

PRESCRIBING INFORMATION

PrPENTAMYCETIN®

Chloramphenicol Ophthalmic Solution USP
0.25%, 0.5%

Chloramphenicol Ophthalmic Ointment USP
1%

Antibiotic

PrPENTAMYCETIN/HC®

Chloramphenicol and Hydrocortisone Eye and Ear Suspension
(chloramphenicol 0.2% and hydrocortisone acetate 1%)

Chloramphenicol and Hydrocortisone Eye and Ear Ointment
(chloramphenicol 1% and hydrocortisone acetate 1%)

Antibiotic/Corticosteroid

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Antibiotic/Corticosteroid

INDICATIONS AND CLINICAL USE

PENTAMYCETIN, Ophthalmic Solution and Ointment

Treatment of superficial ocular infections involving the conjunctiva and/or the cornea, caused by microorganisms shown by bacteriological studies to be susceptible to chloramphenicol.

PENTAMYCETIN/HC, Eye and Ear Suspension and Ointment

For topical use in superficial ocular and auditory infections, such as non-purulent conjunctivitis and otitis externa, caused by microorganisms shown by bacteriological studies to be susceptible to chloramphenicol. Hydrocortisone acetate has anti-inflammatory effects.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of PENTAMYCETIN & PENTAMYCETIN/HC and other antibacterial drugs, PENTAMYCETIN & PENTAMYCETIN/HC should be used only to treat infections that are proven or strongly suspected to be caused by bacteria.

WARNINGS

Bone marrow hypoplasia, including aplastic anemia and death, has been reported following local application of chloramphenicol.

Chloramphenicol should not be used when less potentially dangerous agent would be expected to

provide effective treatment.

Susceptibility/Resistance

Development of Drug Resistant Bacteria

Prescribing PENTAMYCETIN or PENTAMYCETIN/HC in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of resistant organisms.

Potential for Microbial Overgrowth

The prolonged use of chloramphenicol may occasionally result in overgrowth of non-susceptible microorganisms including fungi. If new infection occur, discontinue use and institute alternative therapy.

CONTRAINDICATIONS

Sensitivity to chloramphenicol with signs of local irritation, symptoms of burning, angioneurotic edema, itching, urticaria, vesicular and maculopapular dermatitis. If these signs appear, withdraw the medication and consult your physician.

Hypersensitivity to any components of the medication.

PENTAMYCETIN/HC Suspension and Ointment are especially contraindicated in epithelial herpes simplex, keratitis, vaccinia, varicella, viral diseases of the cornea and conjunctiva, tuberculosis of the eye; fungal diseases of the eye, acute purulent untreated infections of the eye, which, like other diseases caused by microorganisms, may be masked or enhanced by the presence of the steroid.

PRECAUTIONS AND ADVERSE REACTIONS

It should be borne in mind that a patient may become sensitized to chloramphenicol when it is applied topically. Extended ophthalmic use of corticosteroid drugs may cause increased intraocular pressure in certain individuals and in those diseases causing thinning of the cornea or sclera, perforation has been known to occur. It is recommended that intraocular pressure be checked frequently.

Safety of the use of corticosteroids during pregnancy has not been substantiated.

In all serious infections, the topical use of chloramphenicol should be supplemented by appropriate systemic medication.

DOSAGE AND ADMINISTRATION

PENTAMYCETIN, Ophthalmic Solutions

2 drops of the ophthalmic solution to the affected eye(s) every 3 hours or more often if necessary.

PENTAMYCETIN Ophthalmic Ointment

A small amount of ointment to the affected eye(s) every 3 hours or more often if necessary.

PENTAMYCETIN/HC, Eye and Ear Suspension

2 drops to the affected eye(s) or into the affected ear(s) every 3 hours or more often if necessary.

PENTAMYCETIN/HC, Eye and Ear Ointment

A small amount of ointment to the affected eye(s) or into the affected ear(s) every 3 hours or more often if necessary.

Decrease the frequency after 48 hours; the treatment should be continued at least 48 hours after the affected eyes (the affected ears) return to normal.

OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Centre immediately.

