

Ocufen® 0.03% w/v Ophthalmic Solution

(flurbiprofen sodium)

Your medicine is available using the above name but it will be referred to as Ocufen throughout this leaflet

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Ocufen is and what it is used for
2. Before you use Ocufen
3. How to use Ocufen
4. Possible side effects
5. How to store Ocufen
6. Further information

1. What Ocufen is and what it is used for

Ocufen is used for two different purposes:

- Given before and after eye surgery and laser surgery, to control eye inflammation in patients who have been recommended not to use steroids.
- Given before an operation to help prevent the pupil becoming smaller during surgery.

Ocufen belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs).

2. Before you use Ocufen

Do not use Ocufen

- If you are allergic (hypersensitive) to flurbiprofen (or other similar medicines), aspirin, or any of the other ingredients in Ocufen.
- If you have a viral eye infection
- If you have a tendency to bleed easily
- If you are taking medicine that increases the time needed for your blood to clot
- During surgery
- If you are in the third trimester of pregnancy

Take special care with Ocufen

Talk to your doctor before using Ocufen if you suffer from, or have in the past suffered from:

- Viral infections of the eye
- A tendency to bleed

The use of Ocufen after surgery may slow down healing.

Using other medicines

Please tell your doctor or pharmacist if you are using or have recently used any other medicine, including medicines obtained without a prescription.

Other eye medicine should not usually be used with Ocufen. However, if your doctor recommends using Ocufen with another eye medicine, leave at least 5 minutes between putting in Ocufen and the other medicine.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Tell your doctor before you start using Ocufen if you are pregnant or if you are breast-feeding.

Do not use Ocufen if you are in your third trimester of pregnancy.

Ask your doctor or pharmacist for advice before using any medicine.

Driving and using machines

Ocufen may cause blurred vision following administration, if this occurs wait until your vision clears before driving or using machinery.

3. How to use Ocufen

Always use Ocufen exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

In adults

Dose before surgery

The usual dose is 1 drop in the eye(s) undergoing surgery, every half hour starting 2 hours before the operation or laser surgery (4 drops in total per eye being treated).

The final drop should be given at least 30 minutes before surgery.

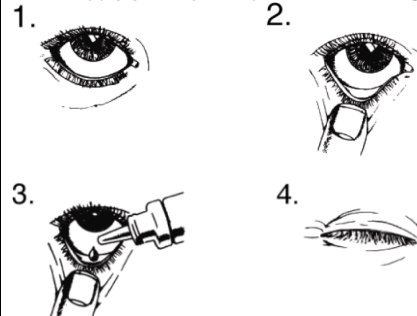
Dose after surgery

24 hours after laser surgery the usual dose is 1 drop, 4 times a day for 1 week.

24 hours after eye surgery the usual dose is 1 drop, 4 times a day for 2 to 3 weeks.

Instructions for use

You must not use the vial if the seal on the vial neck is broken before you use it. Apply your eye drops in the following way:



1. Wash your hands. Twist off the tab to open the vial. Tilt your head back and look at the ceiling.
2. Gently pull the lower eyelid down until there is a small pocket.
3. Turn the vial upside down and squeeze it to release one drop into each eye that needs treatment.
4. Let go of the lower lid and close your eye for 30 seconds.

If a drop misses your eye, try again.

To avoid contamination, do not let the tip of the dropper touch your eye or anything else.

Throw away each vial immediately after use.

After use, the remaining vials should be placed back in the original pouch after each use. Fold ends closed.

The proper application of your eye drops is very important. If you have any questions ask your doctor or pharmacist.

If you use more Ocufen than you should

Putting too many drops in your eye(s) is unlikely to lead to unwanted side-effects. If you have placed too many drops in your eye(s), wash your eye(s) with clean water. Apply your next dose at the normal time.

If, by accident, anyone drinks this medicine, contact your doctor straight away.

If you forget to use Ocufen

If you forget a dose apply it as soon as you remember, unless it is almost time for your next dose, in which case you should miss out the forgotten dose. Then apply your next dose as usual and continue with your normal routine.

Do not use a double dose to make up for a forgotten dose.

If you stop using Ocufen

Ocufen should be used as advised by your doctor. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Ocufen can cause side effects, but not everyone gets them.

Tell your doctor if the following side effects prove troublesome or if they are long lasting

- Irritation of the eye
- Stinging and/or burning in the eye
- Bleeding in the eye
- Blood in the front area of the eye
- Excessive dilatation of the pupil
- Redness of the 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 Yellow Card Scheme at: 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 Ocufer

Keep out of the sight and reach of children.

Discard each vial immediately after use, even if there is some solution remaining.

Do not use Ocufer after the expiry date which is printed on the vial, the pouch the vial comes in and on the bottom of the carton after EXP. The expiry date refers to the last day of that month.

Store unused vials in the original pouch.

Do not store above 25°C.

The carton can be reclosed after opening.

If your medicine becomes discoloured or shows signs of any deterioration you should seek the advice of your pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Ocufer contains

- Each vial contains: Flurbiprofen sodium 0.03% (w/v).
- The other ingredients are polyvinyl alcohol, potassium chloride, sodium chloride, sodium citrate dihydrate, citric acid monohydrate, hydrochloric acid or sodium hydroxide (to adjust pH) and purified water.

What Ocufer looks like and contents of the pack

Ocufer is a sterile eye drop and each clear plastic vial contains 0.4 ml of the medicine.

Ocufer is a clear, colourless solution.

Ocufer is available in packs of 20 x 0.4ml, 40 x 0.4ml and 50 x 0.4ml.

Not all pack sizes may be marketed.

Manufacturer and Product Licence Holder

Manufactured by

Laboratoire Unither, Zi de la Guerie, 50211 Coutances Cedex, France.

Laboratoire Unither, 1 Rue de l'Arquerie, 50200 Coutances, France.

Procured from the EU by Product Licence holder:

Star Pharmaceuticals Ltd., 5 Sandridge Close, Harrow, Middlesex, HA1 1XD.

Repackaged by Servipharm Ltd.

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Blind or partially sighted?

Is this leaflet hard to see or read?

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Flurbiprofen sodium 0.03% w/v Ophthalmic Solution

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In this leaflet:

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2. Before you use Flurbiprofen sodium
3. How to use Flurbiprofen sodium
4. Possible side effects
5. How to store Flurbiprofen sodium
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1. What Flurbiprofen sodium is and what it is used for

Flurbiprofen sodium is used for two different purposes:

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- Given before an operation to help prevent the pupil becoming smaller during surgery.

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2. Before you use Flurbiprofen sodium

Do not use Flurbiprofen sodium

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- If you have a viral eye infection
- If you have a tendency to bleed easily
- If you are taking medicine that increases the time needed for your blood to clot
- During surgery
- If you are in the third trimester of pregnancy

Take special care with Flurbiprofen sodium

Talk to your doctor before using Flurbiprofen sodium if you suffer from, or have in the past suffered from:

- Viral infections of the eye
- A tendency to bleed

The use of Flurbiprofen sodium after surgery may slow down healing.

Using other medicines

Please tell your doctor or pharmacist if you are using or have recently used any other medicine, including medicines obtained without a prescription.

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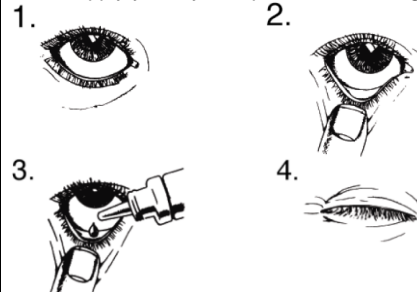
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