APPROVED PROFESSIONAL INFORMATION

PROFESSIONAL INFORMATION

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v, EYE DROPS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v

Each vial contains Chloramphenicol 0, 5% w/v is equivalent to

0, 5mg/mL Chloramphenicol and Phenylmercuric nitrate 0, 002 % w/v is equivalent to 0, 002mg/mL Phenylmercuric nitrate as a preservative.

For full list of excipients, (See section 6.1)

3. PHARMACEUTICAL FORM

CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v is a bright colourless to faint yellow aqueous solution, practically clear and practically free from particles.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v is used for the local treatment of acute eye infections caused by susceptible organisms.

Chloramphenicol is indicated in adults and children.

4.2. Posology and method of administration

Adults (including the Elderly)

One to two drops applied topically to each affected eye up to six times daily or more frequently if required. Severe infections may require one or two drops every fifteen to twenty minutes initially, reducing the frequency of instillation gradually as the infection is controlled.

Paediatric population

As for adults however, 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.

Method of administration:

CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v are ocular use only - Topical administration to the eye as directed by the ophthalmologist.

4.3. Contraindications

CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v should not be administered to patients with a known personal or family history of blood dyscrasias including aplastic anaemia.

A history of hypersensitivity to the Chloramphenicol or any excipients listed in section 6.1.

Pregnancy and lactation (refer to section 4.6)

Porphyria (refer to section 4.4)

4.4. Special warnings and precautions for use

CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v is absorbed systemically from the eye and toxicity has been reported following chronic exposure.

Bone marrow hypoplasia, including aplastic anaemia and death, has been reported following topical use of CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v. Whilst the hazard is a rare one, it should be borne in mind when assessing the benefits expected from the use of the compound. Where CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v is used on a long-term or intermittent basis, it may be advisable to perform a routine blood profile before therapy and at appropriate intervals thereafter to detect any haemopoietic abnormalities.

In severe infections the topical use of chloramphenicol should be supplemented by appropriate systemic treatment. Prolonged use of chloramphenicol eye drops should be avoided as it may increase the likelihood of sensitisation and emergence of resistant organisms. If any new infection appears during treatment, the antibiotic should be discontinued and appropriate measures taken. CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v should be reserved for use only in infections for which it is specifically indicated.

CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v does not provide adequate coverage against *Pseudomonas aeruginosa* and *Serratia marcescens*.

Medical advice should be sought if there is no improvement in the condition after 2 days or if symptoms worsen at any time.

Patients should be referred to their 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

CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v should be used with caution in patients with a history of:

- 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

Soft contact lenses should not be worn during treatment with CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v due to absorption of the preservative onto the lens which may cause damage to the lens. It is recommended that all types of contact lenses be avoided during ocular infections.

The packaging will convey the following information:

- Seek further immediate medical advice at any time if symptoms worsen
- Do not use if you are allergic to chloramphenicol or any of the ingredients

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

Chloramphenicol has been associated with acute attacks of porphyria (disturbance in porphyrin metabolism) and is considered unsafe in patients with acute porphyria.

4.5. Interaction with other medicines and other forms of interaction

The concomitant administration of CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v with other medicines liable to depress bone marrow function, aplastic anaemia should be avoided (see section 4.4).

4.6. Fertility, pregnancy and lactation

Fertility:

CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v safety and efficacy on fertility has not been established

Pregnancy:

The safety of CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v safety in pregnancy has not been established.

Lactation:

CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v may be absorbed systemically following the use of eye drops and may cross the placenta and appear in breast milk. Therefore this product is not recommended for use during lactation or Breast feeding.

4.7. Effects on ability to drive and use machines

CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v has a minor influence on the ability to drive and use machines. Blurring of vision can occur with the drops and patients should be warned not to drive or operate machinery unless their vision is clear.

4.8 Undesirable effects

Adverse reactions reported are included in the table below. The frequencies correspond with: Frequency unknown (cannot be estimated from the available data).

