPTO Homatropine after the expiry date has passed, it may not work.

ISOPTO® Homatropine has been developed for use in the eye only. It is not to be swallowed or injected.

Do not wear contact lenses whilst on ISOPTO® Homatropine treatment.

Before you start to use it

Let your doctor know if any of the following applies before you or your child start using ISOPTO® Homatropine:

You or your child have:

- allergies to any other medicines or any substances such as foods, preservatives or dyes
- previously been diagnosed with glaucoma
- any other medical conditions.

If you:

- **Are pregnant or are intending to become pregnant.** Your doctor will discuss the risks and benefits of using ISOPTO® Homatropine Eye Drops when pregnant.
- **Are breast feeding or intending to breast feed.** ISOPTO® Homatropine should not be used when breast feeding.

If you or your child have or have had any medical conditions, especially the following:

- Keratoconus (a disease in which the cornea thins and changes shape causing distorted vision)
- Down's syndrome (a genetic condition associated with mental retardation)

If you have not told your doctor about any of the above, tell them before you use ISOPTO® Homatropine.

Using other medicines

Tell your doctor or pharmacist if you or your child are taking any other medicines, including medicines that you buy at a pharmacy or health food shop without a doctor's prescription

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when using ISOPTO® Homatropine with other medicines.

How to use ISOPTO® Homatropine Eye Drops

How much to use

Prior to an operation or examination your doctor will put the correct number of drops in your eye(s).

If you have been prescribed ISOPTO® Homatropine Eye Drops for use outside the doctor's surgery, your dosing instructions will be printed on the label your pharmacist put on the bottle or carton.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist.

How to use it

Follow these steps to use ISOPTO® Homatropine:

1. Wash your hands thoroughly

2. Immediately before using a bottle for the first time, break the safety seal around the neck area and throw the loose plastic ring away
3. Remove the cap from the bottle.
4. Hold the bottle upside down in one hand between your thumb and middle finger (see **Diagram 1**).

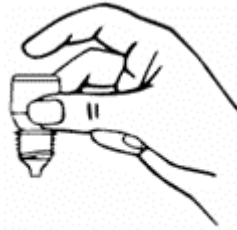


Diagram 1

5. Tilt your head back and look up.
6. Using your other hand, gently pull down the lower eyelid to form a pouch or pocket.
7. Put the tip of the dropper close to, but not touching your eye. Release the required number of drops into the pouch/pocket formed between the eye and eyelid by gently tapping or pressing the base of the bottle with your forefinger (see Diagrams 2 and 3).

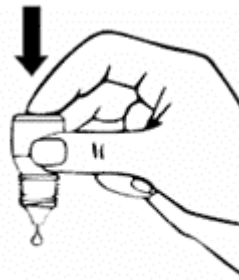


Diagram 2



Diagram 3

8. Close the eye gently and press on the inside corner of the eye with the pad of your index finger for 2 minutes.
9. If necessary repeat the above steps 3-7 for your other eye.
10. Replace the cap on the bottle, closing it tightly.
11. Wash your hands again with soap and water to remove any residue.

There might be a slight burning feeling in the eye(s) shortly after using ISOPTO® Homatropine Eye Drops. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

Do not touch the tip of the dropper tip with your fingers, to the eye or any other surface.

This will help prevent the eye drops becoming dirty or contaminated.

How long to use it

Your doctor or pharmacist will tell you how long to use ISOPTO® Homatropine.

Do not use ISOPTO® Homatropine longer than your doctor tells you.

If you use ISOPTO® Homatropine longer than your doctor or pharmacist tells you, the chance of side effects may increase.

Overuse of ISOPTO® Homatropine can lead to confusion, agitation and rarely coma.

If you are unsure about when or how to stop using ISOPTO® Homatropine Eye Drops you should talk to your doctor or pharmacist.

If you forget to use it

If you forget to use ISOPTO® Homatropine you should put the drops that you missed in the eye(s) as soon as you remember and then go back to using them as recommended by your doctor. If it is almost time for the next dose, skip the dose that you missed and continue using them as recommended.

Never take a double dose to make up for the one that you missed.

If you are not sure what to do, contact your doctor or pharmacist.

If you have trouble remembering to use the medicine, ask your pharmacist for some hints.

If you use too much (overdose)

If you accidentally put too many drops in your eye(s) immediately rinse your eye(s) with warm water.

