

**PACKAGE LEAFLET**

## **Package leaflet: Information for the patient**

### **Brimonidine Bluefish 2 mg/ml eye drops, solution**

brimonidine tartrate

**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 Brimonidine Bluefish is and what it is used for
2. What you need to know before you use Brimonidine Bluefish
3. How to use Brimonidine Bluefish
4. Possible side effects
5. How to store Brimonidine Bluefish
6. Contents of the pack and other information

#### **1. What Brimonidine Bluefish is and what it is used for**

The active ingredient in Brimonidine Bluefish is brimonidine tartrate which belongs to a group of medicines called alpha-2 adrenergic receptor agonists. It works by reducing pressure within the eyeball in the conditions open angle glaucoma or ocular hypertension. It can be used either alone or with another eye drop, if a single medicine is not enough to lower the increased pressure in the eye.

#### **2. What you need to know before you use Brimonidine Bluefish**

##### **Do not use Brimonidine Bluefish**

- If you are allergic to brimonidine or any of the other ingredients of this medicine (listed in section 6).
- If you are taking monoamine oxidase (MAO) inhibitors or certain antidepressants. You must inform your doctor if you are taking any antidepressant drug.
- If you are breast-feeding.
- In infants/babies (from birth until 2 years).

##### **Warnings and precautions**

Talk to your doctor or pharmacist before using Brimonidine Bluefish

- If you suffer or have suffered from depression, reduced mental capacity, reduced blood supply to the brain, heart problems, a disturbed blood supply of the limbs or a blood pressure disorder.
- If you have or have had in the past kidney or liver problems.

##### **Children and Adolescents**

Brimonidine Bluefish is not recommended for use in children (from 2 years until 12 years).

Brimonidine Bluefish should not usually be used in adolescents aged 12 to 17 as clinical studies have not been performed in this age group.

##### **Other medicines and Brimonidine Bluefish**

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

Tell your doctor if you are taking any of the following medicines:

- pain killers, sedatives, opiates, barbiturates or are regularly consuming alcohol
- anaesthetics
- medicines to treat a heart condition or to lower blood pressure
- medicines that can affect the metabolism like chlorpromazine, methylphenidate and reserpine
- medicines which work on the same receptor as Brimonidine Bluefish, for example isoprenaline and prazosin
- monoamine oxidase (MAO) inhibitors and other antidepressants
- medicines for any condition, even if unrelated to your eye condition
- or if the dose of any of your current medicines is changed.

These could affect your treatment with Brimonidine Bluefish.

### **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 taking this medicine. Do not use Brimonidine Bluefish if you are pregnant unless your doctor considers it necessary

Brimonidine Bluefish should not be used while breast-feeding.

### **Driving and using machines**

- Brimonidine Bluefish may cause blurred or abnormal vision. This effect may seem worse at night or in reduced lighting.
- Brimonidine Bluefish may also cause drowsiness or tiredness in some patients.
- If you experience any of these symptoms, do not drive or use machinery until the symptoms are cleared.

### **Brimonidine Bluefish contains benzalkonium chloride.**

This medicine contains 0.05mg benzalkonium chloride in each ml.

Benzalkonium chloride is a preservative 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. 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 Brimonidine Bluefish**

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

### **Adults**

The recommended dose is one drop twice daily in the affected eye(s), approximately 12 hours apart. Do not change the dose or stop taking Brimonidine Bluefish without speaking to your doctor.

### **Children under 12 years**

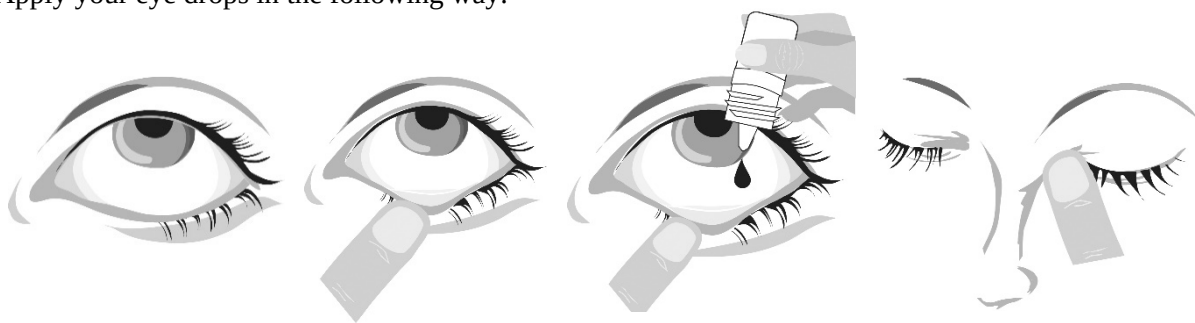
Brimonidine Bluefish must not be used for infants below 2 years of age.

