SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Lumecol 0.5% w/v Eye Drops, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient

Chloramphenicol 0.5g in 100ml

Excipient(s) with known effect Boric acid 15mg/ml

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye Drops, Solution

A bright, colourless to faint yellow aqueous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of acute bacterial conjunctivitis in adults and children aged 2 years and over.

4.2 Posology and method of administration

One drop instilled into the infected eye every 2 hours for the first 48 hours and 4 hourly thereafter. To be used during waking hours only. The course of treatment is 5 days.

Treatment should continue for 5 days even if symptoms improve.

For ocular use.

4.4 Special warnings and precautions for use

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

In severe bacterial conjunctivitis 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 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.

The label will convey the following information:

- If you do not get better within 48 hours talk to a doctor.
- If your eyes get worse see a doctor straight away.
- Do not use these eye drops if you are allergic to chloramphenicol or anything else in the drops.
- After 5 days, throw away any eye drops left.

For external use only.

Keep all medicines out of the sight and reach of children.

Phenylmercuric nitrate is irritant to the skin. Topical application to eyes has been associated with mercurialentis and atypical band keratopathy.

Do not give to a child less than 2 years old as this medicine contains boron and may impair fertility in the future

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

• Disturbed vision

• Severe 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

• Contact lens use

If this product is used following advice from a contact lens practitioner or doctor contact lenses should not be worn during the course of treatment. Soft contact lenses should not be replaced for 24 hours after completing the treatment.

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4.5 Interaction with other medicinal products and other forms of interaction

Bone marrow depressant drugs.

4.6 Fertility, pregnancy and lactation

Safety for use in pregnancy and lactation has not been established. Therefore, use only when considered essential by the physician.

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. More serious side effects include bone marrow depression and rarely aplastic anaemia, angioneurotic oedema, anaphylaxis, urticaria, fever, vesicular and maculopapular dermatitis have been reported and are causes for discontinuation.

The preservative, phenylmercuric nitrate, may cause allergic reaction.

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 at: 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 eye drops 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 Ophthalmological Antiinfective Antibiotic

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

Following topical application to the eye, chloramphenicol may be absorbed into the aqueous humour. Sufficient chloramphenicol may be absorbed from the eye to appear in the systemic circulation.

Specific data on systemic absorption from this dosage presentation is not available.

Chloramphenicol is readily absorbed when given by mouth. Blood concentrations of 10µg per ml or more may be reached about 1 or 2 hours after a single dose of 1g by mouth, and blood concentrations of about 18.5µg per ml have been reported after multiple 1g doses. Choramphenicol palmitate is hydrolysed to chloramphenicol in the gastrointestinal tract prior to absorption, and the sodium succinate, which is given parenterally is probably hydrolysed to free drug mainly in the liver, lungs, and kidneys; such hydrolysis may be incomplete in infants and neonates, contributing to the variable pharmacokinetics in this age group. Chloramphenicol sodium succinate is, even in adults, only partially and variably hydrolysed, so that blood concentrations of chloramphenicol obtained after parenteral administration of the sodium succinate are often lower than those obtained after administration of chloramphenicol by mouth, with up to 30% of a dose excreted unchanged in the urine before hydrolysis can take place.

Chloramphenicol is widely distributed in body tissues and fluids; it enters the cerebrospinal fluid, 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 humours of the eye. Up to about 60% in the circulation is bound to plasma protein. The half-life of chloramphenicol has been reported to range from 1.5 to 4 hours; the half-life is prolonged in patients with severe hepatic impairment and is also much longer in neonates. Renal impairment has relatively little effect on the half-life of the active

drug, due to its extensive metabolism, but may lead to accumulation of the inactive metabolites.

Chloramphenicol is excreted mainly in the urine but only 5 to 10% of an oral dose appears unchanged; the remainder is inactivated in the liver, mostly by conjugation with glucorinic acid. About 3% is excreted in the bile. However, most is reabsorbed and only about 1%, mainly in the inactive form, is excreted in the faeces.

The absorption, metabolism, and excretion of chloramphenicol are subject to considerable interindividual variation, especially in infants and children, making monitoring of plasma concentrations necessary to determine pharmacokinetics in a given patient.

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

Borax

Boric Acid

Phenyl Mercuric Nitrate

Water for Injections

6.2 Incompatibilities

None known

6.3 Shelf life

Contents are sterile until opened

Unopened: 24 months

Opened: 28 days

Although the shelf life once opened is 28 days, patients should be advised to discard the medicine after a 5 day course of treatment.

6.4 Special precautions for storage

Store in a refrigerator (2°C – 8°C).

Keep the bottle in the outer carton in order to protect from light.

6.5 Nature and contents of container

10ml low density polyethylene bottle with low density polyethylene dropper and high density polyethylene cap

6.6 Special precautions for disposal

None

7. MARKETING AUTHORISAITON HOLDER

Medicom Healthcare Ltd
Lynton House, 7-12 Tavistock Square,
Kings Cross, London,
WC1H 9LT,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 18956/0013

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29/01/2025

10 DATE OF REVISION OF THE TEXT

29/01/2025