PATIENT INFORMATION LEAFLET

Mydrilate® 0.5% w/v Eye Drops
Mydrilate® 1.0% w/v Eye Drops

cyclopentolate hydrochloride

Read all of this leaflet carefully before you start taking 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. WHAT MYDRILATE EYE DROPS ARE AND WHAT THEY ARE USED FOR

Mydrilate eye drops are prescription eye drops containing the active ingredient cyclopentolate hydrochloride. They are available in two strengths, 0.5% and 1%.

They belong to a group of medicines known as mydriatic (used for pupil dilation) and cycloplegic (used to block the muscles of the eye that control the shape of the lens).

Mydrilate eye drops are applied on the surface of the eyes for diagnostic purposes during eye examinations and refraction tests.

They can also be used to treat some types of eye inflammation (iritis and uveitis).

2. BEFORE YOU USE MYDRILATE EYE DROPS

Do not use Mydrilate eye drops
- if you are **allergic (hypersensitive) to cyclopentolate hydrochloride, benzalkonium chloride** or any other ingredients listed in section 6
- if you suffer from **glaucoma** (high pressure in the eyeball) or if you are at risk of having it (i.e. your close family suffered from glaucoma, you are over 60, you have increased pressure in the eye, you had an eye injury)
- if you wear **soft contact lenses** - wait at least 15 minutes after removal of contact lenses prior to application. Mydrilate eye drops may discolour the lenses.
- if you suffer from **paralytic ileus** (loss of movement in the gut resulting in **intestinal blockage**)
- in **children with brain damage**, particularly if they may have **seizures or fits**
- if you are **pregnant or breastfeeding**

Mydrilate eye drops should not be used for infants three months of age or younger.

Take special care with Mydrilate eye drops if you:
- suffer from, or are prone to **increased eye pressure** especially in elderly patients

- have an **enlarged prostate** (males only)
- suffer from **heart problems** especially angina, heart attacks or heart failure
- suffer from **ataxia** (condition causing **unsteadiness and coordination problems**)
- have an **inflamed eye(s)** - inflammation greatly increases the risk that more of the eye drops are absorbed into the bloodstream
- are **sensitive to belladonna alkaloids** (drugs such as atropine used mainly to: dilate the pupils, prevent motion sickness, reduce secretion and dry up a runny nose, relieve stomach cramps)

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The following medicines are known to interact with Mydrilate eye drops:
- antihistamines
- medications for mental illness such as butyrophenones and phenothiazines
- tricyclic antidepressants (e.g. amitriptyline, lofepramine, trimipramine)
- amantadine, an antiviral drug used in the treatment of influenza A and Parkinson's disease

Pregnancy and Breast-feeding

Mydrilate eye drops should not be used if you are pregnant, trying to become pregnant or are breast-feeding unless considered essential by your doctor.

Ask your doctor or pharmacist for advice before taking any medications.

Driving and using machines

Using Mydrilate eye drops may cause blurred vision, difficulty in focusing and sensitivity to light. Driving, operating machinery or engaging in hazardous activities such as climbing ladders should be avoided. Complete recovery from these symptoms takes 24 hours.

Important information about one of the ingredients of Mydrilate

This medicine contains 0.1 mg benzalkonium chloride in each millilitre.
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 MYDRILATE EYE DROPS

Always use Mydrilate eye drops exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

When using this product for the first time, screw down the cap firmly on the bottle to pierce the seal at the tip of the plastic nozzle and then unscrew the cap for use. Be sure to replace the cap after use.

To reduce absorption into the blood stream place one finger at the inner corner of the eye near the nose and apply gentle pressure immediately after dispensing the drops. This will prevent the medicine from draining from the eye. Ask your doctor how to do this correctly.

Dosage

For diagnostic eye examinations your doctor will generally give you Mydrilate eye drops as follows:

Adults and the elderly:
- One drop of 0.5 % solution instilled into the eye, repeated after 15 minutes if necessary, approximately 40 minutes before examination.
- Deeply pigmented eyes may require the use of a 1 % solution.

