
APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

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

Read all of this leaflet carefully before you start taking CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v 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 CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v is and what it is used for.
2. What you need to know before you use CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v
3. How to use CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v
4. Possible side effects.
5. How to store CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v Contents of the pack and other information.

1. What CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v is and what it is used for

CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v belongs to a group of medicine called antibiotics.

It works by stopping the growth of bacteria, allowing your body to fight off the infection. CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v are used to treat minor infections of the eye or eyelid caused by bacteria (bacterial conjunctivitis). Signs include sore, red or inflamed eyes, sticky discharge or crust on the lids which may make it difficult to open the eye.

When put in the eye, chloramphenicol works by helping kill the bacteria (germs) and helps the body to get recovery from the infection.

2. What you need to know before you take CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v

Do not take CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v:

- If you are allergic (hypersensitive) to chloramphenicol or to any other ingredient of this medicine
- If you or someone in your family ever had a blood disorder or bone marrow disease including anemia (decrease in the number of red blood cells) when using chloramphenicol in the past.
- If you have a family history of “dyscrasias”, a condition which can cause tiredness, bruising and an increased risk of infections.

Warnings and precautions

- Talk to your doctor before taking CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v
- If you have visual disturbances.
- If you have severe pain in the eye.
- If your eyes sensitive to light.
- If your eye is inflamed and you have a rash on the scalp or face.
- If your eye looks cloudy.
- If you’re black or coloured part of the eye looks unusual.
- If you feel or have a foreign particles in the eye.
- If you have an eye infection that keeps coming back.
- If you have glaucoma (raised pressure in the eye).
- If you have dry eyes.
- If you have eye injury or eye surgery.
- If you are currently using any other eye drops or eye ointment.
- You wear contact lenses. You should not wear contact lenses while using these eye drops and for at least 24 hours after completing your treatment.

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

If you are not sure if the above apply to you, talk to your doctor or pharmacist before using CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v.

Other medicines and CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including using eye drops or eye ointment, herbal medicine and medicines obtained without a prescription (this includes complementary or traditional medicines). Before you start to use this medicine. Your medicine may affect their action and could alter their effect.

Before taking CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v, tell your doctor if you are

using any of the following medicines:

- Medicines for cancer such as methotrexate
- Medicines for the immune system such as azathioprine

Taking CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v with food and drink and alcohol.

CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v topical administration to the eyes no data available with the food and water.

Pregnancy, breast feeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v is administered to you.

Do not take CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v if:

If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking or using any medicine.

You should not breast-feed if you are taking CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v.

This is because small amounts may pass into mothers' milk.

Driving and using machines

No effects on ability to drive and use machines have been reported.

However do not drive or operate machines if you experience any visual disturbance after using the product. Wait until this clears before driving or using machines.

CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v contains Phenylmercuric nitrate

There is a preservative Phenylmercuric nitrate which may cause allergic reaction.

Do not wear contact lenses during treatment. Wait until 24 hours after the end of the treatment before you wear your contact lenses. You can wear glasses during treatment.

3. How to take CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v

Instil 2-3 drops to the affected eye every 2-3 hours. Treatment should be continued for at least 48 hours after the eye appears normal. Discard after 28 days.

Do not share medicines prescribed for you with others.

In the event of an over dosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control center

Instructions for use:

(Please also refer to pictograms at the end of the leaflet)

- First wash your hands
- Avoid touching the eye (or any other surface) with the tip of the bottle
- If you wear soft contact lenses, they should be removed before using the eye drops and wait at least 15 minutes before reinserting.
- These drops are supplied as a sealed bottle with a spiked cap. When using the bottle for the first time, screw the cap down tightly in order to pierce the tip of the bottle
- Tilt your head back and look at the ceiling pull the lower eyelid gently downwards the medicine.
- Hold the bottle upside down above the eye and gently squeeze the bottle to release a drop into your eye.
- Keep the affected eye closed and press your fingertip against the inside corner of the closed eye, and hold for 1 minute, repeat for the other eye if necessary
- Replace and tighten the cap immediately after use.

Be careful not to touch the tip of the bottle on your eye or on any other surface.

Ocular solutions, if handled wrongly, can become contaminated by common bacteria and cause eye infections.

If you do develop any other eye reactions whilst using this product, see your doctor immediately.

