



# Bromfenac 0.9mg/ml eye drops, solution

Bromfenac

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

### 1 What Bromfenac is and what it is used for

This medicine contains the active substance bromfenac and belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It works by blocking certain substances involved in causing inflammation.

Bromfenac is used to reduce eye inflammation following cataract surgery in adults.

### 2 What you need to know before you use Bromfenac

#### Do not use Bromfenac

- if you are allergic to bromfenac or to any of the other ingredients of this medicine (listed in section 6).
- if you have experienced asthma, skin allergy or intense inflammation in your nose when using other NSAIDs. Examples of NSAIDs are: acetylsalicylic acid, ibuprofen, ketoprofen, diclofenac.

#### Warnings and precautions

Talk to your doctor or pharmacist before using this medicine

- if you are using topical steroids (e.g. cortisone), as this may cause unwanted side effects.
- if you have bleeding problems (e.g. haemophilia) or have had them in the past, or you are taking other medicines which may prolong bleeding time (e.g. warfarin, clopidogrel, acetylsalicylic acid).
- if you have eye problems (e.g. dry eye syndrome, corneal problems).
- if you have diabetes.
- if you have rheumatoid arthritis.
- if you had repeated eye surgery within a short period of time.

Wearing contact lenses is not recommended after cataract surgery. Therefore, do not wear contact lenses whilst using Bromfenac.

#### Children and adolescents

Bromfenac should not be used in children and adolescents.

#### Other medicines and Bromfenac

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 may be pregnant or are planning to have a baby, ask your doctor for advice before you use Bromfenac.

Bromfenac should not be used during the last three months of pregnancy. The doctor may prescribe this medicine during pregnancy if expected benefit to mother outweigh the possible risk to the baby.

Bromfenac may be prescribed to breast-feeding women and have no important influence on fertility.

#### Driving and using machines

Your vision may be blurred for a short time after using this eye drops. If you experience blurred vision upon instillation, do not drive or use machines until your vision is clear.

## Bromfenac contains benzalkonium chloride

This medicine contains 0.00155mg benzalkonium chloride in each drop which is equivalent to 0.05mg/ml.

Benzalkonium chloride 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 Bromfenac

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

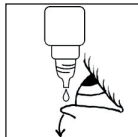
#### Dose

The recommended dose is one drop of Bromfenac in the affected eye(s) twice daily (morning and evening). Do not use more than one drop in the affected eye(s) 2 times daily. Start using the drops the next day after your cataract surgery.

#### Method of administration

*Bromfenac is for ocular use.*

- Wash your hands before using the eye drops.
- Put yourself in a comfortable and stable position.
- Twist off the bottle cap.
- Hold the bottle, pointing down, between your thumb and fingers.
- Tilt your head back.
- Pull down your lower eyelid with a clean finger.
- Bring the bottle tip close to the eye.
- Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper.
- Gently squeeze the bottle to release one drop of Bromfenac.
- Close the bottle cap firmly immediately after use.
- Keep the bottle tightly closed when not in use.



If you use any other eye drops, wait at least five minutes between using Bromfenac and the other drops.

#### Duration of treatment

Continue the drops through the first 2 weeks after your surgery. Do not use Bromfenac longer than 2 weeks.

#### If you use more Bromfenac than you should

Rinse out your eye with warm water. Do not put in any more drops until it is time for your next regular dose. If Bromfenac is accidentally swallowed, a glass of water or other fluid should be taken to water down the medicine.

#### If you forget to use Bromfenac

Use a single dose as soon as you remember. If it is almost time for the next dose, leave out the missed dose. Continue with the next regularly scheduled dose. Do not use a double dose to make up for a forgotten dose.

#### If you stop using Bromfenac

Do not stop using Bromfenac without speaking to your doctor.

In rare cases upon withdrawal of Bromfenac, a flare-up of the inflammatory response, e.g. in the form of retina swelling, due to the cataract operation has been observed.

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 experience decreased or blurred vision the week after the end of treatment, contact your doctor immediately.

If you notice any of the following side effects while using the drops, contact your doctor immediately:

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

Foreign body sensation in the eye, redness and inflammation of the eye, damage and inflammation of the surface of the eye, eye discharge, itching, irritation or pain of the eye, swelling or bleeding of the eyelid, impaired vision due to inflammation, floaters or moving spots before the eyes or diminishing vision that can indicate bleeding or damage of the back of the eye (retina), ocular discomfort, sensitivity to light, reduced or blurred vision, swelling of the face, cough, nosebleeding or runny nose.

##### Rare side effects (may affect up to 1 in 1,000 people)

Damage of the eye surface, redness of the eye, asthma.

##### 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, 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 Bromfenac

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 and outer carton after "EXP". The expiry date refers to the last day of that month.

Discard the bottle 4 weeks after first opening to prevent infection even if there is solution remaining. Write the date of opening on the carton label in the space provided.

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 Bromfenac contains

- The active substance is bromfenac. One ml of solution contains 0.9mg bromfenac (as sodium sesquihydrate).
- The other ingredients are: boric acid, borax, sodium sulphite anhydrous (E221), benzalkonium chloride (see section 2), tyloxapol, povidone (K-30), disodium edetate, water for injections, sodium hydroxide and hydrochloric acid 1M (to keep acidity levels normal).

##### What Bromfenac looks like and contents of the pack

Bromfenac is a clear yellow liquid (solution) supplied in a pack containing one 5ml plastic bottle with a screw cap.

##### Marketing Authorisation Holder

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**This leaflet was last revised in December 2025.**

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**Please be ready to give the following information:**

**Product name: Bromfenac 0.9mg/ml eye drops, solution**

**Reference number: PL 35533/0274**

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