

MYDRIACYL™ Eye Drops

Tropicamide Ophthalmic Solution 0.5% & 1.0%

CONSUMER MEDICINE INFORMATION

What is in this leaflet?

Read this leaflet carefully before you start to use Mydriacyl Eye Drops.

This leaflet answers some common questions about Mydriacyl Eye Drops. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

You can also download the most up to date leaflet from www.novartis.com.au

The updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Mydriacyl against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Mydriacyl is used for

Mydriacyl is used alone or in combination with other eye drops/medicines to enlarge (dilate) the pupil and to prevent the eye from focusing. Your doctor may use Mydriacyl prior to either a surgical procedure or examination of the eye.

Mydriacyl Eye Drops contain the active ingredient tropicamide, which belongs to a class of medicines known as "anticholinergics".

Ask your doctor if you have any questions about why Mydriacyl has been prescribed for you.

Your doctor may have prescribed it for another reason.

Use in children

Mydriacyl is not for use in children. The safety and effectiveness of Mydriacyl in children has not been established.

Before you use Mydriacyl

When you must not use it

Do not use Mydriacyl Eye Drops if:

- You are allergic to tropicamide or to any of the ingredients in Mydriacyl Eye Drops listed at the end of this leaflet under "Product description".

Some of the symptoms of an allergic reaction may include:

- Shortness of breath

- Wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body
- Rash, itching or hives on the skin.
- You are taking any other medicines.

Do not use this medicine if you have been previously diagnosed with angle-closure glaucoma or with a narrow angle between the iris and cornea.

Do not use Mydriacyl Eye Drops if:

- **the safety seal around the closure and neck area is broken**
- **the bottle/package shows signs of tampering**
- **the expiry date on the bottle/carton has passed.**

If you use this medicine after the expiry date has passed, it may not work.

Before you start to use it

Tell your doctor if:

- **you have had an allergy to any other medicines or any other substances such as foods, preservatives or dyes**
- **you are pregnant or intend to become pregnant.**

Your doctor will discuss the risks and benefits of using Mydriacyl Eye Drops when pregnant.

- **you are breastfeeding or intend to breastfeed.**

Your doctor will discuss the risks and benefits of using Mydriacyl Eye Drops when breastfeeding.

If you have not told your doctor about any of the above, tell him/her before you use Mydriacyl Eye Drops.

Using or taking other medicines

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

This is particularly important if you are currently using any other type of eye drops.

Tell your doctor if you are using any of the following:

- Amantadine (Symmetrel) used to treat Parkinson's disease or type A influenza
- Some antihistamines used to treat the symptoms of allergy
- Phenothiazine medicines used to treat major mental illnesses
- Tricyclic antidepressants used to treat depression
- Carbachol, pilocarpine or other cholinesterase inhibitors used to treat glaucoma.

Some medicines may be affected by Mydriacyl or may affect how well it works. You may need different amounts of your medicines, or you may need to take or use different medicines.

If you are unsure if you are using these medicines ask your doctor or pharmacist.

Your doctor or pharmacist will be able to tell you what to do when using Mydriacyl Eye Drops with other medicines.

How to use Mydriacyl

Your doctor will decide on the strength and dose of Mydriacyl Eye Drops dependent on the procedure they will perform.

How much is used

Mydriacyl 1%

The usual dose of Mydriacyl is one or two drops in the affected eye(s), repeated in five minutes.

Your doctor may use additional drops if necessary.

Mydriacyl 0.5%

The usual dose of Mydriacyl is one or two drops, 15 to 20 minutes prior to eye examination.

There might be a slight burning feeling in the eye(s) shortly after using Mydriacyl. If this persists, or is very uncomfortable, tell your doctor.

If you are wearing soft contact lenses, you will be asked to remove them prior to instillation of the drops by your doctor.

The preservative in Mydriacyl Eye Drops, benzalkonium chloride, may be deposited in soft contact lenses.

You may put your soft contact lenses back into your eyes 15 minutes after your procedure.

How to use it

Your doctor will administer Mydriacyl prior to your surgery or eye examination.

If more than one topical ophthalmic product is being used, the products should be administered at least 5 minutes apart.

If used, eye ointments should be administered last.

Things to be careful of

Do not drive or operate any machinery whilst your pupils are dilated.

If you experience any sensitivity to light after using Mydriacyl, you should protect your eyes from bright light.

If you use too much (overdose)

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

If anyone accidentally swallows Mydriacyl Eye Drops, immediately telephone your doctor or Poisons Information Centre on 13 11 26 for advice or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning

Some of the symptoms of an overdose include:

- Flushed or dry skin
- Dry mouth
- Rapid pulse
- Reduced sweating
- Constipation
- Difficulty passing urine.

Side Effects

Tell your doctor as soon as possible if you do not feel well while he/ she is giving you Mydriacyl.

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.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

Tell your doctor if you notice any of the following effects in the eye(s) and the eye area and they worry you:

- Momentary burning or stinging of the eye
- Sore eye and blurred vision
- Sensitivity to light
- Increased pressure in the eye
- Blurry vision
- Eye pain
- Eye irritation
- Red eye
- Dilated pupil (prolonged effect).

Occasionally, some people notice unwanted effects in other areas of the body as a result of using Mydriacyl

Eye Drops. These effects may include:

- Mental and behavioural disturbances
- Dryness of the mouth
- Dryness of the skin (and/or rash)
- Nausea or vomiting
- Headache
- Constipation and abdominal pain
- Flushing
- Need to urinate more often than usual
- Fast or irregular heartbeat, also called palpitations
- Dizziness
- Fainting
- Low blood pressure.

Let your doctor know if you observe any unwanted effects after using Mydriacyl, even if they do not appear in the lists above.

Other side effects not listed above may also occur in some patients.

After using Mydriacyl

Storage

Mydriacyl will be stored by your doctor or pharmacist at the recommended temperature of below 25° C. Mydriacyl should not be stored in a refrigerator (between 2° to 8° C).

Do not freeze. Protect from light.

The lid of the bottle should be tightly closed.

Mydriacyl Eye Drops should be discarded 4 weeks after first opening the bottle.

Product description

What it looks like

Mydriacyl is a colourless liquid that comes in a 15 mL dropper bottle.

Ingredients

Mydriacyl contains the active ingredient, tropicamide.

It is available as either tropicamide 5 mg in 1 mL (0.5%) or tropicamide 10 mg in mL (1.0%).

Mydriacyl also contains:

- Benzalkonium chloride used as a preservative
- Sodium chloride
- Disodium edetate
- Hydrochloric acid and/or sodium hydroxide to adjust pH
- Water-purified.

Supplier

This product is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

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Telephone: 1-800-671-203.

Web site: www.novartis.com.au

Australian registration numbers

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