PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

MINIMS® CHLORAMPHENICOL 0,5 %

Eye drops, solution in single-dose container

Read all of this leaflet carefully before you start using MINIMS® Chloramphenicol

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- MINIMS® Chloramphenicol has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MINIMS® Chloramphenicol is and what it is used for
2. What you need to know before you use MINIMS® Chloramphenicol
3. How to use MINIMS® Chloramphenicol
4. Possible side effects
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6. Contents of the pack and other information

1. What MINIMS® Chloramphenicol is and what it is used for

A 15.1 Ophthalmic preparations with antibiotics and/or sulphonamides

MINIMS® Chloramphenicol contains an antibiotic. It is used to treat infections of your eyes. Sometimes parts of the outer surface of the eye, such as the cornea (the transparent membrane covering the surface of the eye) or the conjunctiva (the lining of the inside of the eyelids and part of the eye), may become infected with bacteria. These eye drops can be used to treat this infection and are effective against many different types of bacteria.

If the eye infection is very severe, your doctor may give you antibiotic tablets as well as this antibiotic eye drops. This medicine is indicated for children, adults and the elderly.

2. What you need to know before you use MINIMS® Chloramphenicol

Do not use MINIMS® Chloramphenicol:

- if you are hypersensitive (allergic) to chloramphenicol or any of the other ingredients of MINIMS® Chloramphenicol (listed in section 6).

Take special care with MINIMS® Chloramphenicol:

If you use these eye drops over a long period of time they could possibly become less effective or produce allergic reactions.

In order to prevent this, make sure that you stop using this medicine as soon as your doctor tells you to.

Other medicines and MINIMS® Chloramphenicol

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Chymotrypsin (solution used during cataract surgery) may not work properly when used at the same time as MINIMS® Chloramphenicol.

Pregnancy, breastfeeding and fertility

Pregnancy and breastfeeding

The safety for use in pregnancy and breastfeeding has not been established.

If chloramphenicol is systematically given to a mother shortly before giving birth or whilst breastfeeding, it may cause a condition in the newborn infant called “grey baby syndrome”, which is characterised by the baby appearing grey in colour.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

Driving and using machines

You may experience blurred vision when you instill MINIMS® Chloramphenicol into your eye. If you experience blurred vision, wait until your vision clears before driving or using machinery.

MINIMS® Chloramphenicol contains borax and boric acid

This medicine contains borax (0,12 mg per drop equivalent to 3,0 mg/ml) and boric acid (0,60 mg per drop equivalent to 15 mg/ml).

3. How to use MINIMS® Chloramphenicol

Do not share medicines prescribed for you with any other person.

Always use MINIMS® Chloramphenicol exactly as your doctor or pharmacist has told you. Check with our doctor or pharmacist if you are not sure.

Do not use this product for longer than the time frame stated by your doctor or eye specialist, as it may become less effective at treating your eye infection.

The drops are for single use only and provided in single use Minims units, to treat both eyes if both eyes are infected. Once opened, use immediately. Discard any unused portion.

Adults (including the Elderly)

The usual dose is 1 to 2 drops to each infected eye up to six times a day.

If you have a severe infection your doctor or eye specialist may ask you to use this medicine more frequently at first, until the infection starts to get better. The frequency of treatment can then be gradually reduced.

If your eyes get worse or are not better after a few days of using these eye drops, see your doctor or eye specialist or pharmacist.

Children

The usual dose is the same as for adults. The maximum duration of treatment is 10 – 14 days.

Use in newborn infants

Your child's doctor may prescribe a lower dose to reduce the risk of side effects. The maximum duration of treatment is 10 – 14 days.

Method of administration

Make sure you follow these instructions carefully:

1. Wash your hands.
2. Use a mirror, this will help you to see what you are doing.
3. Carefully dry your eyes using a tissue, and twist off the cap from the Minims body of the unit.
4. Pull your lower eyelid down gently, and then carefully place 1 or 2 drops inside your lower eyelid. Make sure the dropper does not touch any parts of your eye.
5. Close your eye and blink a few times to make sure your eye is covered by the liquid.
6. Close the eyelids. It is advisable to press gently on the inner corner of your eyelid for 3 minutes. This will help stop the solution draining into your nose and throat. This is especially advisable in children, the elderly and population at risk.
7. Repeat steps 4, 5 and 6 for the other eye if necessary, then throw away the Minims unit, even if some solution remains.

If you wear contact lenses

Your doctor will ask you to remove your contact lenses prior to the administration of the drops.

Do not wear your contact lenses throughout the entire treatment course.

If you use more MINIMS® Chloramphenicol than you should

An overdose is very unlikely to occur. If you suddenly feel unwell after receiving the drops, of if someone accidentally swallowed the eye drops, consult your doctor, eye specialist or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use MINIMS® Chloramphenicol

You should instill the missed dose as soon as you remember, unless it is nearly time for the next dose, but you should not take a double dose to make up for a missed dose.

4. Possible side effects

MINIMS® Chloramphenicol can have side effects.

Not all side effects reported for MINIMS® Chloramphenicol are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using MINIMS® Chloramphenicol, please consult your health care provider for advice.

If any of the following happens, stop using MINIMS® Chloramphenicol and tell your doctor immediately or go to the casualty department at your nearest hospital:

- shortness of breath,
- wheezing or difficulty breathing,

- swelling of the face, lips, tongue or other parts of the body,
- rash, itching or hives on the ~~sin~~skin, or
- fainting

These are all very serious side effects. If you have them, you may have had a serious allergic reaction (anaphylaxis) to MINIMS® Chloramphenicol. You may need urgent medical attention or hospitalisation.

MINIMS® Chloramphenicol may also cause local hypersensitivity reactions, such as irritation, burning, stinging, itching and dermatitis. If this happens, stop using MINIMS® Chloramphenicol.

Aplastic anaemia (condition in which the bone marrow is unable to produce blood cells) and bone marrow depression can occur but these are extremely rare and your doctor will have taken your medical history into account when deciding to prescribe MINIMS® Chloramphenicol. Pale skin, weakness, increased heart rate, out of breath, headache, pain, fever, infection, bruises may be a signs of a severe blood disorder.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

You can also report side effects directly to the company, using the following e-mail address:

PV-SouthAfrica@bauschhealth.com

By reporting side effects, you can help provide more information on the safety of MINIMS® Chloramphenicol.

5. How to store MINIMS® Chloramphenicol

Store all medicines out of reach of children.

- Store in a refrigerator between 2 – 8 °C
- Do not freeze
- Protect from light
- If necessary, the product may be stored at room temperature not exceeding 25 °C for up to 1 month only.
- Keep the units in the outer carton.
- Do not use after the expiry date stated on the carton or unit.
- Discard each Minims unit after single use.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MINIMS® Chloramphenicol contains

- The active substance is chloramphenicol. Each dispensing unit of 0,5 ml contains 2,5 mg chloramphenicol (0,5 % *m/v*)

- The other ingredients are borax, boric acid and purified water.

What MINIMS® Chloramphenicol looks like and contents of the pack

MINIMS® Chloramphenicol is an eye drops solution in a single-dose container.

The eye drops are a clear, colourless solution, reasonably free from visible particulate matter.

MINIMS® Chloramphenicol eye drops are provided in a sealed conical shaped polypropylene tube (unit), fitted with a polypropylene twist and pull-of cap. Each unit contains approximately 0,5 ml of solution.

Each unit is individually overwrapped in a polyester/polyethylene laminate sachet. The sachets are packed in cartons of 20 units.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The Professional Information is available on the company website, www.bausch.co.za, or may be requested telephonically: +27 10 025 2100.