DOSAGE FORMS, COMPOSITION AND PACKAGING; STORAGE AND STABILITY

PENTAMYCETIN (Chloramphenicol Ophthalmic Solution USP 0.25%) 10 mL

Each milliliter contains 2.5 mg (0.25%) of chloramphenicol and 0.5% chlorobutanol as preservative in a sterile buffered solution. Available in bottle with dropper. Refrigerate (2-8°C) until dispensing. Protect from freezing. After dispensing, the solution may be stored at room temperature for 21 days; after that period, discard unused portion. Avoid contamination of the tip of the dropper. Do not use if the dropper-tip cap is detached from the security ring.

PENTAMYCETIN (Chloramphenicol Ophthalmic Solution USP 0.5%) 10 mL

Each milliliter contains 5 mg (0.5%) of chloramphenicol and 0.5% chlorobutanol as preservative in a sterile buffered solution. Available in bottle with dropper. Refrigerate (2-8°C) until dispensing. Protect from freezing. After dispensing, the solution may be stored at room temperature for 21 days; after that period, discard unused portion. Avoid contamination of the tip of the dropper. Do not use if the dropper-tip cap is detached from the security ring.

PENTAMYCETIN (Chloramphenicol Ophthalmic Ointment USP 1%) 3.5 g

Each gram contains 10 mg (1%) of chloramphenicol in a sterile petrolatum base. Available in collapsible tube. Avoid contamination of the tip of the tube. Store between 15 and 30°C. Protect from freezing.

PENTAMYCETIN/HC (Chloramphenicol 0.2% and Hydrocortisone Acetate 1% Eye and Ear Suspension) 5 mL

Each milliliter contains 2 mg (0.2%) of chloramphenicol, 10 mg (1.0%) hydrocortisone acetate in a sterile buffered vehicle. **Shake well before each use.** Available in bottle with dropper. Refrigerate (2-8°C) until dispensing. Protect from freezing. After dispensing, the solution may be stored at room temperature for 21 days; after that period, discard unused portion. Avoid contamination of the tip of the dropper. Do not use if the dropper-tip cap is detached from the security ring.

PENTAMYCETIN/HC (Chloramphenicol 1% and Hydrocortisone Acetate 1% Eye and Ear Ointment) 3.5 g

Each gram contains 10 mg (1%) of chloramphenicol and 10 mg (1%) hydrocortisone acetate in a sterile petrolatum base. Available in collapsible tube. Avoid contamination of the tip of the tube. Store between 15 and 30°C. Protect from freezing.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

Read this carefully before you start taking PENTAMYCETIN each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about PENTAMYCETIN.

What is PENTAMYCETIN used for?

PENTAMYCETIN is used to treat infections in the eye.

Antibacterial drugs like PENTAMYCETIN treat only bacterial infections. They do not treat viral infections.

How Does PENTAMYCETIN work?

PENTAMYCETIN is an antibiotic that:

- Stops the growth of bacteria
- Kills bacteria

What are the ingredients in PENTAMYCETIN?

Ophthalmic Solution:

Medicinal ingredients: Chloramphenicol.

Non-medicinal ingredients: chlorobutanol as preservative, polyethylene glycol, polyoxyethylene stearate, water for injection and hydrochloride acid or sodium hydroxide to adjust pH.

Ophthalmic Ointment

Medicinal ingredients: Chloramphenicol.

Non-medicinal ingredients: petrolatum base

PENTAMYCETIN comes in the following dosage forms:

Pentamycetin (Ophthalmic Solution 0.25% and 0.5%): Bottle of 10 mL

Pentamycetin (Ophthalmic Ointment 1%): Tube of 3.5 g

Do not use PENTAMYCETIN if:

- you are allergic to chloramphenicol or to any of the other ingredients in PENTAMYCETIN.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PENTAMYCETIN. Talk about any health conditions or problems you may have, including if you:

- experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists, consult a physician;

Other warnings you should know about:

- Overuse of this product may produce increased redness of the eye;
- Do not touch tip of tube to any surface to avoid contamination.
- If there is no improvement within two days of starting treatment, stop use and consult a physician.
- Your vision may be blurred for a few minutes after using the product. Do not drive or operate machinery until you can see clearly;

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take PENTAMYCETIN:

- Although you may feel better early in treatment, PENTAMYCETIN should be used exactly as directed.
- Misuse or overuse of PENTAMYCETIN could lead to the growth of bacteria that will not be killed by PENTAMYCETIN (resistance). This means that PENTAMYCETIN may not work for you in the future.
- Do not share your medicine.