Tabulated list of adverse reactions

a. Tabulated list of adverse reactions

System Organ Class	**Frequency**
Blood & lymphatic system disorders	
Blood dyscrasias	Rare
Aplastic anaemia*	Frequency unknown
Bone marrow suppression	Frequency unknown

Idiosyncratic or related to dose and duration of treatment	Frequency unknown
Immune system disorders	
Anaphylactic reaction*	Frequency unknown
Nervous system disorders	
Burning sensation	Frequency unknown
Eye disorders	
Transient irritation, Burning, Stinging and sensitivity reactions such as itching,	Frequency unknown
Skin and subcutaneous tissue disorders	
Angioedema*, Dermatitis* (including vesicular & maculopapular dermatitis) Urticaria,	Frequency unknown
General disorders and administration site conditions	
Pain (stinging sensation) Pyrexia*	Frequency unknown
Jarish-Herxheimer-like reactions may occur. Prolonged use may result in the overgrowth of non-susceptible organisms, including fungi. If irritation, pain, swelling, lacrimation of photophobia occurs after use, eye should be washed out for at least 15 minutes.	Frequency unknown
Hypersensitivity reactions: rashes and Angioedema	Less frequent
Fever, anaphylaxis	Rare

*Causes for discontinuation

f. 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 medicine. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via The '6.04 Adverse Drug Reactions Reporting Form'. Found under SAHPRA's publications: https://www/sahpra.org.za/Publications/Index/8

4.9 Overdose

Symptoms

Accidental ingestion is unlikely to cause systemic toxicity due to the low content of the antibiotic in the product. If irritation, pain, swelling, lacrimation photophobia may occur after undesired eye contact.

Management

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

Pharmacotherapeutic group: Antibiotics

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, including *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Staphylococcus aureus*, *Streptococcus viridans*, *Moraxella* species and *Enterobacteriaceae*, the main pathogens responsible for acute bacterial conjunctivitis.

Mechanism of action

Chloramphenicol exerts its antibacterial effect by reversibly binding to bacterial ribosomes thereby inhibiting bacterial protein synthesis.

5.2. Pharmacokinetic properties

Chloramphenicol is found in measurable amounts in the aqueous humour following local application to the eye.

Chloramphenicol is excreted chiefly in the urine as the glucuronide with small amounts being excreted via the bile and faeces. It has a reported half-life of 1.5 to 5 hours which is increased in patients with liver impairment and neonates.

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Chloramphenicol Ph.Eur

Phenylmercuric nitrate Ph.Eur

Borax Ph.Eur

Boric acid Ph.Eur

Water for Injections Ph.Eur

6.2. Incompatibilities

Not Applicable

6.3. Shelf life

Proposed shelf-life for unopened vial: 24 months.

Proposed shelf-life for opened vial: 28 days

6.4. Special precautions for storage

Store in a refrigerator at a temperature between 2°C and 8°C.

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

Discard remaining contents 28 days after opening.

6.5. Nature and contents of container

LDPE vial:

CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v - A bright colourless to faint yellow aqueous solution, practically clear and practically free from particles. It is available in 10 mL labelled LDPE vial with HIPS spike cap packed in a carton with pack insert.

6.6. Special precautions for disposal and other handling

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

FDC SA (PTY) LTD

Unit J3,Willows Office Park

Farm Road, The Willows, Pretoria East

Pretoria 0081, South Africa

8. REGISTRATION NUMBER(S)

A38/15.1/0647

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

8 FEBRUARY 2008

10. DATE OF REVISION OF TEXT

25 AUGUST 2023

MOCKUP CLEAN PI

Professional Information for Medicines for Human Use

CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v*
Ophthalmic Solution
(Chloramphenicol 0,5 % *w/v*)

S4 SCHEDULING STATUS

1. NAME OF THE MEDICINE
CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v*

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v*
Each vial contains Chloramphenicol 0,5 % *w/v* is equivalent to 0, 5mg/mL Chloramphenicol and Phenylmercuric nitrate 0, 002 % *w/v* is equivalent to 0, 002 mg/mL Phenylmercuric nitrate as a preservative.
For full list of excipients, (See section 6.1)

3. PHARMACEUTICAL FORM
CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* is a bright colourless to faint yellow aqueous solution, practically clear and practically free from particles.

4. CLINICAL PARTICULARS
4.1.Therapeutic indications CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* **is used for the local treatment of acute eye infections caused by susceptible organisms.**
Chloramphenicol is indicated in adults and children.

4.2.Posology and method of administration
Adults (including the Elderly)
One to two drops applied topically to each affected eye up to six times daily or more frequently if required. Severe infections may require one or two drops every fifteen to twenty minutes initially, reducing the frequency of instillation gradually as the infection is controlled.
Paediatric population
As for adults however, 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.

