

**PRESCRIBING INFORMATION
INCLUDING PATIENT MEDICATION INFORMATION**

Pr TETRACYCLINE 1% OPHTHALMIC OINTMENT

Tetracycline Hydrochloride Ophthalmic Ointment USP

STERILE

ANTIBIOTIC

Steri-Med Pharma Inc.
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PRESCRIBING INFORMATION

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Tetracycline Hydrochloride Ophthalmic Ointment USP

MEDICINAL INGREDIENT:

Tetracycline Hydrochloride.....10 mg / g

NON-MEDICINAL INGREDIENTS:

Butylated hydroxytoluene
Mineral oil
Petrolatum

THERAPEUTIC CLASSIFICATION

Antibiotic

ACTIONS AND CLINICAL PHARMACOLOGY

Tetracycline is a broad-spectrum antibacterial agent with activity against a wide range of Gram-positive and Gram-negative bacteria, including obligate anaerobes. Tetracycline is well known to be efficacious against *Chlamydia*, *Mycoplasma* and *Rickettsia*.

INDICATIONS

For the antibiotic treatment of infectious conjunctivitis when caused by organisms susceptible to tetracycline. Laboratory tests should be conducted, including *in vitro* culturing and susceptibility tests, on samples collected prior to treatment.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of TETRACYCLINE 1% Ophthalmic Ointment and other antibacterial drugs, TETRACYCLINE 1% Ophthalmic Ointment should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

CONTRAINDICATIONS

TETRACYCLINE 1% Ophthalmic Ointment should not be used in patients who are hypersensitive to tetracycline or other formulation components (butylated hydroxytoluene, heavy mineral oil, petrolatum).

WARNINGS AND PRECAUTIONS

Susceptibility/Resistance

Development of drug resistant bacteria

Prescribing TETRACYCLINE 1% Ophthalmic Ointment in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

Potential for microbial overgrowth

The rare possibility of superinfection caused by overgrowth of non-susceptible bacteria or fungi should be kept in mind during prolonged or repeated therapy, especially when other antibacterial agents are simultaneously employed. In such instances the drug should be withdrawn and appropriate treatment instituted if necessary.

Patients who may be exposed to direct sunlight and/or ultraviolet light should be warned of the risk of photosensitivity reactions.

ADVERSE EFFECTS

Itching, burning or inflammation may occur in patients who are hypersensitive to the product. If a reaction occurs, discontinue use of the product.

Blurred vision may occur after administration of this product. If no improvement occurs within a few days, medical advice is needed.

Tetracycline topical ophthalmic ointment has no systemic action; in rare cases it may cause irritation of the eyelid mucosa.

Candidiasis occurrence is possible and is mainly due to overgrowth of *Candida albicans*; and there may be overgrowth of the resistant coliform organisms, such as *Pseudomonas* and *Proteus* species.

Hypersensitivity reactions, including rashes, fixed drug eruptions, exfoliative dermatitis are rare but possible.

Myopia in patients taking tetracyclines may be due to transient hydration of the lens.

Cases of increased muscle weakness in patients with myasthenia gravis and exacerbation of lupus erythematosus are reported when tetracycline is applied over prolonged periods.

DOSAGE AND ADMINISTRATION

Properly cleanse the eye, removing exudate, debris and any foreign object before treating. Apply a thin layer over the cornea every two hours. To apply, insert the tip of the tube beneath the lower eyelid and express a small amount of the ointment into the conjunctival sac. Care should be taken not to contaminate the tip during administration. Treatment should continue for

two days after the eye appears normal, or as recommended by the treating healthcare professional.

DRUG INTERACTIONS

- Do not use makeup containing retinoids when tetracycline is applied.
- Ocular inflammation has occurred following the concomitant use of ocular preparations preserved with thimerosal in some patients using tetracycline.
- The predominantly bacteriostatic tetracyclines may antagonize the action of penicillins; therefore, it is recommended that the two types of drugs should not be used together, especially when a rapid bactericidal action is necessary.

STORAGE CONDITIONS

Store at room temperature (15-30°C). Protect from freezing. Keep tightly closed.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Pr TETRACYCLINE 1% Ophthalmic Ointment

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Read this carefully before you start taking TETRACYCLINE 1% Ophthalmic Ointment and 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 TETRACYCLINE 1% Ophthalmic Ointment.

What is TETRACYCLINE 1% Ophthalmic Ointment used for?

