Package leaflet: Information for the user

Murine Irritation & Redness Relief 0.012% w/v Eye Drops Naphazoline hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.

• If you get any of the side effects, talk to your pharmacist or doctor. This includes any possible side effects not listed in this leaflet. See section 4.

• You must talk to a doctor if you do not feel better or if you feel worse after 24 hours.

What is in this leaflet

- 1. What MURINE Irritation & Redness Relief is and what it is used for
- 2. What you need to know before you take MURINE Irritation & Redness Relief
- 3. How to use MURINE Irritation & Redness Relief
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1. What MURINE Irritation & Redness Relief is and what it is used for

MURINE Irritation & Redness Relief is an eye drop solution. It is used to clear redness and soothe eyes which have been irritated by, for example, dusty atmospheres, wind, swimming, smoke, air pollutants, or close work such as reading and computer use.

This medicine contains the active ingredient naphazoline hydrochloride which belongs to the group of medicines called local vasoconstrictors which act by narrowing the blood vessels in the eye, thereby reducing redness and swelling.

MURINE Irritation & Redness Relief is fast acting and has a long lasting action.

You must talk to a doctor if you do not feel better or if you feel worse after 24 hours.

2. What you need to know before you use MURINE Irritation & Redness Relief

Do not use:

• if you are allergic to naphazoline hydrochloride or to any of the other ingredients in this medicine (listed in section 6)

- if you suffer from raised pressure inside your eyeball (glaucoma)
- if you suffer from inflammation of the iris (the coloured part of the eye)
- if you suffer from damage to your corneas (outer layer of the eyes)

• This product must not be used prior to peripheral iridectomy in eyes susceptible to angle closure.

- if you suffer from any other serious eye disease
- if you have had eye surgery

• if you have taken monoamine oxidase inhibitors (MAOIs) in the last 14 days (medicines used to treat conditions such as depression).

- if you wear contact lenses
- if you are under 12 years of age

Warnings and precautions

Consult your pharmacist or doctor before using this medicine if you think you have, or are being treated for any of the following:

- high blood pressure (hypertension)
- depression
- problems with your heart or your blood circulation (cardiovascular abnormalities)
- thickening of the blood vessels (arteriosclerosis)
- diabetes
- over-active thyroid gland (hyperthyroidism)

• an eye condition characterised by continued redness, pain, or blurred vision• any eye condition for which you are under the care of your doctor.

Or experience eye pain or changes in your eyesight.

Children

MURINE Irritation & Redness Relief is not recommended in children under 12 years of age.

You should stop using this medicine if you are about to undergo an operation during which you are to be given a general anaesthetic.

Other medicines and MURINE Irritation & Redness Relief

If you are taking any other medicines you should speak to your doctor or pharmacist before using this product, particularly if you :

• are taking digoxin, quinidine or tricyclic antidepressants

- have taken monoamine oxidase inhibitors (MAOIs) within the last 14 days
- are taking antihypertensive (high blood pressure) medication
- are using any other eye treatments

You should wait at least 15 minutes between using Murine Irritation & Redness Relief and administering any other product into the eye and any eye ointment should always be applied last.

Use with contact lenses

MURINE Irritation & Redness Relief contains benzalkonium chloride which 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.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

If you experience blurring of vision, do not drive or operate machinery until your sight has cleared.

Murine Irritation & Redness Relief contains benzalkonium chloride

This medicine contains 0.034 mg benzalkonium chloride in each drop which is equivalent to 0.1 mg/ml. 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 Murine Irritation & Redness Relief

Always use this medicine exactly as described in this leaflet or as your pharmacist has told you. Check with your pharmacist if you are not sure.

This medicine is for use only in the eyes.

This product is for intermittent or occasional use only.

The recommended dose is 1 or 2 drops into each eye 2 or 3 times daily.

Continued use may increase redness of the eye. Do not use the medicine if it changes colour or becomes cloudy.

If you have increased redness of the eye or no improvement after 24 hours, stop taking the product and see a doctor.

Directions for use:

Adults and Children 12 years and over:

- Wash your hands before use.
- You should avoid touching the dropper on to any surface.

Murine Irritation & Redness Relief 0.012% w/v Eyedrops naphazoline hydrochlorideGently squeeze 1 or 2 drops into each eye 2 or 3 times daily.

If you use more of these eye drops than you should

Speak to your doctor or pharmacist immediately. Symptoms of overdose by mouth may include nausea, headache, low body temperature, bradycardia, sweating, drowsiness, coma, particularly in children.

Overuse may produce increased redness of the eye. Should this occur, discontinue use. If the redness continues consult a doctor.

If you forget to take the medicine

Take the next dose when needed. Do not take more than 3 doses in 24 hours.

4. Possible side effects

Like all medicines, MURINE Irritation & Redness Relief can cause side effects, although not everybody gets them.

Stop using the product and seek medical help immediately if you experience:

- allergic reactions such as itching or rashes
- pain in the eye and change in vision

• stinging or irritation in the eye caused by using too many drops or using them too often.

Other side effects may include:

• Eye irritation, eye pain. Continued and excessive use may lead to increased redness of the eye and to developing of other eye conditions.

- nausea
- headache, dizziness

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 national reporting system listed below. By reporting side effects you can help provide more information on the safety of this medicine.

Ireland: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: <u>medsafety@hpra.ie</u>

5. How to store Murine Irritation & Redness Relief

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Discard any unused contents one month after first opening the bottle.

Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP or . The expiry date refers to the last day of that month.

Do not use if the solution changes colour or becomes cloudy.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What MURINE Irritation & Redness Relief contains

• The active ingredient is naphazoline hydrochloride 0.012%w/v.

• The other ingredients are benzalkonium chloride, boric acid (E284), borax (E285), disodium edetate, and purified water.

What MURINE Irritation & Redness Relief looks like and contents of pack

The eye drops solution is a clear, colourless liquid presented in a white plastic bottle with drop-forming plug and cap. Each bottle contains 5 or 10ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder (IE):

Elara Pharmaservices Europe Limited, 239 Blanchardstown Corporate Park, Ballycoolin, Dublin, D15KV21, Ireland.

Manufacturer:

Tubilux Pharma S.p.A., Via Costarica 20/22, 00071 Pomezia (Roma), Italy

This leaflet was last revised in September 2023.