Package leaflet: Information for the user

Optilamid 10 mg/ml, oogdruppels suspensie

Brinzolamide

Read all of this leaflet carefully before you start taking 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, please ask your doctor, your pharmacist or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Optilamid 10 mg/ml, oogdruppels suspensie is and what it is used for

Optilamid 10 mg/ml, oogdruppels suspensie contains brinzolamide which belongs to a group of medicines called carbonic anhydrase inhibitors. It reduces pressure within the eye.

Optilamid 10 mg/ml, oogdruppels suspensie is used to treat high pressure in the eye. This pressure can lead to an illness called **glaucoma.**

If the pressure in the eye is too high, it can damage your sight.

2. What you need to know before you use Optilamid 10 mg/ml, oogdruppels suspensie

Do not use Optilamid 10 mg/ml, oogdruppels suspensie
- **if you have severe kidney problems.**
- **if you are allergic** to brinzolamide or any of the other ingredients of this medicine (listed in section 6).
- **if you are allergic to medicines called sulphonamides.** EXAMPLES include medicines used to treat diabetes and infections and also diuretics (water tablets). **Optilamid 10 mg/ml, oogdruppels suspensie** may cause the same allergy.
- **if you have too much acidity in your blood** (a condition called hyperchloraemic acidosis).

If you have further questions ask your doctor for advice.

Warnings and Precautions
Talk to your doctor or pharmacist or nurse:
- **if you have kidney or liver problems.**
- **if you have dry eyes or cornea problems.**
- **if you are taking other sulphonamide medicines**
- **if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using brinzolamide or other related medicines.**

Take special care with brinzolamide:
Serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in association with brinzolamide treatment. Stop using brinzolamide and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Children and adolescents
Optilamid 10 mg/ml, oogdruppels suspensie is not to be used by infants, children or adolescents under 18 years of age unless advised by your doctor.

Other medicines and Optilamid 10 mg/ml, oogdruppels suspensie
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines including medicines obtained without a prescription.
If you are taking another carbonic anhydrase inhibitor (acetazolamide or dorzolamide, see section 1: What Optilamid 10 mg/ml, oogdruppels suspensie is and what it is used for), talk to your doctor.

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 or pharmacist for advice before using this medicine.

Women who may become pregnant are advised to use effective contraception during Optilamid 10 mg/ml, oogdruppels suspensie treatment. The use of Optilamid 10 mg/ml, oogdruppels suspensie is not recommended during pregnancy or breast-feeding. Do not use Optilamid 10 mg/ml, oogdruppels suspensie unless clearly indicated by your doctor.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Do not drive or use machines until your vision is clear. You may find that your vision is blurred for a time just after using Optilamid 10 mg/ml, oogdruppels suspensie .

Optilamid 10 mg/ml, oogdruppels suspensie may impair the ability to perform tasks requiring mental alertness and/or physical coordination. If affected, take care when driving or using machines.

If you wear soft contact lenses.
Optilamid 10 mg/ml, oogdruppels suspensie contains 0.15 mg benzalkonium chloride in each ml of eye drops suspension. Benzalkonium chloride may 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.

Benzalkonium chloride may also 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.

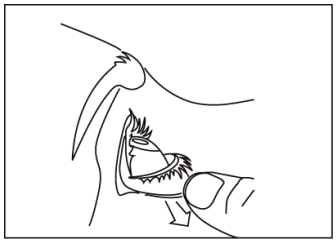
3. How to use Optilamid 10 mg/ml, oogdruppels suspensie

Always use Optilamid 10 mg/ml, oogdruppels suspensie exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist or nurse if you are not sure.

Only use Optilamid 10 mg/ml, oogdruppels suspensie for your eyes. Do not swallow or inject.

The recommended dose is
1 drop in the affected eye or eyes, twice a day - morning and night.
Use this much unless your doctor told you to do something different. Only use Optilamid 10 mg/ml, oogdruppels suspensie in both eyes if your doctor told you to. Use it for as long as your doctor told you to.

How to use



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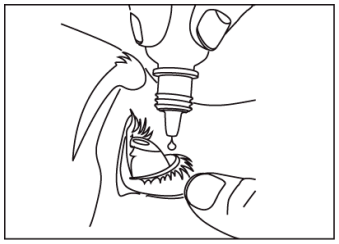

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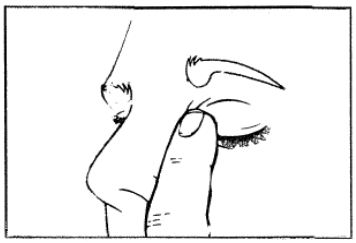

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- Get the Optilamid 10 mg/ml, oogdruppels suspensie bottle and a mirror
- Wash your hands
- Shake the bottle and twist off the cap. After the cap is removed, if the tamper evident snap collar is loose, remove before using product.
- Hold the bottle, pointing down, between your thumb and forefinger
- Tilt your head back. Pull down your eyelid with a clean finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here (picture 1)
- Bring the bottle tip close to the eye. Use the mirror if it helps
- Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops
- Squeeze one drop into the formed pocket (picture 2)
- After using Optilamid 10 mg/ml, oogdruppels suspensie , press a finger to the corner of your eye, by the nose (picture 3) for at least 1 minute. This helps to stop Optilamid 10 mg/ml, oogdruppels suspensie getting into the rest of the body.
- If you take drops in both eyes, repeat the steps for your other eye.
- Put the bottle cap back on firmly immediately after use
- Use up one bottle before opening the next bottle.

