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| CLIENTE / Customer : | FARMIGEA |
| BOZZA / Proof date : | n° 12 del 15 - 02 - 2017 |
| PRODOTTO / Product : | Dorzolamide ED 5ml leaflet EN CODICE / Code : 912031/02 |
| CARTA / Paper : Meccanografica senza legno | GR/MQ / Gr/mq : 50 |
| F.TO POSA STESA / Size flat : 135 X 425 | POSA PIEGATA / Size folden : 135 X 28 |
| STAMPA SU LATO / Printing : | BIANCA / Top side : X VOLTA / Reverse side : X |
| DIREZIONE FIBRA PARALLELA AL LATO / Fiber parallel to side : | LUNGO ( mm.) |
| COLORI / Fold No. : | NERO |
| NOTE / Notes : | Cod. LAETUS IIIIIIIXXIX (2060) |

912031/02

**PACKAGE LEAFLET: INFORMATION FOR THE PATIENT**

# DORZOLAMIDE 20 mg/ml EYE DROPS, SOLUTION

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

**What is in this leaflet**



## 1. WHAT YOUR MEDICINE IS AND WHAT IT IS USED FOR

It is an eye drop and each bottle contains 5 ml of the medicine.

The active ingredient in Dorzolamide 20mg/ml eye drops, solution is dorzolamide hydrochloride which belongs to a group of medicines called 'carbonic anhydrase inhibitors'. This medicine is used to reduce pressure within the eye in glaucoma or ocular hypertension (raised pressure in the eye) and can be used either alone or in addition to other medicines called 'beta-blockers'.

## 2. BEFORE YOU USE YOUR MEDICINE

**Do not use this medicine if you:**
- Are allergic (hypersensitive) to dorzolamide hydrochloride or to any of the other ingredients in this medicine (listed in section 6).
- Have severe kidney impairment or problems, or a prior history of kidney stones.

**Warnings and precautions**

Talk to your doctor or pharmacist before using this medicine, if you:
- Have any medical problems now or have had in the past, including eye problems and eye surgeries, and about any allergies to any medications.
- Develop any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelids, contact your doctor immediately.
- Suspect that this medicine is causing an allergic reaction (for example, skin rash, severe skin reaction or itching) stop its use and contact your doctor immediately.
- Now have, or have had, any liver problems in the past.
- Wear contact lenses (see sub-section below: "This medicine contains the preservative benzalkonium chloride").

**Children**

This medicine has been studied in infants and children less than 6 years of age who have raised pressure in the eye(s) or have been diagnosed with glaucoma. For more information, talk to your doctor.

**Other medicines and Dorzolamide 20mg/ml Eye Drops, Solution**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines particularly another carbonic anhydrase inhibitor such as acetazolamide, or a sulfa drug.

**Pregnancy and breast-feeding**

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. This medicine should not be used in pregnancy or during breast-feeding.

**Driving and using machines**

This medicine may cause dizziness and blurred vision in some patients. Do not drive or operate machinery until you feel well or your vision is clear.

**This medicine contains the preservative benzlkonium chloride** which may cause eye irritation and is known to discolour soft contact lenses. If you wear contact lenses, remove these before applying the eye drops. Wait at least 15 minutes before putting your lenses back.

## 3. HOW TO USE YOUR MEDICINE

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

If you wear contact lenses, remove these before applying the eye drops. Wait at least 15 minutes before putting your lenses back.

**Dosage**

The appropriate dosage and duration of treatment will be established by your doctor.

- When this medicine is used alone, the usual dose is one drop in the affected eye(s) in the morning, in the afternoon and in the evening.
- When this medicine is used with a beta-blocker eye drop, the usual dose is one drop in the affected eye(s) in the morning and in the evening.

If you are using this medicine with another eye drop, the drops should be applied at least 10 minutes apart.

**Instructions for use:**

This medicine is for use as eye drops only; do not swallow.

Always wash your hands before applying eye drops. Apply one drop of this medicine in each affected eye in the following way:

1. Tilt your head back and look at the ceiling.
2. Gently pull the lower eyelid down until there is a small pocket.
3. Squeeze the upturned dropper bottle to release a drop into your eye.
4. Whilst keeping the affected eye closed, press your finger against the corner of the closed eye (the side where the eye meets the nose) and hold for 1 minute.
5. Replace and tighten the cap immediately after use.