Your doctor will tell you how long your treatment with CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v Will last. You should not take CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v for longer than absolutely necessary.

If you take more CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v than you should

If you accidentally apply too much drops, you should wash your eye with plenty of water, if any painful symptoms continue after this, you should tell your doctor immediately.

If you forget to take CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v

Apply the drops as soon as you remember. However, if it is almost time for your next dose, do not double your dose and carry on with the normal schedule dose.

If you stop using CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v

No data available

4. Possible side effects

CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v can have side effects.

Not all side effects reported for CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v are included in this leaflet. Should your general health worsen or if you experience any untoward effects while

taking CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v, please consult your doctor, pharmacist or other healthcare professional for advice.

Like all medicines, Chloramphenicol can cause side effects, although not everybody gets them.

Some people find that their eyes sting or their sight is blurred immediately after using the drops. These effects should wear off after a short time. If prolonged irritation, swelling, watery eyes or sensitivity to light occurs, then exposed eye should be washed with water for 15 minutes. If the symptoms continue after this, an eye examination may be required.

Hypersensitivity reactions including rashes, fever, and swelling may occur especially after topical use. Anaphylaxis has occurred but is rare.

Prolonged use of antibiotics may result in the overgrowth of non-susceptible organisms, including fungi. Should new infections appear during treatment, the medication should be stopped and appropriate measures taken.

Disorders of cellular elements of the blood and lack of bone marrow development has been reported following long term oral administration of chloramphenicol eye drops.

If irritation, pain, swelling, lacrimation, or photophobia occurs after use, the eye should be washed out for at least 15 minutes. If symptoms persist, a doctor should be consulted.

Stop using CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v and seek medical help immediately if you have any of the following allergic reactions:

- Wheeziness (shortness of breath), fever, swelling of your face, lips or tongue, itching or rash with swelling of skin (the rash could be puffy (swollen) or blotchy, or look like little blisters).
- A sore throat, bruising or being unable to overcome an infection. On very rare occasions, patients using chloramphenicol have had changes in their blood cells causing severe tiredness or easy bruising.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

Unknown Frequency side effects:

- Aplastic anaemia (Body stops producing enough new blood cells),
- Bone marrow failure (is the reduction or cessation of blood cell production),
- Anaphylactic reaction (Anaphylactic reaction),
- Burning sensation in the eyes,
- Irritation in the eyes,
- Burning sensation in the eyes,
- Stinging and sensitivity reactions such as itching,

- Angioedema (swelling under the skin),
- Dermatitis (an itchy inflammation of the skin),
- Urticaria (Hives),
- Pain,
- Pyrexia (raised body temperature),

If any of the side effects get serious, or if you experience one of the above –mentioned serious side effects, call the nearest doctor immediately. If you experience any side effects not listed in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via the “6.04 Adverse Drug reaction Reporting Form” found online under SAHPRA’s publications: <https://www.sahpra.org.za/publications/Index/8>. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Keep this medicine out of the sight and reach of children.

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

Protect from light.

Discard the bottle 28 days after opening, even if there is solution remaining.

Do not use chloramphenicol after the expiry date which is stated on the carton and label after 'Expiry'. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

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

The active substance is chloramphenicol.

The other ingredients are

Borax,

Boric acid,

Phenyl mercuric nitrate (as preservative),

Water for injection.

What CHLORAMPHENICOL EYE DROPS BP 0, 5% w/v looks like and contents of the pack

LDPE vial:

It is available in 10 mL labelled LDPE vial with spike cap packed in a carton with pack insert.

HOLDER OF CERTIFICATE OF REGISTRATION

FDC SA (Pty) Limited

Unit J3, The Willows Office Park,

Farm Road, The willows, Pretoria East

Pretoria, 0081,

South Africa

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A38/15.1 /0647

Access to the corresponding Professional Information

Scan the QR code to access the corresponding professional Information (PI) and HCR details



MOCKUP CLEAN PIL

		LEAFLET		Minipharma Code No.: Front: 2990 / Back: 2991	
Size	122 (L) x 620 (H) mm				
Folded Size	-----				
No. of Folds	-----				
GSM	40 gsm				
Paper	Bible Paper				
Specification No.	-----				
Colour		Pantone Black C			
		Pantone Reflex Blue C			
SAP Code: 2000014722		Supercodes SAP Code: 2000013371			
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