Method of administration:
CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* are ocular use only - Topical administration to the eye as directed by the **ophthalmologist**.

4.3.Contraindications:

CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* should not be administered to patients with a known personal or family history of blood dyscrasias including aplastic anaemia.
A history of hypersensitivity to the Chloramphenicol or any excipients listed in section 6.1.
Pregnancy and lactation (refer to section 4.6)
Porphyria (refer to section 4.4)

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Chloramphenicol has been associated with acute attacks of porphyria (disturbance in porphyrin metabolism) and is considered unsafe in patients with acute porphyria.

4.5.Interaction with other medicines and other forms of interaction
The concomitant administration of CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* with other medicines liable to depress bone marrow function, aplastic anaemia should be avoided (see section 4.4).

4.6 Fertility, pregnancy and lactation
Fertility:
CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* safety and efficacy on fertility has not been established
Pregnancy:
The safety of CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* safety in pregnancy has not been established.
Lactation:
CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* may be absorbed systemically following the use of eye drops and may cross the placenta and appear in breast milk. Therefore this product is not recommended for use during lactation or Breast feeding.

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Angioedema* Dermatitis* (including vesicular & maculopapular dermatitis) Urticaria,	Frequency unknown
General disorders and administration site conditions	
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Jarish-Herxheimer-like reactions may occur. Prolonged use may result in the overgrowth of non-susceptible organisms, including fungi. If irritation, pain, swelling, lacrimation of photophobia occurs after use, eye should be washed out for at least 15 minutes	Frequency unknown
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Fever, anaphylaxis	Rare

*Causes for discontinuation

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4.9 OverdoseSymptoms
Accidental ingestion is unlikely to cause systemic toxicity due to the low content of the antibiotic in the product. If irritation, pain, swelling, lacrimation photophobia may occur after undesired eye contact.

Management
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
Pharmacotherapeutic group: Antibiotics
ATC code: S01AA01Chloramphenicol is a broad spectrum antibiotic with bacteriostatic activity and is effective against a wide range of Gram-negative and Gram-positive organisms, including *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Staphylococcus aureus*, *Streptococcus viridans*, *Moraxella* species and *Enterobacteriaceae*, the main pathogens responsible for acute bacterial conjunctivitis.

Mechanism of action
Chloramphenicol exerts its antibacterial effect by reversibly binding to bacterial ribosomes thereby inhibiting bacterial protein synthesis.

5.2 Pharmacokinetic properties
Chloramphenicol is found in measurable amounts in the aqueous humour following local application to the eye.
Chloramphenicol is excreted chiefly in the urine as the glucuronide with small amounts being excreted via the bile and faeces. It has a reported half-life of 1.5 to 5 hours which is increased in patients with liver impairment and neonates.

5.3 Preclinical safety data
Not applicable

6. PHARMACEUTICAL PARTICULARS
6.1.List of excipients
Chloramphenicol Ph.Eur
Phenylmercuric nitrate Ph.Eur
Borax Ph.Eur
Boric acid Ph.Eur
Water for Injections Ph.Eur

6.2.Incompatibilities
Not Applicable

6.3.Shelf life
Proposed shelf-life for unopened vial: 24 months.
Proposed shelf-life for opened vial: 28 days

6.4.Special precautions for storage
Store in a refrigerator at a temperature between 2 °C and 8 °C.
Keep the bottle in the outer carton in order to protect from light.
Discard remaining contents 28 days after opening.

6.5.Nature and contents of containerLDPE vial:
CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* - A bright colourless to faint yellow aqueous solution, practically clear and practically free from particles. It is available in 10 mL labelled LDPE vial with HIPS spike cap packed in a carton with pack insert.

6.6.Special precautions for disposal and other handling
No special requirements for disposal.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
FDC SA (PTY) LTD
Unit J3, The Willows Office Park,
Farm Road, The Willows, Pretoria East,
Pretoria, 0081, South Africa.