DO NOT ALLOW THE DROPPER TIP TO TOUCH THE EYE, AREAS AROUND THE EYE, OR ANY SURFACE. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision.

The dispenser tip is designed to provide a single drop; therefore, do NOT enlarge the hole of the dispenser tip.

**Children**

This medicine has been studied in infants and children less than 6 years of age who have raised pressure in the eye(s) or have been diagnosed with glaucoma. For more information, talk to your doctor.

**If you use more this medicine than you should**

If you put too many drops in your eye or the contents of the container are swallowed, you should contact your doctor immediately since it may cause sleepiness, nausea, dizziness, headache, fatigue, abnormal dreams and difficulty in swallowing which may require hospital treatment.

**If you forget to use your medicine**

If you forget a dose, apply it as soon as you have realised it. However, if it is almost time for your next dose, skip the missed dose and continue with the next dose as planned. Do not use a double dose to make up for a forgotten dose.

**If you stop using your medicine**

Do not stop using this medicine without talking to your doctor first.

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

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Serious side effects**

**Stop using this medicine and immediately contact your doctor** if you develop any of the following symptoms (general allergic reaction): rash; swelling of the face, lips, tongue, or throat; difficulty in breathing or swallowing.

The following side effects have been reported with this medicine either during clinical trials or during post-marketing experience:

**Very Common possible side effects: (these may affect more than 1in 10 users)**
- Burning and stinging of the eyes.

**Common: may affect up to 1 in 10 patients:**
- Disease of the cornea with sore eye and blurred vision (superficial punctate keratitis), inflammation or irritation of the eyelid, discharge with itching of the eyes (conjunctivitis), watery eyes, blurred vision.
- Fatigue, weakness, headache, feeling sick (nausea), bitter taste.

**Uncommon: may affect up to 1 in 100 patients:**
- Inflammation of the iris.

**Rare: may affect up to 1 in 1,000 patients:**
- Tingling or numbness of the hands or feet.
- Swelling of the cornea (with symptoms of visual disturbances), low pressure in the eye, , development of fluid under the retina (choroidal detachment, following filtration surgery), temporary shortsightedness which resolves when treatment is stopped, eye irritation including redness, eye pain, eyelid crusting.
- Kidney stones, dizziness, nose bleed, throat irritation, dry mouth.
- Severe skin reactions including blisters, localized skin rash (contact dermatitis), and general allergic type reactions such as rash, swelling of the lips, eyes and mouth, shortness of breath, and more rarely wheezing.

**Not Known: (frequency cannot be estimated from the available data)**
- Shortness of breath.
- Foreign body sensation in eye (feeling that there is something in your eye).

**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. 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

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

## 5. HOW TO STORE YOUR MEDICINE

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

Do not use this medicine if you notice that the tamper evident seal has been broken or damaged before you first open it.

Do not use this medicine after the expiry date which is stated on the bottle label and the carton following EX or EXP.

This medicine should be used within 28 days after first opening, even if the bottle is not empty; any residual product should be thrown away.

Do not store the bottle above 25˚C.

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 this medicine contains**
- The active substance is dorzolamide. Each ml of solution contains 20 mg dorzolamide (as 22.26 mg dorzolamide hydrochloride).
- The other ingredients are benzalkonium chloride (preservative), hydroxyethylcellulose, mannitol, sodium citrate, water for injection, and sodium hydroxide or hydrochloric acid (to adjust pH).

**What this medicine looks like and contents of the pack**

This medicine is a clear, colourless to nearly colourless, slightly viscous solution.in a plastic bottle containing 5 ml of the solution.

This medicine is available in packs of 1, 2 or 3 bottles.

Not all pack sizes may be marketed in every country.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder:**

Blumont Pharma Ltd., 23 Moortown Close, Grantham, NG31 9GG, United Kingdom

**Manufacturer:**

Farmigea S.p.A, Via G.B. Oliva 8, 56121 Pisa, Italy

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Call 01476 978568 for help.

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