

## Package leaflet: Information for the user

### Zimed® Preservative Free 0.3 mg/mL, eye drops, solution Bimatoprost

**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 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 Zimed® Preservative Free 0.3 mg/mL, eye drops, solution is and what it is used for
2. What you need to know before you use Zimed® Preservative Free 0.3 mg/mL, eye drops, solution
3. How to use Zimed® Preservative Free 0.3 mg/mL, eye drops, solution
4. Possible side effects
5. How to store Zimed® Preservative Free 0.3 mg/mL, eye drops, solution
6. Contents of the pack and other information

#### **1. What Zimed® Preservative Free 0.3 mg/mL, eye drops, solution is and what it is used for**

Zimed® Preservative Free 0.3 mg/mL, eye drops, solution is an antiglaucoma preparation. It belongs to a group of medicines called prostamides.

Zimed® Preservative Free 0.3 mg/mL, eye drops, solution is used to reduce high pressure in the eye. This medicine may be used on its own or with other drops called beta-blockers which also reduce pressure.

Your eye contains a clear, watery liquid that feeds the inside of the eye. Liquid is constantly being drained out of the eye and new liquid is made to replace this. If the liquid cannot drain out quickly enough, the pressure inside the eye builds up. This medicine works by increasing the amount of liquid that is drained. This reduces the pressure inside the eye. If the high pressure is not reduced, it could lead to a disease called glaucoma and eventually damage your sight.

This medicine does not contain a preservative.

#### **2. What you need to know before you use Zimed® Preservative Free 0.3 mg/mL, eye drops, solution**

**Do not use this medicine:**

- If you are allergic to bimatoprost or any of the other ingredients of this medicine (listed in section 6).

**Warnings and precautions**

Talk to your doctor or pharmacist before using Zimed<sup>®</sup> Preservative Free 0.3 mg/mL, eye drops, solution

**Please tell your doctor or pharmacist, if:**

- You have any breathing problems
- You have liver or kidney problems
- You have had a cataract surgery in the past
- You have or have had low blood pressure or low heart rate
- You have had a viral infection or inflammation of the eye

If you have a history of contact hypersensitivity to silver, you should not use this product.

During treatment, Zimed<sup>®</sup> Preservative Free 0.3 mg/mL, eye drops, solution may cause a loss of fat around the eye, which may cause your eyelid crease to deepen, your eye to appear sunken (enophthalmos), your upper eyelid to droop (ptosis), the skin around your eye to tighten (involution of dermatochalasis) and the lower white part of your eye to become more visible (inferior scleral show). The changes are typically mild, but if pronounced, they can affect your field of vision. The changes may disappear if you stop taking Zimed<sup>®</sup> Preservative Free 0.3 mg/mL, eye drops, solution.

Zimed<sup>®</sup> Preservative Free 0.3 mg/mL, eye drops, solution may also cause your eyelashes to darken and grow, and cause the skin around the eyelid to darken too. The colour of your iris may also go darker. These changes may be permanent. The change may be more noticeable if you are only treating one eye.

**Children and adolescents**

Zimed<sup>®</sup> Preservative Free 0.3 mg/mL, eye drops, solution has not been tested in children under the age of 18 and therefore should not be used by patients under 18 years.

**Other medicines and Zimed<sup>®</sup> Preservative Free 0.3 mg/mL, eye drops, solution**

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

**Pregnancy, breast-feeding and fertility**

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

Zimed<sup>®</sup> Preservative Free 0.3 mg/mL, eye drops, solution may get into breast milk so you should not breast-feed while you are taking this medicine.

**Driving and using machines**

Your sight may become blurred for a short time just after using Zimed<sup>®</sup> Preservative Free 0.3 mg/mL, eye drops, solution. You should not drive or use machines until your sight is clear again.

**3. How to use Zimed<sup>®</sup> Preservative Free 0.3 mg/mL, eye drops, solution**

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

The recommended dose is one drop once daily, in the evening, once daily in each eye that needs treatment. Zimed® Preservative Free 0.3 mg/mL, eye drops, solution should only be applied to the eye.

If you use Zimed® Preservative Free 0.3 mg/mL, eye drops, solution with another eye medicine, wait at least 5 minutes between using Zimed® Preservative Free 0.3 mg/mL, eye drops, solution and the other eye medicine.

Do not use more than once a day as the effectiveness of treatment may be reduced.

### **Instructions for use:**

You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first use it.

Before using the product in the patient eye, it is recommended to expel the first drops outside the eye to check the force needed to get only one drop as recommended for the treatment. It is also recommended not to touch the blue tip because once the seal is broken and the white cap removed, the container is completely open and ready to expel drops.



- Wash your hands. Tilt your head back and look at the ceiling.
- Gently pull down the lower eyelid until there is a small pocket.
- Turn the bottle upside down and squeeze it to release one drop into each eye that needs treatment.
- Let go of the lower lid, and close your eye for 30 seconds.

Wipe off any excess that runs down the cheek.

After use and prior to recapping, the bottle should be shaken once in a downwards direction, without touching the dropper tip, in order to remove any residual liquid on the tip.

If you wear contact lenses, take your lenses out before using this medicine. Wait 15 minutes after using the drops, and before you put your lenses back in.

If a drop misses your eye, try again.

To help prevent infections and avoid eye injury, do not let the tip of the bottle touch your eye or anything else. Put the cap back on and close the bottle straight after you have used it.