How do I use PENTAMYCETIN Ointment?

Apply a small amount of ointment to the affected eye or eyes, every 3 hours or more often if necessary.

Applying PENTAMYCETIN Ointment into the eye:

- Wash hands with soap and water.
- Sit in front of a mirror so you can see what you are doing.
- Take the lid off the ointment.
- Tilt your head back.
- Gently pull down your lower eyelid and look up.
- Hold the tube above the eye and gently squeeze a 1 cm line of ointment along the inside of the lower eyelid, taking care not to touch the eye or eyelashes with the tip of the tube.
- Blink your eyes to spread the ointment over the surface of the eyeball.
- Your vision may be blurred when you open your eyes - DON'T rub your eyes. The blurring will clear after a few moments if you keep blinking.
- Wipe away any excess ointment with a clean tissue.
- Repeat this procedure for the other eye if you have been advised to do so by your doctor or pharmacist.
- Replace the cap on the tube.
- Take care not to touch the tip of the tube with your fingers.
- Contact lenses should not be worn until the infection has resolved.

How do I use PENTAMYCETIN Ophthalmic Solution?

Instill 2 drops to the affected eye every 3 hours or more often if necessary.

Applying PENTAMYCETIN Ophthalmic Solution into the eye:

- Wash hands with soap and water.
- Tilt the head back or lie down and look toward the ceiling.
- With the eyes open, gently pull the lower eyelid below the eyelashes away from the eye to form a pouch.
- Hold the bottle at least 2 cm away and squeeze one drop into the pouch.
- Slowly release the lower lid.
- Gently close the eye for one or two minutes. Do not rub the eye and try not to blink.
- If multiple drops are used, wait three to five minutes between each drop.
- Do not let the bottle directly touch the eye.
- Contact lenses should not be worn until the infection has resolved.

Overdose:

If you think you have taken too much PENTAMYCETIN, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using PENTAMYCETIN?

These are not all the possible side effects you may feel when taking PENTAMYCETIN. If you experience any side effects not listed here, contact your healthcare professional.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Local irritation: symptoms of burning, swelling (angioneurotic edema), itching, hives (urticarial), rash (vesicular and maculopapular dermatitis)			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on [Adverse Reaction Reporting](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

PENTAMYCETIN (Ophthalmic Solution 0.25% and 0.5%):

Refrigerate (2-8°C) until dispensing. Protect from freezing. After dispensing, the solution may be stored at room temperature for 21 days; after that period, discard unused portion. Avoid contamination of the tip of the dropper. Do not use if the dropper-tip cap is detached from the security ring.

PENTAMYCETIN (Ophthalmic Ointment USP 1%):

Store between 15 and 30°C. Protect from freezing.

Keep out of reach and sight of children.

If you want more information about PENTAMYCETIN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](#); the manufacturer's website www.sandoz.ca, or by calling 1-800-361-3062.

This leaflet was prepared by Sandoz Canada Inc.

Last Revised: May 7, 2018

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

Read this carefully before you start taking PENTAMYCETIN/HC each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about PENTAMYCETIN/HC.

What is PENTAMYCETIN/HC used for?

PENTAMYCETIN/HC is used to treat infections in the eye and ear.

Antibacterial drugs like PENTAMYCETIN/HC treat only bacterial infections. They do not treat viral infections.

How Does PENTAMYCETIN/HC work?

PENTAMYCETIN/HC contains two medicines:

- chloramphenicol (antibiotic) that kills bacteria and stops it from growing.
- hydrocortisone acetate (corticosteroid) that prevents inflammation.

What are the ingredients in PENTAMYCETIN/HC?

Eye and Ear Suspension

Medicinal ingredients: Chloramphenicol and Hydrocortisone Acetate

Non-medicinal ingredients: povidone, polysorbate, water for injection and hydrochloride acid or sodium hydroxide to adjust pH.

Eye and Ear Ointment

Medicinal ingredients: Chloramphenicol and Hydrocortisone Acetate

Non-medicinal ingredients: petrolatum base

PENTAMYCETIN/HC comes in the following dosage forms:

Pentamycetin/HC (Eye and Ear Suspension): Bottle of 5 mL

Pentamycetin/HC (Eye and Ear Ointment): Tube of 3.5 g

Do not use PENTAMYCETIN/HC if:

- you are allergic to chloramphenicol or to any of the other ingredients in PENTAMYCETIN.
- you have an inflamed cornea (front part of the eye), also known as keratitis.
- you have a viral or fungal infection in the eye.

