1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

CHLORAMEX OPHTHALMIC OINTMENT

Ointment

Read all of this leaflet carefully before using CHLORAMEX OPHTHALMIC OINTMENT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- CHLORAMEX OPHTHALMIC OINTMENT 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 CHLORAMEX OPHTHALMIC OINTMENT CONTAINS

The active substance is chloramphenicol. Each 1 g of CHLORAMEX OPHTHALMIC OINTMENT contains 10 mg of chloramphenicol.

The other ingredients are hard paraffin, liquid paraffin, wool fat, yellow soft paraffin.

WHAT CHLORAMEX OPHTHALMIC OINTMENT IS USED FOR

CHLORAMEX OPHTHALMIC OINTMENT belongs to a group of medicines called antibiotics. CHLORAMEX OPHTHALMIC OINTMENT is used for the treatment of bacterial infections of the eye and eyelid.

When put in the eye, CHLORAMEX OPTHALMIC OINTMENT works by helping killing the bacteria (germs) and allowing the body to overcome the infection.

BEFORE YOU USE CHLORAMEX OPHTHALMIC OINTMENT

You should not use CHLORAMEX OPHTHALMIC OINTMENT

- If you are hypersensitive (allergic) to chloramphenicol or to any of the other ingredients in CHLORAMEX OPHTHALMIC OINTMENT.
- If you have a known personal or family history of serious blood disorders (blood dyscrasias), including aplastic anaemia.

Take special care with CHLORAMEX OPHTHALMIC OINTMENT:

Special care should be taken with CHLORAMEX OPHTHALMIC OINTMENT

- As it is for use in the eye only (see HOW TO USE CHLORAMEX OPHTHALMIC OINTMENT).
- If you have an allergic reaction like rash, fever, swelling and difficulty in breathing.
- If ingested as you can experience nausea, vomiting and diarrhoea.
- If you suffer from any blood disorders.
- If you use CHLORAMEX OPHTHALMIC OINTMENT for a long time, you may become resistant to treatment.
- If any new infection appears during treatment, you should stop using the ointment and speak to your doctor.
- If there is no improvement in the condition after 2 days or if symptoms worsen at any time.
- If you have visual disturbances.

- If you have severe pain in the eye.
- If you are sensitive to light.
- If your eye is inflamed and you have a rash on the scalp or face.
- If your eyes look cloudy.
- If the coloured part of the eye looks unusual.
- If you have a foreign body in the eye.
- If you wear contact lenses.

If you have had any of the following:

- Recent eye infections such as conjunctivitis.
- Glaucoma (raised pressure in the eye).
- Dry eye syndrome.
- Eye surgery or laser treatment in the last 6 months.
- Eye injury.
- Current use of other eye drops or eye ointment.

Pregnancy and breastfeeding

The safety of CHLORAMEX OPHTHALMIC OINTMENT during pregnancy and whilst breastfeeding has not been established.

Chloramphenicol crosses the placenta and is found in breast milk.

If you are pregnant or breastfeeding, please consult your doctor, pharmacist or other healthcare provider for advice before using CHLORAMEX OPHTHALMIC OINTMENT

Driving and using machinery

Since adverse reactions such as burning, stinging sensations and blurring of vision have been reported in patients receiving CHLORAMEX OPHTHALMIC OINTMENT, do not drive, use machinery or perform any tasks that require concentration, until you are certain that CHLORAMEX OPHTHALMIC OINTMENT does not adversely affect your ability to do so (see POSSIBLE SIDE EFFECTS).

Using other medicines with CHLORAMEX OPHTHALMIC OINTMENT

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines.)

The use of CHLORAMEX OPHTHALMIC OINTMENT with other medicines that are likely to cause a reduction in the production of cells by the bone marrow should be avoided.

CHLORAMEX OPHTHALMIC OINTMENT is inactivated in the liver and may, therefore, interact with medicines that are metabolised by liver enzymes.