Brimonidine Bluefish is not recommended for use in children (from 2 years until 12 years).

### **Instructions for use**

Brimonidine Bluefish comes as eye drops. Always wash your hands before applying eye drops. Your prescription label tells you how many drops to use at each dose. If you use Brimonidine Bluefish with another eye drop, wait 5-15 minutes before applying the second eye drop.

Apply your eye drops 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.

If a drop misses your eye, try again.

To avoid contamination, do not let the tip of the bottle touch your eye or anything else. Replace and tighten the cap straight after use.

### **If you use more Brimonidine Bluefish than you should**

#### *Adults*

In adults who were instilling more drops than prescribed, the side effects reported were those already known to occur with brimonidine.

Adults who accidentally swallowed brimonidine experienced decrease in blood pressure, which in some patients was followed by the increase in blood pressure.

#### *Children*

Serious side effects were reported in children who accidentally swallowed brimonidine. Signs included sleepiness, floppiness, low body temperature, paleness and breathing difficulties. Should this happen, contact your doctor immediately.

#### *Adults and Children*

If Brimonidine Bluefish has been accidentally swallowed or if you have used more Brimonidine Bluefish than you should, please contact your doctor immediately.

### **If you forget to use Brimonidine Bluefish**

If you forget to take a dose, apply it as soon as you remember. If, however, it is almost time for your next dose, you should omit the missed dose altogether and then follow your normal routine.

### **If you stop using Brimonidine Bluefish**

To be effective Brimonidine Bluefish must be used every day. Do not stop using Brimonidine Bluefish until your doctor tells you to.

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.

The following side effects may be seen with Brimonidine Bluefish.

#### Affecting the eye

*Very common (may affect more than 1 in 10 people):*

- Irritation of the eye (eye redness, burning, stinging, a feeling of something in the eye, itching, follicles or white spots on the see-through layer which covers the surface of the eye)
- Blurred vision
- An allergic reaction in the eye

*Common (may affect up to 1 in 10 people):*

- Local irritation (inflammation and swelling of the eyelid, swelling of the see-through layer which covers the surface of the eye, sticky eyes, pain and tearing)
- Sensitivity to light
- Erosion on the surface of the eye and staining
- Eye dryness
- Whitening of the see-through layer which covers the surface of the eye
- Abnormal vision
- Inflammation of the see-through layer which covers the surface of the eye

*Very rare (may affect up to 1 in 10,000 people):*

- Inflammation within the eye
- Reduction in pupil size

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

- Itching of eyelids

#### Affecting the body

*Very common (may affect more than 1 in 10 people):*

- Headache
- Dry mouth
- Tiredness/drowsiness

*Common (may affect up to 1 in 10 people):*

- Dizziness
- Cold-like symptoms
- Symptoms involving the stomach and digestion
- Abnormal taste
- General weakness

*Uncommon (may affect up to 1 in 100 people):*

- Depression
- Palpitations or changes in heart rate
- Dry nose
- General allergic reactions

*Rare (may affect up to 1 in 1,000 people):*

- Shortness of breath

*Very rare (may affect up to 1 in 10,000 people):*

- Sleeplessness
- Fainting
- High blood pressure
- Low blood pressure

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

- Skin reactions including redness, face swelling, itching, rash and widening of blood vessels

### **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 in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Brimonidine Bluefish**

- 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 after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- **Throw the bottle away 28 days after opening, even if there is solution remaining.**

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 Brimonidine Bluefish contains**

- The active substance is brimonidine tartrate. One ml solution contains 2,0 mg brimonidine tartrate equivalent to 1,3 mg brimonidine.
- The other ingredients are benzalkonium chloride, poly(vinyl alcohol), sodium chloride, sodium citrate, citric acid monohydrate, purified water and hydrochloric acid and sodium hydroxide for pH-adjustment.

### **What Brimonidine Bluefish looks like and contents of the pack**

Brimonidine Bluefish is a clear slightly greenish-yellow solution. Each bottle contains 5 ml. Brimonidine Bluefish is available in packs of 1 bottle, 3 bottles and 6 bottles.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

[To be completed nationally]

#### **Manufacturer**

Famar Anonymous Industrial Single Member Company of Pharmaceuticals and Cosmetics  
63, Agiou Dimitriou street  
17456 Alimos, Attica  
Greece

**This medicinal product is authorised in the Member States of the European Economic Area under the following names:**

| <b>Name</b>                                      | <b>Member State</b> |
|--------------------------------------------------|---------------------|
| Brimonidin Bluefish                              | Sweden              |
| Brimonidin Bluefish                              | Iceland             |
| Brimonidin-Bluefish 2 mg/ml Augentropfen, Lösung | Germany             |

**This leaflet was last revised in 2025-03-06**