8 REGISTRATION NUMBER(S)
A38/15.1/0647

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
8 FEBRUARY 2008

10.DATE OF REVISION OF TEXT
25 August 2023

Professionele Inligting oor Medikasie vir Menslike Gebruik

CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v*
Oftalmies Oplossing
(Chlooramfenikol 0,5 % *w/v*)

S4 SKEDULERINGSTATUS

1. NAAM VAN DIE MEDIKASIE
CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v*

2. KWALITATIEWE EN KWANTITATIEWE SAMESTELLING
CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v*
Elke flessie bevat Chlooramfenikol 0,5 % *w/v*, gelykstaande aan 0,5 mg/mL Chlooramfenikol en Fenielkwiknitraat 0, 002 % *w/v*, gelykstaande aan 0,002 mg/mL Fenielkwiknitraat, as 'n preserveermiddel.
(Kyk afdeling 6.1 vir volledige lys hulpstowwe,)

3. FARMASEUTIESE FORMAAT
CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* is 'n deursigtige, kleurlose tot dowwe geel wateroplossing, feitlik helder en feitlik vry van deeltjies.

4. KLINIESE BESONDERHEDE
4.1 Terapeutiese aanduidings
CHLORAMPHENICOL OOGDRUPPELSBP 0,5 % *w/v* word gebruik vir die plaaslike behandeling van akute ooginfeksies wat deur vatbare organismes veroorsaak word. Chlooramfenikol word vir volwassenes en kinders aangedui.

4.2. Dosering en metode van toediening
Volwassenes (bejaardes ingesluit)
Een tot twee druppels word topies op elke aangetaste oog toegedien tot ses keer per dag of meer gereeld indien nodig. Ernstige infeksies kan aanvanklik een of twee druppels elke vyftien tot twintig minute vereis, wat die frekwensie van instillasie geleidelik verminder soos die infeksie beheer word.Pediatriese bevolking
Netsoos vir volwassenes, egter, kan dosisaanpassing by pasgebore babas nodig wees as gevolg van verminderde sistemiese eliminasie as gevolg van onvolwasse metabolisme en die risiko van dosisverwante nadelige effekte.
Die maksimum duur van behandeling is 10 – 14 dae.

Toedieningsmetode:
CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* is slegs vir okulêre gebruik - Topikale toediening aan die oog soos voorgeskryf deur die oogarts.

4.3 Teenaanduidings (kontra-indikasies) CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* moenie toegedien word aan pasiënte met 'n bekende persoonlike geskiedenis of familiegeskiedenis van bloeddiskrasieë nie. Dit sluit aplastiese anemie in.
'n Geskiedenis van hipersensitiwiteit vir Chloramfenikol of enige hulpstowwe soos gelys in afdeling 6.1.
Swangerskap en laktasie (verwys na afdeling 4.6)
Porfirie (verwys na afdeling 4.4)

4.4 Spesiale waarskuwings en voorsogmaatreëls vir gebruik
CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* word sistemies vanuit die oog geabsorbeer en toksisiteit is gerapporteer na chroniese blootstelling.
Beenmurghipoplasie, insluitend aplastiese anemie en dood, is aangemeld na aktuele gebruik van CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v*. Alhoewel die gevaar 'n seldsame een is, moet dit in gedagte gehou word wanneer die voordele beoordeel word wat van die gebruik van die verbinding verwag word. Waar CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* op 'n langtermyn- of onderbroke basis gebruik word, kan dit raadsaam wees om 'n roetine-bloedprofiel voor terapie en met toepaslike tussenposes daarna uit te voer om enige hemopoiëtiese abnormaliteite op te spoor.

In ernstige infeksies moet die topikale gebruik van chlooramfenikol aangevul word deur toepaslike sistemiese behandeling. Langdurige gebruik van chlooramfenikol oogdruppels moet vermy word aangesien dit die waarskynlikheid van sensitisering en opkoms van weerstandbiedende organismes kan verhoog. Indien enige nuwe infeksie tydens behandeling voorkom, moet die antibiotika gestaak word en toepaslike maatreëls getref word.
CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* moet gereserveer word vir gebruik slegs in infeksies waarvoor dit spesifiek aangedui is.
CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* bied nie voldoende dekking teen *Pseudomonas aeruginosa* en *Serratia marcescens* nie.
Mediese advies moet ingewin word indien daar na 2 dae geen verbetering in die toestand is nie of as simptome te eniger tyd vererger.

