

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Ocumont 1% w/w Eye Ointment

Boots Infected Eyes 1% w/w Eye Ointment

Almus Infected Eye 1% w/w Eye Ointment

Ocufresh Infected Eye 1% w/w Eye Ointment

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chloramphenicol 1% w/w

For a full list of excipients, see Section 6.1

## 3 PHARMACEUTICAL FORM

Eye Ointment.

Homogeneous, yellowish-white ointment.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Treatment of acute bacterial conjunctivitis.

### 4.2 Posology and method of administration

Administration: For topical ocular use only.

Adults, children aged 2 years and over, and elderly:

The recommended dose is to apply about 1 cm of ointment to the affected eye(s).

If using chloramphenicol eye drops during the day, apply the ointment at night. If using the eye ointment alone, apply 3 to 4 times a day. Your doctor, pharmacist or nurse will advise on the most suitable treatment.

The course of treatment is 5 days; treatment should continue for 5 days even if symptoms improve.

### 4.3 **Contra-indications**

Known hypersensitivity to chloramphenicol or to any of the excipients.

Family or personal history of blood dyscrasias including myelosuppression and aplastic anaemia.

### 4.4 **Special warnings and precautions for use**

Chloramphenicol is absorbed systemically from the eye and toxicity has been reported following chronic exposure (see section 4.8).

In severe infections and in cases where infection is not confined to the conjunctivae, the topical use of chloramphenicol should be supplemented by appropriate systemic treatment. Therefore, the patient should be referred to seek medical advice.

The use of topical chloramphenicol may occasionally result in overgrowth of non susceptible organisms, including fungi. If any new infection appears during the treatment, the patient should be referred to the doctor.

Prolonged or frequent intermittent topical application of chloramphenicol should be avoided since it may increase the likelihood of sensitisation and emergence of resistant organisms.

Do not use for more than 5 days without consulting your doctor, pharmacist or nurse.

The label will convey the following information:

- If you do not get better within 48 hours, talk to your doctor
- If your eye gets worse see your doctor straight away
- Do not use this ointment if you are allergic to chloramphenicol or anything else in the ointment
- After five days, throw away any eye ointment left, unless a longer course of treatment has been advised by your doctor, pharmacist or nurse
- For Ocular use only.

Patients should be referred to a doctor if any of the following apply:

- Disturbed vision
- Any significant pain within the eye
- Photophobia
- Eye inflammation associated with a rash on the scalp or face
- The eye looks cloudy
- The pupil looks unusual
- Suspected foreign body in the eye

Patients should also be referred to their doctor if any of the following in his/her medical history apply:

- Previous conjunctivitis in the recent past
- Glaucoma
- Dry eye syndrome
- Eye surgery or laser treatment in the last 6 months
- Eye injury
- Current use of other eye drops or eye ointment

If you wear contact lenses, seek advice either from your optometrist, contact lens practitioner or doctor before you use this product. You should not wear your contact lenses during the course of treatment. If you wear soft contact lenses do not start wearing them for at least 24 hours after you have finished using the eye ointment.

#### **4.5 Interaction with other medicinal products and other forms of interactions**

The concomitant administration of chloramphenicol with other drugs liable to depress bone marrow function should be avoided.

#### **4.6 Fertility, pregnancy and lactation**

Safety for use in pregnancy and lactation has not been established. As this product is for sale without prescription, it is not recommended for use during pregnancy.

In view of the fact that chloramphenicol may appear in breast milk, use of the product during lactation should be avoided..

#### **4.7 Effects on ability to drive and use machines**

Transient blurring of vision may occur immediately after use and patients should be warned that driving or using machinery should not occur until the vision is clear.

#### **4.8 Undesirable effects**

Transient burning or stinging sensations may occur.

Serious side effects include hypersensitivity reactions that may manifest as angioneurotic oedema, anaphylaxis, urticaria, fever, and vesicular and maculopapular dermatitis and are causes for immediate discontinuation.

Bone marrow depression, including the idiosyncratic type of irreversible and fatal aplastic anaemia that is recognised to occur with systemic therapy, has been reported in association with topical administration of chloramphenicol.

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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.

#### **4.9 Overdose**

Accidental ingestion of the ointment is unlikely to cause systemic toxicity due to the low content of the antibiotic in the product. If irritation, pain, swelling, lacrimation or photophobia occur after undesired eye contact, the exposed eye(s) should be irrigated for at least 15 minutes. If symptoms persist after this, an ophthalmological examination should be considered.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

ATC Code: S01AA01

Chloramphenicol is a broad spectrum antibiotic with bacteriostatic activity and is effective against a wide range of gram-negative and gram-positive organisms.

### **5.2 Pharmacokinetic properties**

Chloramphenicol enters the aqueous humour following topical application.

Chloramphenicol is widely distributed in body tissues and fluids: it enters the CSF, giving concentrations of about 50% of those existing in the blood even in the absence of inflamed meninges; it diffuses across the placenta into the foetal circulation, into breast milk, and into the aqueous and vitreous humour of the eye.

### **5.3 Preclinical safety data**

Nothing of relevance which is not included in other sections of the SPC.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Liquid paraffin  
White petroleum

### **6.2 Incompatibilities**

None known

### **6.3 Shelf life**

Unopened: 48 months  
Opened: 4 weeks

### **6.4 Special precautions for storage**

Do not store above 25°C

Although the shelf life once opened is 4 weeks, patients will be advised to discard the medicine after completing the 5 days course of treatment, unless a longer course of treatment has been advised by your doctor, pharmacist or nurse

### **6.5 Nature and contents of container**

Aluminium tube and polyethylene cap containing 4g of homogeneous, yellowish-white ointment.

### **6.6 Special precautions for disposal**

None stated

## **7 Marketing authorisation holder**

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

## **8 MARKETING AUTHORISATION NUMBER(S)**

PL 31103/0018

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

13/12/2024

## **10 DATE OF REVISION OF THE TEXT**

10/01/2025