### **If you use more Zimed® Preservative Free 0.3 mg/mL, eye drops, solution than you should**

If you use more of this medicine than you should, it is unlikely to cause you any serious harm. Put your next dose in at the usual time. If you are worried, talk to your doctor or pharmacist.

### **If you forget to use Zimed® Preservative Free 0.3 mg/mL, eye drops, solution**

If you forget to use this medicine, use a single drop as soon as you remember, and then go back to your regular routine. Do not take a double dose to make up for a forgotten dose.

**If you stop using Zimed® Preservative Free 0.3 mg/mL, eye drops, solution**

Zimed® Preservative Free 0.3 mg/mL, eye drops, solution should be used every day to work properly. If you stop using Zimed® Preservative Free 0.3 mg/mL, eye drops, solution the pressure inside your eye may go up, therefore talk to your doctor before stopping this treatment.

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. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

**Very common** (may affect more than 1 in 10 people)Affecting the eye region

- Loss of fat in the eye region which can lead to deepening of your eyelid crease, sunken eye (enophthalmos), drooping eyelid (ptosis), tightening of the skin around your eye (involution of dermatochalasis), and the lower white part of your eye to become more visible (inferior scleral show).
- Slight redness (up to 24% of people)

**Common** (may affect up to 1 in 10 people)Affecting the eye

- Small breaks in the surface of the eye, with or without inflammation
- Irritation
- Itchy eyes
- Pain
- Dryness
- A feeling that something is in your eye
- Longer eyelashes
- Darker skin colour around the eye
- Red eyelids

**Uncommon** (may affect up to 1 in 100 people)Affecting the eye

- Tired eyes
- Sensitivity to light
- Darker iris colour
- Itchy and swollen eyelids
- Tears
- Swelling of the see-through layer which covers the surface of the eye
- Blurred vision

Affecting the body

- Headaches
- Hair growth around the eye

**Not known** (frequency cannot be estimated from the available data)Affecting the eye

- Sticky eyes
- Ocular discomfort

### Affecting the body

- Asthma
- Worsening of asthma
- Worsening of the lung disease called chronic obstructive pulmonary disease (COPD)
- Shortness of breath
- Symptoms of allergic reaction (swelling, redness of the eye and rash of the skin)
- Dizziness
- Increased blood pressure
- Skin discolouration (periocular)

In addition to the side effects for Zimed<sup>®</sup> Preservative Free 0.3 mg/mL, eye drops, solution, the following side effects have been seen with other preserved multidose formulations of bimatoprost and may occur in patients taking Zimed<sup>®</sup> Preservative Free 0.3 mg/mL, eye drops, solution:

- Burning sensation in the eye
- An allergic reaction in the eye
- Inflamed eyelids
- Difficulty in seeing clearly
- Worsening vision
- Darker eyelashes
- Retinal bleeding
- Inflammation within the eye
- Cystoid macular oedema (swelling of the retina within the eye leading to worsening vision)
- Iris inflammation
- Eyelid twitching
- Eyelid shrinking, moving away from surface of the eye
- Nausea
- Skin redness around the eye
- Weakness
- An increase in blood-test results that show how your liver is working

Other side effects reported with eye drops containing phosphates:

In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Zimed<sup>®</sup> Preservative Free 0.3 mg/mL, eye drops, solution**

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

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

Store below 25°C. Store in the original bottle and keep the bottle in the outer carton in order to protect from light.

You must throw away the bottle, at the latest, 28 days after you first opened it, even if there are still some drops left. This will prevent infections. To help you remember, write down the date you opened it in the space on the box.

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 to protect the environment.

## **6. Contents of the pack and other information**

### **What Zimed® Preservative Free 0.3 mg/mL, eye drops, solution contains**

- The active substance is bimatoprost.  
One mL of solution contains 0.3 mg bimatoprost.
- The other ingredients are sodium chloride, disodium hydrogen phosphate heptahydrate, citric acid monohydrate and purified water. Small amounts of hydrochloric acid or sodium hydroxide may be added to keep the level of acid (pH levels) normal.

### **What Zimed® Preservative Free 0.3 mg/mL, eye drops, solution looks like and contents of the pack**

Zimed® Preservative Free 0.3 mg/mL, eye drops, solution is a sterile colourless clear solution supplied in a plastic bottle with a screw cap. Each bottle contains 3 mL of solution. This is enough for 4 weeks' usage.

Each pack contains one bottle.

Novelia® system Low Density Polyethylene bottle closed with a white nozzle and cap subassembly (High Density Polyethylene and silicone). Silicone, which is one of the components, also comes into contact with the solution.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

Medicom Healthcare Limited  
Lynton House  
7-12 Tavistock Square  
Kings Cross  
London, WC1H 9LT  
United Kingdom

### **Manufacturer**

Famar Health Care Services Madrid SAU  
Avda. Leganés, 62  
28923 Alcorcón (Madrid) Spain

or

Pharma Stulln GmbH  
Werksstraße 3  
92551 Stulln  
Germany

**This medicinal product is authorised in the Member States of the EEA under the**

**following names:**

France: Zimed<sup>®</sup> sans conservateur 0,3 mg/mL collyre en solution

Germany: Bimatoprost Stulln<sup>®</sup> 0,3 mg/mL Augentropfen, Lösung

Italy: Bimatoprost Medicom 0,3 mg/ml collirio, soluzione

Netherlands: Bimatoprost Stulln<sup>®</sup> 0,3 mg/ml oogdruppels, oplossing

Spain: Zimed 0,3 mg/ml colirio en solución

United Kingdom: Zimed<sup>®</sup> Preservative Free 0.3 mg/mL, eye drops, solution

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