Pasiënte moet na hul dokter verwys word indien hulle enige van die volgende ondervind:
- Versteurde visie
- Erge pyn in die oog
- Fotofobie
- Oogontsteking geassosieer met 'n uitslag op die kopvel of gesig
- Die oog lyk troebel
- Die pupil lyk onnatuurlik
- Vermoedelik 'n vreemde voorwerp in oog

CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* moet met omsigtigheid gebruik word by pasiënte met 'n geskiedenis van:
- Vorige konjunktivitis in die onlangse verlede
- Gloukoom
- Droë oog-sindroom
- Oogchirurgie of laserbehandeling in die afgelope 6 maande
- Oogbesering
- Huidige gebruik van ander oogdruppels of oogsalf
- Kontaklensgebruik

Sagte kontaklense moet nie tydens behandeling met CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* gedra word nie as gevolg van absorpsie van die preserveermiddel op die lens wat skade aan die lens kan veroorsaak. Daar word aanbeveel dat alle soorte kontaklense tydens ooginfeksies vermy word. Die verpakking sal die volgende inligting oordra:
- Soek enige tyd verdere onmiddellike mediese advies indien simptome vererger
- Moenie gebruik as u allergies is vir chlooramfenikol of enige van die bestanddele nie Feniel-kwiknitraat is irriterend vir die vel. Topiese toediening op oë word geassosieer met mercurialentis en a-tipiese bandkeratopatie.

Chlooramfenikol word geassosieer met akute aanvalle van porfirie (versteuring in porfirienmetabolisme) en word as onveilig beskou by pasiënte met akute porfirie.

4.5 Interaksie met ander medisyne en ander vorme van interaksie
Die gelyktydige toediening van CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* en ander medikasie wat geneig is om beenmurgfunksie, a-plastiese anemie, te onderdruk, moet vermy word (kyk afdeling 4.4).

4.6 Vrugbaarheid, swangerskap en laktasie
Vrugbaarheid:
CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* se veiligheid en doeltreffendheid t.o.v. vrugbaarheid is nie vasgestel nie.
Swangerskap:
CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* se veiligheid t.o.v. swangerskap is nie vasgestel nie.
Laktasie:
CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* kan sistemies geabsorbeer word na die gebruik van oogdruppels en kan die plasenta oorsteek en in borsmelk voorkom. Daarom word hierdie produk nie aanbeveel vir gebruik tydens laktasie of borsvoeding nie.

4.7 Effekte op vermoë om te bestuur en masjiene te gebruik
CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* het 'n geringe invloed op die vermoë om te bestuur en masjiene te gebruik. Vervaagde sig kan a.g.v. die druppels voorkom en pasiënte moet gewaarsku word om nie te bestuur of masjinerie te gebruik nie, tensy hul visie helder is.

4.8 Ongewenste effekte
Gerapporteerde newe-reaksies is in die tabel hieronder ingesluit. Die frekwensies stem ooreen met: Frekwensie onbekend (kan nie uit die beskikbare data geskat word nie).
Tabellys van nadelige effekte:

a. Tabellys van nadelige effekte:

Klas Stelselorgaan	Gereeldheid
Bloed- & limfstelselkwale	
Bloeddiskrasies	Skaars
A-plastiese anemie*	Gereeldheid Onbekend
Beenmurgonderdrukking	Gereeldheid Onbekend
Idiosinkraties of verwant aan dosis en duur van behandeling	
Immuunstelselkwale	
Anafilaktiese reaksie*	Gereeldheid Onbekend
Senustelselkwale	
Brandende sensasie	Gereeldheid Onbekend
Oogkwale	
Verbygaande irritasie, Brandgevoel, Prikkeling- en sensitiwiteitreaksies soos jeuk,	Gereeldheid Onbekend
Vel- en ondervelse weefselkwale	
Angioedeem* Dermatitis*(sluit vesikulêre & makulopapulê dermatitis in) Urtikarie,	Gereeldheid Onbekend
Algemene kwale en administrasieperseeltoestande	
Pyn (steeksensasie) Pireksie*	Gereeldheid Onbekend
Jarish-Herxheimeragtige reaksies mag plaasvind. Verlengde gebruik mag lei tot die geil groei van nie-vatbare organismes, wat fungi insluit.. As irritasie, pyn, swelling, traanafskeidig of fotofobia na gebruik plaasvind, moet die oog vir mistens 15 minute afgespoel word.	Gereeldheid Onbekend
Hipersensitiwiteitreaksies: uitslag en Angioedeem	Minder gereeld
Koors, anafilakse	Skaars