- TETRACYCLINE 1% Ophthalmic Ointment is used to treat certain infections in your eye.
- Antibacterial drugs like TETRACYCLINE 1% Ophthalmic Ointment treat only bacterial infections. They do not treat viral infections.

How does TETRACYCLINE 1% Ophthalmic Ointment work?

TETRACYCLINE 1% Ophthalmic Ointment is an antibiotic. It works by killing or stopping the growth of the bacteria that cause your infection. If symptoms of infection persist for more than 2 or 3 days, contact your healthcare professional.

What are the ingredients in TETRACYCLINE 1% Ophthalmic Ointment?

Medicinal ingredients: Tetracycline Hydrochloride

Non-medicinal ingredients: Butylated hydroxytoluene, Mineral oil, Petrolatum

TETRACYCLINE 1% Ophthalmic Ointment comes in the following dosage forms:

Ointment: 1%

Do not use TETRACYCLINE 1% Ophthalmic Ointment if you:

- Are allergic to tetracycline hydrochloride or any other ingredients of TETRACYCLINE 1% Ophthalmic Ointment.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Tetracycline 1% Ophthalmic Ointment. Talk about any health conditions or problems you may have.

Warnings that you should know about:

TETRACYCLINE 1% Ophthalmic Ointment may increase your sensitivity to sunlight and may cause exaggerated sunburns. Avoid exposure to sunlight or ultraviolet light while taking TETRACYCLINE 1% Ophthalmic Ointment.

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

The following may interact with TETRACYCLINE 1% Ophthalmic Ointment:

- Make-up or Skincare products containing retinoids (such as vitamin A or retinol)
- Thimerosal
- Penicillins

How to take TETRACYCLINE 1% Ophthalmic Ointment:

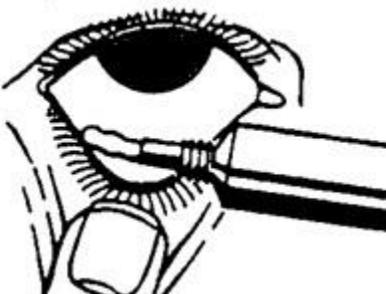
- Follow your healthcare professional instructions carefully about how much TETRACYCLINE 1% Ophthalmic Ointment to apply and when to apply it.
- Although you may feel better early in the treatment, TETRACYCLINE 1% Ophthalmic Ointment should be used exactly as directed.
- Misuse or overuse of TETRACYCLINE 1% Ophthalmic Ointment could lead to the growth of bacteria that will not be killed by TETRACYCLINE 1% Ophthalmic Ointment (resistance). This means that TETRACYCLINE 1% Ophthalmic Ointment may not work for you in the future.
- Do not share your medicine.

Usual dose:

Apply a thin layer over the cornea every two hours.

Administration:

1. Properly cleanse the eye, removing exudate, debris and any foreign object before treating.
2. Wash hands before use.
3. Remove tube cap.
4. Gently pull down the lower eyelid until there is a “pocket” (see picture below).
5. Apply a ribbon of ointment 0.5-1 cm along in this pocket (see picture below).
6. Let go of the lower eyelid and close the eye for 30 seconds.
7. If you use ointment in both eyes, repeat the steps for the other eye.
8. To avoid contamination and injury, do not let the tip of the tube touch your eye or your eyelid.
9. Close and tighten the cap.



Overdose:

In case of drug overdose of Tetracycline 1% Ophthalmic Ointment, including ingestion, contact your healthcare professional, hospital emergency department or regional poison control centre, even if there are no symptoms.

Missed Dose:

If you forget to apply the ointment, simply apply it as soon as you remember. Then go back to the original schedule as directed by your healthcare professional. Do not apply 2 doses to make up for the missed dose.

What are possible side effects from using TETRACYCLINE 1% Ophthalmic Ointment?

These are not all the possible side effects you may feel when taking TETRACYCLINE 1% Ophthalmic Ointment. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Blurred vision
- Irritation in the eyes
- Near sightedness

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	
Allergic Reaction: Burning, Itching, Inflammation			✓

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>) 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:

Store at room temperature (15-30°C). Keep tightly closed.
Protect from light and freezing.

Keep out of reach and sight of children.

If you want more information about Tetracycline 1% Ophthalmic Ointment:

- Talk to your healthcare professional.
- Find the full prescribing information that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>), or by calling 1-855-543-9917.

This leaflet was prepared by Steri-Med Pharma Inc.

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