SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Eykappo 5 mg/ml eye drops solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Eykappo 5 mg/ml eye drops solution contains 5 mg/ml chloramphenicol.

3 PHARMACEUTICAL FORM
Eye drops, solution.

Clear, colourless, aqueous eye drops solution
Osmolality: 260-320 mOsm/Kg
pH: 6.8 -7.8

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
Chloramphenicol is indicated in adults and children for the treatment of acute bacterial conjunctivitis.
Considerations should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration
Posology

Adults (including the elderly) and children
One to two drops applied topically to each affected eye up to six times daily or more frequently if required. To decrease the risk for recurrent infection, treatment should continue for an additional 2 days after symptoms disappear. The maximum recommended treatment duration is 14 days.

Paediatric population
Dosage adjustment may be necessary in newborn infants because of reduced systemic elimination due to immature metabolism and the risk of dose-related adverse effects. The maximum duration of treatment is 10-14 days.

Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute following instillation of the drops.

**Method of administration**

For ocular use.

Eykappo eye drops solution is a sterile solution that does not contain a preservative. Patients should be instructed to wash their hands before use and avoid allowing the tip of the container to come into contact with the eye or surrounding structures as this could cause injury to the eye.

Patients should also be instructed that ocular solutions, if handled improperly, can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

### 4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

### 4.4 Special warnings and precautions for use

In severe infections topical use of chloramphenicol should be supplemented with appropriate systemic treatment.

Prolonged use should be avoided as it may increase the likelihood of sensitisation and the emergence of resistant organisms.

Contact lenses should not be worn in an infected eye. Contact lenses should be removed during the period of treatment.

Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the drops. (This blocks the passage of the drops via the naso lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisable in children).
4.5 **Interaction with other medicinal products and other forms of interaction**
Since low systemic concentrations of chloramphenicol are expected after topical use, the risk for relevant interactions is expected to be low.

4.6 **Fertility, Pregnancy and lactation**

**Pregnancy and breast-feeding**
Safety for use in pregnancy and lactation has not been established, therefore, use only when considered essential by the physician. Chloramphenicol passes the placenta and is excreted in breast milk.

**Fertility**
No fertility data are available.

4.7 **Effects on ability to drive and use machines**
May cause transient blurring of vision on installation. Warn patients not to drive or operate hazardous machinery unless vision is clear.

4.8 **Undesirable effects**

**Local**
Sensitivity reactions such as transient irritation, burning, stinging, itching and dermatitis, may occur.

**Paediatric population**
The adverse reaction profile in children is expected to be similar to adults.

**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 (www.mhra.gov.uk/yellowcard).

4.9 **Overdose**
Not applicable.
5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Ophthalmological antibiotic, ATC code: S01AA01

Chloramphenicol is an antibiotic which is mainly bacteriostatic in action, but exerts a bactericidal effect against some strains of gram-positive cocci and against *Haemophilus influenzae* and *Neisseria*. It has a broad spectrum of action against both gram-positive and gram-negative bacteria, rickettsiae and chlamydia.

5.2 Pharmacokinetic properties
Chloramphenicol penetrates into ocular tissues and aqueous humour. Part of the chloramphenicol administered topically may be absorbed systemically by way of the nasolacrimal duct. Limited data, however, indicate no significant increases of chloramphenicol serum concentration after topical administration.

After oral administration, chloramphenicol is rapidly absorbed. Chloramphenicol is inactivated by conjugation with glucuronic acid or by reduction to inactive aryl amines in the liver. Excretion is mainly renal, though some bile excretion occurs following oral administration. Elimination is subject to high variability but the half-life is estimated to 1.5–4 hours. The half-life is prolonged in patients with severe hepatic impairment and in neonates.

5.3 Preclinical safety data
There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Boric acid
Borax
Sodium hydroxide or/and Hydrochloric acid (for pH adjustment)
Water for injection
6.2 Incompatibilities
   Not applicable

6.3 Shelf life
   2 years.
   After opening: 28 days

6.4 Special precautions for storage
   Store between 2° and 8°C. Do not freeze. Protect from light.

6.5 Nature and contents of container
   The eye drop solution is presented as a 10 ml clear, colourless aqueous solution in an
   11 ml LDPE white opaque ophthalmic dropper container.
   Pack sizes: 1 bottle in cardbox.

6.6 Special precautions for disposal
   Any unused medicinal product or waste material should be disposed of in accordance
   with local requirements.

7 MARKETING AUTHORISATION HOLDER
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8 MARKETING AUTHORISATION NUMBER(S)
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