*Redes om opte hou

f. Verslagdoening van vermoedelik nadelige reaksies
Dit is belangrik om vermoedelik nadelige reaksies na die magtiging van die medisinale produk te rapporteer. Dit laat voortgesette monitering van die voordeel/risikobalans van die medikasie toe. Gesondheidsorgpersoneel word gevra om enige vermoedelike nadelige reaksies by SAHPRA aan te meld via die '6.04 vorm vir die Aanmeld van Nadelige Reaksies op Medikasies'. Dit word gevind onder Sahpra se publikasies:
https: //www/sahpra.org.za/publications/index/8

4.9 Oordosis
Simptome
Dit is onwaarskynlik dat toevallige inname sistemiese toksisiteit sal veroorsaak as gevolg van die lae inhoud van die antibiotikum in die produk. Irritasie, pyn, swelling, traanafskeiding, of fotofobie kan voorkom na ongewenste kontak met die oë.

Behandeling
Die blootgestelde oog (/oë) moet minstens 15 minute lank afgespoel word. As simptome hierna voortduur, moet 'n oogheelkundige ondersoek oorweeg word.

5. FARMAKOLOGIESE EIENSKAPPE
5.1. Farmakodinamiese eienskappe
Farmakoterapeutiese groep: Antibiotika
ATC-kode: S01AA01
Chlooramfenikol is 'n breëspektrum antibiotika met bakteriostatiese aktiwiteit en is effektief teen 'n wye reeks Gram-negatiewe en Gram-positiewe organismes, insluitend *Haemophilus influenzae, Streptococcus pneumoniae, Staphylococcus aureus, Streptococcus viridans, Moraxella pathogenae en Enterobacteriaceae*, die hoofpatogene wat verantwoordelik is vir bakteriële konjunktivitis.

Werkingsmeganisme
Chlooramfenikol oefen sy antibakteriese effek uit deur omkeerbaar aan bakteriële ribosome te bind en sodoende bakteriële proteïensintese te inhibeer.

5.2. Farmakokinetiese eienskappe
Chlooramfenikol word in meetbare hoeveelhede in die waterige humor aangetref na plaaslike toediening op die oog.

Chlooramfenikol word hoofsaaklik in die urine uitgeskei as die glukuronied met klein hoeveelhede wat via die gal en ontlasting uitgeskei word. Dit het 'n gerapporteerde halfleeftyd van 1,5 tot 5 uur wat verhoog word in pasiënte met lewerkwale en neonate.

5.3 Pre-kliniese veiligheidsdata
Nie van toepassing nie

6. FARMASEUTIESE BESONDERHEDE
6.1. Lys van hulpstowwe
Chlooramfenikol Ph.Eur
Fenielkwiknitraat Ph.Eur
Boraks Ph.Eur
Boorsuur Ph.Eur
Water vir inspuitings Ph.Eur

6.2. Onversoenbaarheid
Nie van toepassing nie

6.3. Raklewe
Voorgestelde rakleeftyd vir onoopgemaakte flessie: 24 maande.
Voorgestelde raklewe vir oop flessie: 28 dae

6.4. Spesiale voorsorgmaatreëls vir berging
Bêre in 'n yskas teen 'n temperatuur van tussen 2 °C en 8 °C.
Hou die bottel in die buitekarton om teen lig te beskerm.
Gooi oorblywende inhoud weg 28 dae nadat dit oopgemaak is.

6.5. Aard en inhoud van houer
LDPE-flessie:
CHLORAMPHENICOL EYE DROPS BP 0,5 % *w/v* - 'n Helder kleurlose tot dowwe geel waterige oplossing, feitlik helder en feitlik vry van deeltjies. Dit is beskikbaar in 'n 10 mL gemerkte LDPE-flessie met HIPS-pendop verpak in 'n kartonhouer met insetsel.

6.6. Spesiale voorsorgmaatreëls vir wegdoening en ander hantering
Geen spesiale vereistes vir wegdoening nie.
Enige ongebruikte medisyne of afvalmateriaal moet in ooreenstemming met plaaslike vereistes weggedoen word.

7. HOUER VAN SERTIFIKAAT VAN REGISTRASIE
FDC SA (EDMS) BPK
Eenheid J3, The Willows Office Park,
Plaasweg, Die Wilgers, Pretoria-Oos,
Pretoria, 0081, Suid-Afrika.

8. REGISTRASIENOMMER(S)
A38/15.1/0647

9. DATUM VAN EERSTE MAGTIGING/HERNUWING VAN DIE MAGTIGING
8 FEBRUARIE 2008

10. DATUM VAN HERSIENING VAN TEKS
25 Augustus 2023