



PACKAGE LEAFLET: INFORMATION FOR THE USER

777195BMP/2J

Ocumont 1% w/w Eye Ointment

Chloramphenicol



Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better after 5 days or if you feel worse at any time.

In this leaflet you will find the following information:

1. What your medicine is and what it is used for
2. Before you use your medicine
3. How to use your medicine
4. Possible side effects
5. How to store your medicine
6. Contents of the pack and other information

1. WHAT YOUR MEDICINE IS AND WHAT IT IS USED FOR

It is an eye ointment and each tube contains 4 grams of the medicine. The active ingredient in this ointment is chloramphenicol, which is an antibiotic (medicines used for infections caused by bacteria).

This ointment is used to treat acute bacterial conjunctivitis, which is an infection of the outer surface of the eye that causes redness, discomfort and discharge from the affected eye. However, this ointment is not suitable for treating severe infections that have spread to the deeper layers of the eye.

2. BEFORE YOU USE YOUR MEDICINE

Do not use this Ointment if:

- You are allergic to chloramphenicol or any of the other ingredients of this medicine (listed in Section 6 for more details)
- You or anyone in your family has had blood problems such as a low white blood cell, red blood cell or platelet count.

This ointment is for children over 2 years, adults and the elderly. Do not use in children below the age of 2 years without advice from a doctor.

Warnings and Precautions

Do not use this ointment and seek advice from a doctor if

- Your eye sight is affected, for example, reduced or blurred vision
- You have pain within the eye
- Your eyes are sensitive to light
- Your eye is inflamed and you have a rash on the scalp or face
- Your eye looks cloudy
- The pupil of your eye looks unusual
- You have or think you may have a

foreign body in the eye

- You have recently had an eye infection
- You have or have had glaucoma (raised pressure in the eye) or dry eyes
- You have had eye surgery or laser treatment in the last 6 months
- Your eye has had an injury
- You are using any eye drops or eye ointment
- You wear contact lenses. If you have been advised to use this ointment, do not wear your lenses during the course of treatment. Soft contact lenses should not be replaced for 24 hours after completing the treatment.

Before using this ointment, tell your pharmacist if you suffer from any other eye problems.

Other medicines and Ocumont Eye Ointment

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Do not use this ointment if you are taking bone marrow depressant drugs (drugs which reduce bone marrow activity resulting in low blood cell counts) such as azathioprine or are receiving chemotherapy.

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 or pharmacist for advice before using this ointment.

Driving and using machines

Do not drive or operate machines if you have blurred vision after using this ointment. You should wait until your vision clears before driving or using machines.

3. HOW TO USE YOUR MEDICINE

- Always use this ointment exactly as your pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Use only in the eye, do not take it by mouth. The contents are sterile until the seal is broken. Do not use if the seal is broken before first opening.

Dose

Children over 2 years, adults and the elderly:

The dose is about 1 cm of ointment to be put in the affected eye(s).

If using just the eye ointment, use it 3 to 4 times a day.

If using eye drops during the day and the ointment at night - put the ointment in just before going to bed.

The course of treatment is 5 days; so, keep using the ointment for 5 days even if you feel better.

Use your ointment in the following way:

1. Always wash and dry your hands before you put the eye ointment in the eye.
2. Remove the cap.

3. Take special care that the nozzle of the tube does not touch your eye, the skin around your eye or your fingers.
4. You may use a mirror to help you see what you are doing.
5. Place the nozzle of the tube close to your eye and gently pull the lower eyelid downwards and look up.
6. Squeeze the tube gently and put about 1 cm of ointment in the space between the lower lid and the eye.
7. Close your eye for a moment.
8. Where both eyes are to be treated, repeat steps from 3 to 7.
9. Replace the cap securely after use.

Do not

- use this ointment for more than 5 days without consulting your doctor
- share your ointment with anyone else

If you use too much or swallow your ointment, contact your doctor although it is unlikely to cause you any harm.

If you forget to use a dose of this ointment, put it in as soon as possible, but if it is almost time for the next dose then miss the skipped dose and return to your normal dosing schedule. Do not use a double dose to make up for a missed dose.

Talk to your doctor if your eyes do not improve within 48 hours.

If your eye gets worse see your doctor straight away.

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

4. POSSIBLE SIDE EFFECTS

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

Stop using this ointment and immediately contact your doctor if you get any of the following symptoms (general allergic reaction): breathing problems, fever, swelling of the face, lips or tongue or rash with swelling of the skin

Or, very rarely, bruising, bleeding, infections and weakness (symptoms of blood disorder).

As with other eye preparations, you may occasionally experience eye burning, stinging, sensitivity or visual blurring after initial application. If this continues or increases, stop using the ointment.

Chloramphenicol may not work against certain types of infections and other types of bacteria or fungi, which are not killed, may take over from the original infection. This may seem as if the original infection has not cleared up or has got worse.

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 By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE YOUR MEDICINE

Keep out of the sight and reach of children.

Do not store the tube above 25°C.

Do not use this ointment after the expiry date which is stated on the tube and the carton.

After 5 days throw away any eye ointment left. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

The active ingredient in **Ocumont Eye Ointment** is chloramphenicol 1% w/w which is equivalent to chloramphenicol 10 mg per gram. This product also contains liquid paraffin and white petroleum as excipients. Each tube of Ocumont Eye Ointment contains 4 grams of yellowish-white ointment.

Marketing Authorisation Holder:

Blumont Pharma Ltd.,
23 Moortown Close, Grantham,
United Kingdom NG31 9GG

Manufacturer:

Tubilux Pharma S.p.A.,
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PL Number: 31103/0018

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