If you are using other eye drops, leave at least 5 minutes between putting in Optilamid 10 mg/ml, oogdruppels suspensie and the other drops. Eye ointments should be administered last.

If you use more Optilamid 10 mg/ml, oogdruppels suspensie than you should
If you get too much in your eyes, rinse it all out with warm water. Do not put in any more drops until it is time for your next regular dose.

If you forget to use Optilamid 10 mg/ml, oogdruppels suspensie
Use a single drop as soon as you remember, and then go back to your regular routine. **Do not** use a double dose to make up for a forgotten dose.

If you stop using Optilamid 10 mg/ml, oogdruppels suspensie
If you stop using Optilamid 10 mg/ml, oogdruppels suspensie without speaking to your doctor, the pressure in your eye will not be controlled which could lead to loss of sight.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them. You can usually carry on using the drops, unless the effects are serious.

Stop using brinzolamide and seek medical attention immediately if you notice any of the following symptoms:

• reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).

The following side effects have been seen with Optilamid 10 mg/ml, oogdruppels suspensie :

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

Effects in the eye:
blurred vision, eye irritation, eye pain, eye discharge, itchy eye, dry eye, abnormal eye sensation, redness of the eye.

General side effects:
bad taste.

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

Effects in the eye:
sensitivity to light, inflammation or infection of the conjunctiva, eye swelling, eyelid itching, redness or swelling, growth on surface of eye, increased pigmentation of the eye, tired eyes, eyelid crusting, or increased tear production.

General side effects:
decreased or reduced heart function, palpitations, decreased heart rate, difficulty breathing, shortness of breath, cough, decreased red blood cell count in blood, increased chlorine level in blood, dizziness, drowsiness, difficulty with memory, depression, nervousness, generalized weakness, fatigue, feeling abnormal, pain, shaking, decreased sex drive, male sexual difficulty, cold symptoms, chest congestion, sinus infection, throat irritation, throat pain, abnormal or decreased sensation in mouth, inflammation of the lining of the oesophagus, abdominal pain, nausea, vomiting, upset stomach, frequent bowel movements, diarrhoea, intestinal gas, digestive disorder, kidney pain, muscle pain, muscle spasms, back pain, nose bleeds, , runny nose, stuffy nose, sneezing, rash, abnormal skin sensation, itching, headache, dry mouth.

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

Effects in the eye:
corneal swelling, double or reduced vision, abnormal vision, decreased eye sensation, swelling around the eye, increased pressure in eye, damage to the optic nerve.

General side effects:
memory impairment, drowsiness, chest pain, upper respiratory tract congestion, sinus congestion, nasal congestion, dry nose, ringing in ears, hair loss, generalized itching, feeling jittery, irritability, irregular heart rate, body weakness, difficulty sleeping.

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

Effects in the eye:
eyelid abnormality, visual disturbance, corneal disorder, eye allergy, decreased growth or number of eyelashes.

General side effects:
increased allergic symptoms, decreased sensation, tremor, loss or decrease in taste, decreased blood pressure, increased blood pressure, increased heart rate, joint pain, asthma, pain in extremity, skin redness, inflammation, or itching, abnormal liver blood tests, swelling of the extremities, frequent urination, decreased appetite, reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes, which can be

preceded by fever and flu-like symptoms. These serious skin rashes can be potentially life-threatening (Stevens-Johnson syndrome, toxic epidermal necrolysis).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system <to be completed nationally>. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Optilamid 10 mg/ml, oogdruppels suspensie

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 box after "EXP". The expiry date refers to the last day of the month.

This medicine does not require any special storage conditions.

You must throw away a bottle four weeks after you first opened it, to prevent infections. Write down the date you opened each bottle in the space below and on the bottle label and box. For a pack containing a single bottle, write only one date.

Opened (1)
Opened (2)
Opened (3)

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 Optilamid 10 mg/ml, oogdruppels suspensie contains
The active substance is brinzolamide 10 mg/ml.
The other ingredients are: benzalkonium chloride, carbomer 974P, edetate disodium, mannitol, purified water, sodium chloride. Tiny amounts of hydrochloric acid or sodium hydroxide are added to keep acidity levels (pH levels) normal.

What Optilamid 10 mg/ml, oogdruppels suspensie looks like and the contents of the pack

Optilamid 10 mg/ml, oogdruppels suspensie is a white to off-white homogenous suspension.
The primary container is a 10 ml low density polyethylene (LDPE) sterile bottle contains 5 ml of suspension, with a LDPE sterile insert dropper and a high density polyethylene (HDPE) sterile cap with a tamper proof seal.

Cartons containing 1 or 3 bottles.
Not all pack sizes may be marketed.

The Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder
Pharmaceutical Works POLPHARMA SA
19, Pelplińska Street,
83-200 Starogard Gdański,

Poland

Manufacturer
Pharmaceutical Works POLPHARMA SA
19, Pelplińska Street,
83-200 Starogard Gdański, Poland

Lusomedicamenta Sociedade Técnica Farmacêutica, S.A.
Rua Norberto de Oliveira, no 1/5, Póvoa de Santo Adrião, 2620-111,
Portugalia

This medicinal product is authorised in the member states of the EEA under the following names:

Lithuania	Optilamid 10 mg/ml akių lašai (suspensija)
Latvia	Optilamid 10 mg/ml,
Poland	Optilamid 10 mg/ml acu pilieni, suspensija

Deze bijsluiter is voor het laatst goedgekeurd in januari 2024.