Children 6 – 16 years:
- One drop of 1 % solution instilled into the eye, repeated after 15 minutes if necessary, approximately 40 minutes before examination.

Children under 6 years:
- One or two drops of 1 % solution instilled into the eye, repeated after 15 minutes if necessary, approximately 40 minutes before examination.

For inflammatory conditions of the eye Mydrilate eye drops are generally used as follows:

Adults and the elderly:
- One or two drops of 0.5 % solution instilled into the eye up to 4 times daily or as required.
- Deeply pigmented eyes may require the use of a 1 % solution.

Children:
- At the discretion of the physician.

Mydrilate eye drops should not be used for infants three months of age or younger.

If you accidentally swallow Mydrilate eye drops
You should wash your hands after use. If Mydrilate eye drops are accidentally swallowed, contact your doctor or pharmacist **immediately** describing the symptoms.

If you use more Mydrilate eye drops than you should
Contact your doctor, hospital, or pharmacy if you have used more Mydrilate eye drops than prescribed.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines Mydrilate eye drops can cause side effects although not everybody gets them.

If you experience the following side effects, you should stop using Mydrilate Eye Drops **immediately** and seek urgent medical advice:
- irregular heart rate
- urinary retention (difficulty passing urine)

The following side effects have been observed in children or infants. If they occur, treatment should be stopped immediately and urgent medical advice should be sought:
- fits, a jerk or spasm of a part of the body (usually a leg or an arm), difficulty speaking or speaking in nonsensible ways (reported in a small number of patients)
- collapse, affecting breathing, heart rate and blood pressure

Other side effects that have been observed are:
- increased pressure in the eyeball
- temporary stinging of the eye
- sensitivity to light due to pupil dilation
- dry mouth

- flushing
- dry skin
- heart palpitations
- slow or faster heartbeat
- urinary urgency (difficulty in holding your bladder)
- painful urination
- constipation
- vomiting
- dizziness and staggering
- following prolonged use: eye irritation, hyperaemia (excessive blood in the vessels of the eye), oedema (excessive fluid in the eye) and conjunctivitis (commonly called "redeye" - inflammation of the outermost layer of the eye and inner surface of the eyelids)

Children and infants
Other side effects that have been observed in children are:
- rash
- psychiatric reactions
- behavioural disturbances
- bloating of the stomach in infants
- intestinal tissue death (called necrotising enterocolitis) may occur in premature babies

The frequency of all the possible side effects listed above is classed as 'not known', which means that it cannot be estimated from the available data.

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 any side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard
or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

5. HOW TO STORE MYDRILATE EYE DROPS

Keep out of the sight and reach of children.

Do not freeze. Store in the original package in order to protect from light.

Before first opening:

Store in a refrigerator (between 2°C - 8°C).

Prior to first opening:

Remove from refrigerator and store at room temperature for 30 minutes.

After first opening:

Do not store above 25°C. Do not refrigerate. Discard 28 days after first opening.

Do not use the eye drops after the expiry date which you will find printed on the packaging.

6. FURTHER INFORMATION

What Mydrilate eye drops contain:
Mydrilate eye drops 5 ml dropper bottle contain either 0.5% or 1% of the active ingredient Cyclopentolate Hydrochloride.
Each solution also contains the inactive ingredients: boric acid, potassium chloride, benzalkonium chloride solution and purified water.

What Mydrilate eye drops look like:
The eye drops are available in 5 ml dropper bottles.

Marketing authorisation holder for UK: Esteve Pharmaceuticals Ltd, The Courtyard Barns, Choke Lane, Cookham Dean, Maidenhead, Berkshire SL6 6PT, United Kingdom

Marketing authorisation holder for Ireland: Esteve Pharmaceuticals GmbH, Hohenzollerndamm 150-151, 14199 Berlin, Germany.

EU batch release site: Esteve Pharmaceuticals Ltd, The Granary, The Courtyard Barns, Choke Lane, Cookham Dean, Maidenhead, Berkshire SL6 6PT, UK

Manufacturer: Holopack Verpackungstechnik GmbH, Bahnhofstrasse, 74429 Sulzbach-Laufen, Germany

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