If you think that you or someone else has swallowed ISOPTO® Homatropine, immediately telephone the nearest Poisons Information Centre (in Australia call 13 1126; in New Zealand call 0800 POISON or 0800 764 766), your doctor or go to Casualty in the nearest hospital, Do this even if there are no signs of discomfort or poisoning.

While using ISOPTO® Homatropine Eye Drops

Things you must do

Tell all doctors and pharmacists who are treating you that ISOPTO® Homatropine Eye Drops is being used.

You should tell your doctor if you become pregnant while you are using ISOPTO® Homatropine

While you are using ISOPTO® Homatropine, it is likely that your eye(s) will be very sensitive to light. Make sure that you take appropriate precautions to protect your eye(s) from light.

Things you must not do

Do not:

- stop using ISOPTO® Homatropine without first asking your doctor

- give this medicine to anyone else, even if they appear to have the same condition as you.
- let children handle ISOPTO® Homatropine.
- use ISOPTO® Homatropine to treat other complaints unless your doctor or pharmacist tells you to.
- use more drops than prescribed by your doctor

Things to be careful of

You should not drive, operate any machinery or engage in any other hazardous activities if ISOPTO® Homatropine affects your vision.

Be careful not to get ISOPTO® Homatropine into your child's mouth and remember to wash your hands and your child's hand after using ISOPTO® Homatropine.

Ask your doctor or pharmacist if you are concerned about the length of time that you or your child have been using ISOPTO® Homatropine Eye Drops.

Side Effects

All medicines can have side effects. Sometimes they are serious, however most of the time they are not. You may need to seek medical treatment if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Tell your doctor as soon as possible if you do not feel well while using ISOPTO® Homatropine.

Most of the side effects from ISOPTO® Homatropine occur in or around the eye. These include:

- slight stinging and burning feeling in the eye
- discharge with itching of the eyes and crusty eyelids
- swelling
- irritation
- eye pain

- red eye
- rash around the skin of the eye
- sensitivity to light
- dilated pupils

Occasionally some people notice untoward effects in the rest of their body as a result of using ISOPTO® Homatropine. These include

- thirst or dryness of the mouth.
- confusion
- behavioural disturbances
- sleepiness
- increased heart rate

ISOPTO® Homatropine may cause other reactions similar to other anticholinergic drugs.

These include

- unsteady walking
- incoherent speech
- restlessness
- hallucinations
- hyperactivity
- seizures
- disorientation
- failure to recognise people

If any of the following happen, stop using ISOPTO® Homatropine and tell your doctor immediately or go to Accident & Emergency at your nearest hospital:

- first sign of a skin rash or any other sign of allergy (eg hives).
- abdominal swelling (infants)
- unusual signs of drowsiness
- high temperature
- flushing
- unable to pass urine

Other side effects not listed above may also occur in some patients. Let your doctor know if you observe any unwanted effects while using ISOPTO® Homatropine, even if they do not appear in the list above.

Do not feel alarmed by this list of possible side effects. You may not experience any of them.

After using ISOPTO® Homatropine Eye Drops

Storage

Store ISOPTO® Homatropine Eye Drops in a cool, dry place where the temperature stays below 25°C.

Do not leave ISOPTO® Homatropine in the car, in the bathroom or in other warm, damp places.

Heat and temperature can destroy some medicines

Do not freeze ISOPTO® Homatropine.

Keep ISOPTO® Homatropine, and all other medicines, in a safe place away from children.

A locked cupboard at least one and a half meters above the ground is a good place to store medicines.

Disposal

Discard each bottle of ISOPTO® Homatropine 4 weeks after it has been opened.

Write the date the bottle was opened on the label to remind you when to discard the bottle.

If your doctor tells you to stop using ISOPTO® Homatropine or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product Description

What it looks like

ISOPTO® Homatropine Eye Drops is a clear liquid that comes in a 15 mL dropper bottle.

Ingredients

Active drug:

Homatropine hydrobromide.

Other ingredients:

Sodium chloride, benzalkonium chloride, polysorbate 80, hypromellose, sodium hydroxide/or hydrochloric acid (to adjust pH) and purified water.

Supplier

In Australia this product is supplied by:

Alcon Laboratories (Australia) Pty Ltd
25 Frenchs Forest Rd East
FRENCHS FOREST NSW 2086

AUST R 25353

In New Zealand this product is distributed by:

Alcon New Zealand Limited
c/o Pharmaco New Zealand Limited
AUCKLAND New Zealand

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