To help avoid side effects and ensure proper use, talk to your healthcare professional

before you take PENTAMYCETIN/HC. Talk about any health conditions or problems you may have, including if you:

- experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists, consult a physician;
- are pregnant or planning to become pregnant.

Other warnings you should know about:

- Overuse of this product may produce increased redness of the eye;
- Do not touch tip of tube to any surface to avoid contamination.
- If there is no improvement within two days of starting treatment, stop use and consult a physician.
your vision may be blurred for a few minutes after using the product. Do not drive or operate machinery until you can see clearly;

How to take PENTAMYCETIN/HC:

- Although you may feel better early in treatment, PENTAMYCETIN/HC should be used exactly as directed.
- Misuse or overuse of PENTAMYCETIN/HC could lead to the growth of bacteria that will not be killed by PENTAMYCETIN/HC (resistance). This means that PENTAMYCETIN/HC may not work for you in the future.
- Do not share your medicine.”

How do I use PENTAMYCETIN/HC Ointment?

Apply one application in the affected eye or ear, every 3 hours or more often if necessary.

Applying PENTAMYCETIN/HC Ointment into the eye:

- Wash hands with soap and water.
- Sit in front of a mirror so you can see what you are doing.
- Take the lid off the ointment.
- Tilt your head back.
- Gently pull down your lower eyelid and look up.
- Hold the tube above the eye and gently squeeze a 1cm line of ointment along the inside of the lower eyelid, taking care not to touch the eye or eyelashes with the tip of the tube.
- Blink your eyes to spread the ointment over the surface of the eyeball.
- Your vision may be blurred when you open your eyes - DON'T rub your eyes. The blurring will clear after a few moments if you keep blinking.
- Wipe away any excess ointment with a clean tissue.
- Repeat this procedure for the other eye if you have been advised to do so by your doctor or pharmacist.
- Replace the cap on the tube.
- Take care not to touch the tip of the tube with your fingers.
- Contact lenses should not be worn until the infection has resolved.

How do I use PENTAMYCETIN/HC Solution?

Instill 2 drops to the affected eye or ear every 3 hours or more often if necessary.

Applying PENTAMYCETIN/HC Solution into the eye:

- Wash hands with soap and water.
- Tilt the head back or lie down and look toward the ceiling.
- With the eyes open, gently pull the lower eyelid below the eyelashes away from the eye to form a pouch.
- Hold the bottle at least 2 cm away and squeeze one drop into the pouch.
- Slowly release the lower lid.
- Gently close the eye for one or two minutes. Do not rub the eye and try not to blink.
- If multiple drops are used, wait three to five minutes between each drop.
- Do not let the bottle directly touch the eye.
- Contact lenses should not be worn until the infection has resolved.

Administering PENTAMYCETIN/HC Solution or Ointment in the ear:

- Lie on the side or tilt the head over so that the infected ear is facing upwards.
- Gently pull the earlobe upwards, away from the neck, and squeeze the drops or a small amount of ointment into the ear.
- Let the drops flow against the side of the ear canal and gently massage the ear around the opening to help the drops work down.
- Keep the head tilted for a few minutes.

Overdose:

If you think you have taken too much PENTAMYCETIN/HC, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using PENTAMYCETIN/HC?

These are not all the possible side effects you may feel when taking PENTAMYCETIN/HC. If you experience any side effects not listed here, contact your healthcare professional.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Local irritation: symptoms of burning, swelling (angioneurotic edema), itching, hives (urticarial), rash (vesicular and maculopapular dermatitis)			✓

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- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

PENTAMYCETIN/HC (Eye and Ear Suspension):

Refrigerate (2-8°C) until dispensing. Protect from freezing. After dispensing, the solution may be stored at room temperature for 21 days; after that period, discard unused portion. Avoid contamination of the tip of the dropper. Do not use if the dropper-tip cap is detached from the security ring.

PENTAMYCETIN/HC (Ointment):

Store between 15 and 30°C. Protect from freezing

Keep out of reach and sight of children.

If you want more information about PENTAMYCETIN/HC:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](#); the manufacturer's website www.sandoz.ca, or by calling 1-800-361-3062.

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