

OCUFEN® EYE DROPS

[flurbiprofen sodium 300 µg per mL]

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about OCUFEN® eye drops including how to use the eye drops. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using OCUFEN® eye drops against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What OCUFEN® eye drops are used for

OCUFEN® contains flurbiprofen sodium, which belongs to a class of non-steroidal, anti-inflammatory drugs (NSAID's) which are medicines used to relieve pain,

swelling or other symptoms of inflammation. Your doctor may use OCUFEN® before surgery to stop miosis (contraction of the pupil of the eye) during eye surgery so that they can have better access for your operation. Your doctor may have prescribed OCUFEN® eye drops for another reason. Ask your doctor if you have any questions about why OCUFEN® eye drops have been prescribed for you.

Before you use OCUFEN® eye drops

When you must not use it

Do not use OCUFEN® eye drops if:

- you have an allergy to flurbiprofen sodium or any of the ingredients listed at the end of this leaflet
- you have an eye infection due to *Herpes simplex* virus
- you are breastfeeding or have the intention of breast feeding

Do not use OCUFEN® eye drops if:

- the packaging shows signs of tampering
- the product does not look quite right
- the expiry date on the ampoule has passed.

If you use this medicine after the expiry date has passed, it may not work effectively.

Do not put OCUFEN® eye drops into your eye(s) while you are wearing soft contact lenses. You can put your soft contact lenses back into your eyes 15 minutes after you have used OCUFEN® eye drops.

It is not known if OCUFEN® eye drops are safe and useful for children and adolescents under 18 years.

These drops are for topical use only.

Before you start to use it

Tell your doctor if

1. you have any allergies to:

- any other medicines, including aspirin or any other non-steroidal anti-inflammatory drugs (medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis)
 - any other substances, such as foods, preservatives or dyes
2. you are pregnant or intend to become pregnant. Like most medicines, OCUFEN® eye drops are not recommended during pregnancy, unless the benefits outweigh the risk to the baby.
 3. you are breast-feeding or intend to breast-feed.
 4. you have or have had any medical conditions, especially the following:
 - eye infections
 - eye infection caused by *Herpes simplex* virus.

Using other medicines

Tell your doctor if you are using eye drops containing acetylcholine chloride or carbachol (which are used to enlarge pupils) as OCUFEN® may interact with these medications.

Tell your doctor if you are using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using OCUFEN® eye drops.

How to use OCUFEN® eye drops

How much to use

Your doctor will tell you how many drops you need to use. Use OCUFEN® eye drops only as prescribed by your doctor.

The usual dose is a total of four (4) drops of OCUFEN® eye drops administered in the eye(s) by instilling 1 drop every 30 minutes starting two (2) hours before the surgery or operation.

Follow all directions given to you by your doctor carefully.

The directions may differ from the information contained in this leaflet.

If you are using more than one eye drop product, wait 5 minutes before using the second product.

How to use it

You may find it easier to put drops in your eye while you are sitting or lying down.

If you are wearing soft contact lenses, remove them before putting the drops in your eye.

1. Wash your hands well with soap and water.
2. Open the container by completely twisting off the tab, do not pull off.
3. Hold the ampoule upside down in one hand between your thumb and forefinger or index finger.
4. Using your other hand, gently pull down your lower eyelid to form a pouch or pocket.
5. Tilt your head back and look up.
6. Put the tip of the ampoule close to your lower eyelid. Do not let it touch your eye.
7. Release one drop into the pouch or pocket formed between your eye and eyelid by gently squeezing the ampoule.
8. Close your eye. Do not blink or rub your eye.

9. While your eye is closed, place your index finger against the . inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body. Ask your doctor for more specific instruction of this technique.
10. Throw away the ampoule together with the unused solution. DO NOT save the unused solution.
11. Wash your hands again with soap and water to remove any residue.

Wait 15 minutes before replacing your contact lenses.

Be careful not to touch the dropper tip against your eye, eyelid or anything else.

How long to use it

Continue using OCUFEN® eye drops for as long as your doctor prescribes.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use the drops as soon as you remember, and then go back to using them as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not use double the amount to make up for the dose that you missed.

If you use too much (overdose)

If you accidentally put several drops in your eye(s), immediately flush your eye(s) with water or saline.

If you think that you or anyone else may have swallowed any or all of the contents of an ampoule(s) of OCUFEN® eye drops drink fluids to dilute the medication and immediately telephone your doctor or Poisons Information Centre (Australia: telephone 13 11 26 New Zealand: telephone 0800 POISON or 0800 764 766) for advice, or go to casualty at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are using OCUFEN® eye drops

Things you must do

If you develop an eye infection, receive an eye injury, or have eye surgery tell your doctor.

If you become pregnant while using OCUFEN® eye drops tell your doctor immediately.

If you wear contact lenses, remove them before using OCUFEN® eye drops. Leave your lenses out for at least 15 minutes after putting in the eye drops.

Tell your doctor if your condition gets worse or does not get better while using OCUFEN® eye drops.

Things you must not do

Do not give OCUFEN® eye drops to anyone else, even if they have the same condition as you.

Things to be careful of

Your vision may blur for a short time after you put in your OCUFEN® eye drops. If this happens you should wait until you can see well again before you drive or use machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using OCUFEN® eye drops may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your optical practitioner, doctor or pharmacist if you notice any of the following and they worry you:

- transient burning
- stinging
- irritation of the eye(s)
- excess widening of the pupil
- eye redness
- bleeding in the front chamber of the eye
- allergic reactions.

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice any other effects.

After using OCUFEN® eye drops

Storage

Keep your OCUFEN® eye drops in a cool place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Do not carry the eye drops in pockets of your clothes. Heat and dampness can destroy some medicines.

Keep the ampoules where children cannot reach them.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines

Disposal

If your doctor tells you to stop using the eye drops or they have passed their expiry date, ask your pharmacist what to do with any remaining ampoules.

Product description

What OCUFEN® eye drops look like:

Clear, colourless, sterile solution in an ampoule containing 0.4 mL of solution, and packed in a foil pouch in a carton.

Ingredients

Active ingredient:

Flurbiprofen sodium 300 µg/mL

Inactive ingredients:

- Polyvinyl alcohol
- potassium chloride
- sodium citrate
- sodium chloride
- citric acid
- purified water
- sodium hydroxide and/or hydrochloric acid

Manufacturer/Supplier

ALLERGAN AUSTRALIA PTY LTD

810 Pacific Highway,
Gordon NSW 2072
ABN 85 000 612 831
Toll free: 1800 252 224 (Australia)

ALLERGAN NEW ZEALAND LIMITED

Cnr Manu Tapu Drive & Joseph Hammond Place,
Auckland International Airport,
Auckland,
New Zealand
Freephone: 0800 659 912 (NZ)

OCUFEN® eye drops can be identified by registration number: AUST R 55364

Date of preparation: June 2012

® marks owned by Allergan, Inc

©2012 Allergan, Inc.