

Package Leaflet - Information for the User

MYDRIACYL® 1% w/v eye drops, solution Tropicamide

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 your 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 get serious,** or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT MYDRIACYL 1% IS AND WHAT IT IS USED FOR

MYDRIACYL 1 % belongs to a group of medicines known as anticholinergics.

It is used to enlarge the pupil of your eye (mydriasis) to allow for easier examination of the inside of the eyeball and **to relax the muscles in your eye** (cycloplegia) when your vision is being tested.

MYDRIACYL 1 % may also be used before or after you have surgery on your eye.

2. BEFORE YOU USE MYDRIACYL 1%

Do not use MYDRIACYL 1%...

- If you have or think that you **may get glaucoma.**
- If you are **allergic** to tropicamide or any of the other ingredients listed in section 6.

Ask your doctor for advice.

Take special care...

- Not for injection. MYDRIACYL 1% eye drops should only be administered in the eye(s).
- Consult your doctor for advice; use of this product may cause:
 - Increase in the pressure in your eye. You should have your eye pressure checked before initiation of therapy, especially in elderly.
 - Changes in behavior (especially in infants and children).
- If your eyes are red.
- If you are not able to use medicines called belladonna alkaloids, (you may be more likely to experience side effects).

If any of these apply, you may still be able to use MYDRIACYL 1%, but discuss it with your doctor first.

Use in children

- Do not use MYDRIACYL 1.0 % in small infants because of the risk of serious adverse reactions.
- Take special care if MYDRIACYL 1.0% is being administered to infants, small or premature children, children with: Down syndrome, spastic paralysis, brain damage. Consult your doctor for advice as serious adverse reactions may occur with the use of this product.

Pregnancy and breast-feeding

If you are pregnant or might get pregnant, or if you are breast-feeding a baby, **talk to your doctor** before you use MYDRIACYL 1%.

Driving and using machines

You may experience **temporary drowsiness**, blurred vision and sensitivity to light when using this medicine. **Do not drive or use any machines unless your vision is clear.** This may take **up to 6 hours** after you have used MYDRIACYL 1%.

Using other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is particularly important if you are taking medicines for the treatment of allergies, depression, anxiety, heart disease, asthma or other breathing problems, motion sickness, Parkinson’s disease, bladder or gastrointestinal problems.

Important information if you wear Contact Lenses

Do not use the drops while wearing **contact lenses.** Wait at least 15 minutes after use before putting your lenses back in. There is a preservative in MYDRIACYL 1% (benzalkonium chloride) that can discolour soft contact lenses.

3. HOW TO USE MYDRIACYL 1%

The usual dose

The usual dose for cycloplegia is 1 or 2 drops in your eye(s), repeated after 5 minutes. If the eye is not examined within 20 to 30 minutes another drop may be added to prolong the effect.

Remove the loose collar from the cap when the bottle is first opened.

Always use MYDRIACYL 1% exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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3. HOW TO USE MYDRIACYL 1% (continued)

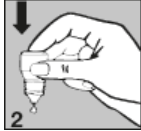
How to use

- Wash your hands before you start.
- Twist off the bottle cap.
- Hold the bottle pointing down, between your thumb and fingers.
- Tilt your head back.
- Pull down your lower eyelid with a 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. It could infect the drops.

- **Gently press on the base** of the bottle to release one drop at a time (picture 2).



- **Do not squeeze the bottle**, only a gentle press on the bottom is needed.
- **Press the corner of your eye** nearest to your nose with a finger for **2 minutes** immediately after use. This will reduce the amount of the medicine getting to the rest of your body. Keep the eyelid closed for 2 minutes.
- If you use drops in both eyes, repeat the steps for your other eye. Put the bottle cap firmly back on immediately after use.
- Do not get MYDRIACYL 1% in your child's mouth; wash your hands and your child's hands immediately after administration.
- **MYDRIACYL 1% may be harmful, especially in children**, if too much is used or **if it is accidentally swallowed**. If this happens, the body surface of infants and children should be kept moist. Contact your doctor or hospital emergency department immediately.
- **If a drop misses your eye**, try again.
- **If you use more MYDRIACYL 1% than you should** rinse it all out with lukewarm water see your doctor as soon as possible.

Symptoms of overdose may include: flushing and dryness of the skin (a rash may be present in children), blurred vision, rapid and irregular pulse, fever, abdominal swelling in infants, convulsions, hallucinations, or loss of coordination.

In case of severe overdose or accidental ingestion, immediately seek advice from your doctor, pharmacist as serious reactions may occur (especially in children).

- **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.

If you have any further questions on the use of MYDRIACYL 1 %, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, MYDRIACYL 1 % can cause side effects, although not everybody gets them.

- **You may experience some or all of the following effects in your eye(s):**
Temporary blurred vision, sensitivity to light, pain, irritation, redness, increase in pupil size, increased pressure in the eye (which may cause headache).
- **You may also experience effects in other areas of your body including:**
Dizziness, headache, fainting, decreased blood pressure, nausea and rash. Psychotic reactions and behavioural disturbances have been reported with this class of drug, especially in children, flushing of the skin, dryness of mucous membranes, dryness of skin, irregular heartbeat, decrease in sweating and dryness of the mouth, constipation, inability to (completely) empty the bladder.
- **In children, other effects that may occur include:**
Skin rash, changes in behaviour, enlarged or abnormal abdomen (in infants). More extreme reactions such as confusion, excitement, hallucinations, increasing drowsiness, rapid breathing and changes in pulse rate require urgent medical advice and attention.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme

at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MYDRIACYL 1%

- Keep out of the reach and sight of children.
- Do not store in a refrigerator or freezer or above 25 °C.
- Keep the container in the outer carton.
- Keep the container tightly closed.
- Do not use the drops after the expiry date (marked 'Exp') on the bottle and the carton. The expiry date refers to the last day of that month.
- Do not use eye drops which have changed colour or contain a precipitate (visible solids).
- **Stop using the bottle 4 weeks after first opening**, to prevent infections.
- 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.
- Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours.

6. FURTHER INFORMATION

What MYDRIACYL 1% contains

- The active substance is tropicamide 10 mg/ml
- The other ingredients are sodium chloride, disodium edetate, benzalkonium chloride, hydrochloric acid and/or sodium hydroxide (to adjust pH) and purified water.

What MYDRIACYL 1% looks like and contents of the pack

MYDRIACYL 1% is a clear, colourless solution supplied in a pack containing a 5 ml plastic bottle with a screw cap.

Marketing authorisation holder:

Alcon Eye Care UK Limited
Park View, Riverside Way
Watchmoor Park, Camberley
Surrey, GU15 3YL
United Kingdom.

Manufacturer:

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