

**ANNEX III**  
**B PACKAGE LEAFLET**

## Package leaflet: Information for the user

### Omidria 10 mg/mL + 3 mg/mL concentrate for solution for intraocular irrigation phenylephrine/ketorolac

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

#### What is in this leaflet

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

#### 1. What Omidria is and what it is used for

Omidria is a medicine used during surgery on the eye. It contains the active substances phenylephrine and ketorolac. Phenylephrine acts to keep the pupil dilated (widened). Ketorolac is a painkiller that belongs to the group called non-steroidal anti-inflammatory drugs (NSAIDS); it also helps stop the pupil from contracting (getting smaller).

Omidria is used in adults to rinse the eye during surgery to implant a new lens (part of the eye that focuses light passing through the pupil to allow you to see clearly). This is known as intraocular lens replacement. The medicine is used to keep the pupil dilated (widened) during surgery and to reduce eye pain after the procedure.

#### 2. What you need to know before you use Omidria

##### Do not use Omidria:

- if you are allergic to phenylephrine or ketorolac or any of the other ingredients of this medicine (listed in section 6);
- if you have an eye condition called narrow-angle glaucoma.

##### Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Omidria if you:

- have heart disease;
- have raised blood pressure;
- have overactive thyroid gland (hyperthyroidism);
- are allergic to acetylsalicylic acid or other painkillers called non-steroidal anti-inflammatory drugs (NSAIDs);
- have asthma.

If any of the above applies to you, please inform your doctor. Your doctor will decide if Omidria is suitable for you.

### **Children and adolescents**

Omidria should not be used in children and adolescents aged below 18 years as it has not been studied in these groups.

### **Other medicines and Omidria**

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

- Especially, tell your doctor if you are using a medication to dilate (widen) the pupil of the eye (e.g., atropine or homatropine). Using this type of medication at the same time as Omidria may increase blood pressure and cause the heart to beat faster in some patients.
- Also tell your doctor if you are taking an opioid pain reliever or a non-drowsy antihistamine. These medications, when taken at the same time as Omidria, can change how effectively Omidria is able to dilate (widen) your pupil for surgery.
- One of the active substances in Omidria can react with several types of anaesthetics. Your doctor will know about this. If your eye surgery will involve general anaesthesia, talk to your doctor about this.

### **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 for advice before taking this medicine.

Omidria should not be used during pregnancy. If you are able to become pregnant, you should be using suitable contraception before you are given Omidria.

Omidria should not be used during breast-feeding.

### **Driving and using machines**

This medicine has major influence on the ability to drive and use machines. As your vision may be affected, you should not drive or use machines until your vision has cleared. This may be several hours up to about a day, depending on other medications your doctor may use during surgery.

## **3. How Omidria is used**

Omidria will be given to you in a hospital or clinic by a qualified doctor or surgeon who is specialised in eye surgery.

Omidria is used as a solution to rinse the eye (irrigation solution) during surgery to replace the lens.

### **If you are given more Omidria than you should have been**

Phenylephrine, one of the active substances of Omidria, may cause a rapid rise in blood pressure if too much is given and enough passes into the blood to affect other parts of the body. It may also cause headache, anxiety, nausea, vomiting, and abnormal rapid heart rhythm.

Your doctor will monitor you for any signs or symptoms of side effects and will treat them if necessary.

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

## **4. Possible side effects**

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

Side effects listed below are typically mild to moderate in intensity and usually resolve on their own without any long-term effects.

**Side effects affecting the eye:**

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

- eye pain;
- inflammation of the front of the eye;
- red eyes;
- swelling of the cornea (the clear layer over the front of the eye);
- sensitivity to light.

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

- eye discomfort;
- eye inflammation;
- eye irritation;
- eye redness;
- problems with the cornea such as scratches or dryness;
- dilated pupil;
- blurred vision;
- reduction in sharpness of vision;
- small, dark shapes moving in the field of vision;
- itchy eyes;
- eyelid pain;
- sensation of foreign bodies in the eyes;
- glare;
- increased eye pressure.

**Side effects affecting the body:**

**Common side effects:**

- ocular inflammation

**Uncommon side effects:**

- nausea;
- pain;
- headache.

**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 Yellow Card Scheme at: [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 Omidria is stored**

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 carton after “EXP”. The expiry date refers to the last day of that month.

Do not store above 25 °C. Keep the vial in the outer carton in order to protect from light.

Do not use if the solution is cloudy, or if it contains particles.

The diluted solution is to be used within 6 hours after dilution.

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 Omidria contains**

The active substances are phenylephrine (as hydrochloride) and ketorolac (as trometamol). Each 4.0 mL vial of solution contains 40.6 mg (10.2 mg/mL) of phenylephrine and 11.5 mg (2.88 mg/mL) of ketorolac.

The other ingredients are

- Citric acid monohydrate
- Sodium citrate dihydrate
- Sodium hydroxide (to adjust alkalinity level)
- Hydrochloric acid (to adjust acidity level)
- Water for injection

### **What Omidria looks like and contents of the pack**

Clear, colourless to slightly yellow, sterile concentrate for solution for intraocular irrigation.

Supplied in a single-use vial designed to deliver 4.0 mL of concentrate for solution into 500 mL of irrigation solution for intraocular use. Colourless 5 mL type 1 glass vial closed with a butyl rubber stopper and a polypropylene flip-off cap.

Multipack contains 10 cartons, each carton contains one single-use vial.

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### **Manufacturer**

Manufacturing Packaging Farmaca (MPF) B.V.,  
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The Netherlands

For any information about this medicine, please contact the Marketing Authorisation Holder:

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### **The following information is intended for healthcare professionals only:**

To prepare Omidria for intraocular irrigation, dilute 4.0 mL (the content of 1 vial) of Omidria concentrate for solution in 500 mL of standard ophthalmological irrigation solution.

The following instructions must be adhered to:

- The vial should be visually inspected for particulate matter. Only a clear, colourless to slightly yellow concentrate for solution without visible particles should be used.
- Using aseptic technique, withdraw 4.0 mL of concentrate for solution using an appropriate sterile needle.
- 4.0 mL of concentrate for solution should be injected into a 500 mL bag/bottle of irrigation solution.
- The bag/bottle should be gently inverted in order to mix the solution. The solution should be used within 6 hours of preparation.
- The bag/bottle must be visually inspected for particulate matter. Only a clear, colourless solution without visible particles should be used.
- No other medicinal products should be added to the prepared irrigation solution.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.