Tell your doctor if you are taking any of the following medicines:

- Anticoagulants, such warfarin as their effects may be increased with the use of CHLORAMEX OPHTHALMIC OINTMENT.
- Hypoglycaemics (medicines used to help people with type 2 diabetes manage their condition) such as chlorpropamide and tolbutamide as their effect increases with the use of CHLORAMEX OPHTHALMIC OINTMENT.
- Antiepileptics (medicines used for the treatment of epileptic seizures) such as phenytoin and phenobarbitone.
- Rifampicin, an antibiotic used to treat several types of bacterial infections including tuberculosis.
- CHLORAMEX OPHTHALMIC OINTMENT may decrease the effect of iron.

- CHLORAMEX OPHTHALMIC OINTMENT may decrease the effect of Vitamin B_{12}.
- CHLORAMEX OPHTHALMIC OINTMENT may impair the action of oral contraceptives.

HOW TO USE CHLORAMEX OPHTHALMIC OINTMENT

For use in the eye only.

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

Always use CHLORAMEX OPHTHALMIC OINTMENT exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The recommended dosage is a small amount of the ointment to be applied to the eye four times daily.

1. Wash and dry your hands.
2. Open the tube. Be careful not to touch or breathe on the tip of the tube.
3. Look straight upwards and gently pull the lower lid downwards to uncover the lower part of your eye ball. This exposes the inner surface of the lower eyelid and is a good place to apply the ointment.
4. Squeeze the tube and apply a small amount of the ointment to the inner surface of the lower eyelid. Make sure the tip of the tube does not touch the eye or skin around the eye and your fingers.
5. Repeat steps 3 to 4 for the second eye if it is infected.
6. Replace the cap securely after use. Make sure your fingers do not touch the tip of the tube.
7. Be careful not to touch or breathe on tip of the tube.

Eyelid infections:

Apply four times daily to the affected area with the fingertip.

CHLORAMEX OPHTHALMIC OINTMENT must not be taken by mouth. If you accidentally swallow any of the ointment, you should contact your doctor.

If you use more CHLORAMEX OPHTHALMIC OINTMENT than you should

If you accidentally apply too much ointment, you should wash your eye with plenty of water. If any painful symptoms continue after this, you should contact your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use CHLORAMEX OPHTHALMIC OINTMENT

Use CHLORAMEX OPHTHALMIC OINTMENT as soon as you remember, if within a few hours after missing an application. Do not use double the amount to make up for forgotten application.

POSSIBLE SIDE EFFECTS

CHLORAMEX OPHTHALMIC OINTMENT can have side effects.

Not all side effects reported for CHLORAMEX OPHTHALMIC OINTMENT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using CHLORAMEX OPHTHALMIC OINTMENT, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking CHLORAMEX OPTHALMIC OINTMENT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Serious allergic reaction which causes swelling of the face or throat;
- allergic skin reaction.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CHLORAMEX OPTHALMIC OINTMENT. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Tiredness due to blood disorders (e.g. Bone marrow depression, aplastic anaemia).

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported less frequently:

- Burning, stinging sensations;
- inflammation of the skin;
- fever.

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

STORAGE AND DISPOSING OF CHLORAMEX OPHTHALMIC OINTMENT

Store in a cool place at or below 25 °C.

Protect from light.

Keep the tube tightly closed.

Keep in original packaging until required for use.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

KEEP OUT OF REACH OF CHILDREN.

PRESENTATION OF CHLORAMEX OPHTHALMIC OINTMENT

3,5 g ointment is packed in a printed cylindrical collapsible aluminium tube with an applicator-nozzle, sealed using a white HDPE cap. One tube is placed in a unit cardboard carton together with a leaflet.

IDENTIFICATION OF CHLORAMEX OPHTHALMIC OINTMENT

CHLORAMEX OPHTHALMIC OINTMENT is a translucent pale yellow ointment, with a slightly greasy odour.

REGISTRATION NUMBER

H1193 (Act 101/1965)

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE APPLICANT

PHARMACARE LIMITED

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