SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

GEMYSETIN 1% Eye Ointment
Sterile

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g eye ointment contains:
Active substance:
Chloramphenicol 10 mg
Excipients with known effect:
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye ointment.
Almost colorless, translucent, greasy and homogenous ointment in sterile aluminum tubes.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Chloramphenicol is used in serious infections for which less potentially drugs are ineffective or contraindicated. GEMYSETIN 1% Eye Ointment is indicated for the treatment of superficial ophthalmic infections involving the conjunctiva or cornea caused by chloramphenicol-susceptible organisms. It is effective against pathogens causing common eye infections such as *Staphylococcus aureus, Streptococci, E. coli, Haemophilus influenzae, Klebsiella/Enterobacter spp., Moraxella lacunata, Neisseria spp*. This product does not provide adequate coverage against *Pseudomonas aeruginosa* and *Serratia marcescens.*

4.2 Posology and method of administration

Posology/frequency and duration of administration
Adults, and children aged 2 years and over
If only the eye ointment is to be used, approximately 1 cm of ointment is applied to the affected eye(s) 3 to 4 times a day.

If it is to be used together with chloramphenicol eye drops during the day, GEMYSETIN eye ointment should only be applied before going to bed at night.

The course of treatment is 5 days.

Method of administration
GEMYSETIN is for topical ophthalmic use only. It is applied in the area between the lower eyelid and the eye.

Additional information on special populations
Renal impairment
There are no reports regarding topical ophthalmic use in this population.

Hepatic impairment
There are no reports regarding topical ophthalmic use in this population.

Pediatric population
The eye ointment should not be used in children under 2 years of age, as there have been very rare reports of leukemia and gray baby syndrome.

Geriatric population
There are no reports regarding topical ophthalmic use in this population.

4.3 Contraindications
- Contraindicated in known hypersensitivity to chloramphenicol or to any of the excipients.
- Contraindicated in known personal or family history of blood dyscrasias including aplastic anemia.

4.4 Special warnings and precautions for use
The eye ointment should not be used in children under 2 years of age, as there have been very rare reports of leukemia and gray baby syndrome.

Prolonged use of chloramphenicol ointment is not advisable. Chloramphenicol eye ointment should not be used for more than 5 days unless approved by a doctor.

If symptoms worsen at any time during treatment or do not improve within 48 hours, the diagnosis should be reviewed.

The tube of eye ointment should be discarded after the 5-day treatment period.

GEMYSETIN eye ointment is not recommended in cases of severe pain in the eye, visual impairment, photophobia, abnormal pupils, blurred vision, glaucoma, dry eye syndrome, injury to the eye, suspicion of a foreign body in the eye, having an eye surgery or laser treatment in the past 6 months.

No lenses should be used during treatment. Soft lenses can be worn 24 hours after treatment.

4.5 Interaction with other medicinal products and other forms of interaction
The concomitant administration of chloramphenicol with other drugs liable to depress bone marrow function should be avoided.

4.6 Fertility, Pregnancy and Lactation
General recommendation
Pregnancy category is C.

Women of childbearing potential / Birth Control (Contraception)
Animal studies are insufficient with respect to effects on pregnancy /and-or/ embryonal/fetal development /and-or/ parturition /and-or/ postnatal development (see section 5.3). Potential risk for humans is unknown.

Pregnancy
Chloramphenicol is absorbed systemically following the use of eye ointment. Chloramphenicol crosses the placenta. Therefore GEMYSETIN should not be used during pregnancy.

Lactation
Chloramphenicol passes into breast milk. Therefore GEMYSETIN should not be used during breast-feeding.

Reproduction ability / Fertility
No adequate data are available for chloramphenicol from human or nonclinical fertility studies.

4.7 Effects on ability to drive and use machinery
Transient blurred vision may occur following ointment application. Therefore, patients should not operate hazardous machinery or vehicles until their vision is clear.

4.8 Undesirable effects
Undesirable effects of GEMYSETIN are categorized by frequency and organ class as follows: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000) and very rare (<1/10,000), not known (cannot be estimated from the available data).

The frequency of the following undesirable effects by system organ class cannot be estimated from the available data.

Blood and lymphatic system disorders
- Very rare : Hematologic events (bone marrow depression, aplastic anemia and death)

Skin and subcutaneous tissues disorders
- Not known : Sensitivity reactions such as transient irritation, burning, stinging, itching and dermatitis

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization 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 national reporting system.

4.9 Overdose
High dose intoxication cases with chloramphenicol-containing eye ointments are unknown.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Ophthalmologicals, Antibiotics
ATC code: S01AA01

Mechanism of action
Chloramphenicol is a broad-spectrum antibiotic, which has activity against many types of Gram-positive and Gram-negative bacteria. Chloramphenicol is not effective against fungi, protozoa, and viruses.

Acute bacterial conjunctivitis is commonly caused by staphylococci or streptococci in adults, and *Haemophilus influenzae* and *Moraxella catarrhalis* (formerly known as *Branhamella*

catarrhalis) particularly in children.

Chloramphenicol is effective against Gram-positive cocci including staphylococci such as *Staph. epidermidis* and some strains of *Staph. aureus*, and streptococci such as *Str. pneumoniae*, *Str. pyogenes,* and the viridans streptococci.

Gram-negative cocci such as *Haemophilus influenzae* are usually highly sensitive. *Moraxella catarrhalis*, a Gram-negative aerobic diplococcus frequently found as a commensal of the upper respiratory tract, is also highly sensitive.

5.2 Pharmacokinetic properties
General Properties
Absorption
Evidence suggests that chloramphenicol is absorbed systemically via topical ophthalmic use.

Distribution
Any chloramphenicol that is absorbed will be widely distributed in the body tissues and fluids. It is found in cerebrospinal fluid, is secreted in saliva, with the highest concentrations occurring in the kidneys and liver.
Chloramphenicol also diffuses across the placenta into the fetal circulation and into breast milk.

Biotransformation
It has a reported half-life of 1.5 to 5 hours, which is increased in patients with liver impairment and neonates (to between 24 and 28 hours).

Elimination
Chloramphenicol is excreted chiefly in the urine as the glucuronide with small amounts being excreted via the bile and feces.

Linearity / Non-linearity
No data are available.

5.3 Preclinical safety data
The active substance contained in this medicinal product has been in clinical use for many years. Related studies have been completed. Possible adverse effects on its use are available in relevant sections (see sections 4.4, 4.6, 4.8, 4.9).

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Paraffin liquid
Paraffin soft white

6.2 Incompatibilities
None known.

6.3 Shelf life
48 months.

6.4 Special precautions for storage
Store at room temperature below 30°C. Protect from light.

6.5 Nature and contents of packaging
Lacquered aluminum tube sealed with a HDPE cap.
Each cardboard box contains 5 g of eye ointment.

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

7. MARKETING AUTHORIZATION HOLDER
DEVA Holding A.Ş.
Halkalı Merkez Mah. Basın Ekspres Cad. No:1
34303 Küçükçekmece – İSTANBUL / TÜRKİYE

8. MARKETING AUTHORIZATION NUMBER
54/91

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION
Date of first authorization : 26.08.1960
Date of last renewal : 22.06.2011

10. REVISION DATE OF TEXT