

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Opticyclin eye ointment

2. Qualitative and quantitative composition

Tetracycline Hydrochloride 1%

For full list of excipient refer to section 6.1

3. Pharmaceutical form

Eye ointment

4. Clinical particulars

4.1 Therapeutic indications

Tetracyclines belong to the family of medicines called antibiotics. Tetracycline ophthalmic preparations are used to treat infections of the eye. They may also be used along with other medicines that are taken by mouth for infections of the eye.

Tetracyclines are available only with your doctor's prescription.

4.2 Posology and method of administration

For patients using the eye ointment form of tetracyclines:

- To use:
 - First, wash your hands. Then pull the lower eyelid away from the eye to form a pouch. Squeeze a thin strip of ointment into the pouch. A 1-cm (approximately 1/3-inch) strip of ointment is usually enough unless otherwise directed by your doctor. Gently close the eyes and keep them closed for 1 or 2 minutes to allow the medicine to come into contact with the infection.
 - To keep the medicine as germ-free as possible, do not touch the applicator tip to any surface (including the eye). After using tetracyclines eye ointment, wipe the tip of the ointment tube with a clean tissue and keep the tube tightly closed.

To help clear up your infection completely, keep using this medicine for the full time of treatment, even if your symptoms have disappeared. Do not miss any doses.

Dosing

The dose medicines in this class will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of these medicines. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- For eye infections:
 - For ophthalmic dosage form (ointment):
 - Adults and children—Use every two to four hours.

4.3 Contraindications

Patients with known hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

After application, this medicine usually causes your vision to blur for a few minutes.

If your symptoms do not improve within a few days, or if they become worse, check with your doctor.

Avoid excessive exposure to sun or UV radiation during treatment with tetracyclines to avoid potential occurrence of photodermatitis.

4.5 Interaction with other medicinal products and other forms of interaction

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. Tell your healthcare professional if you are taking any other prescription or nonprescription (over-the-counter [OTC]) medicine.

4.6 Pregnancy and lactation

Pregnancy

Tetracycline ophthalmic preparations have not been shown to cause birth defects or other problems in humans.

Lactation

Tetracycline ophthalmic preparations have not been reported to cause problems in nursing babies.

4.7 Effects on ability to drive and use machines

After application, this medicine usually causes your vision to blur for a few minutes.

4.8 Undesirable effects

There have not been any common or important side effects reported with this medicine. However, if you notice any unusual effects, check with your doctor. In very rare cases allergic reaction and overgrowth of non-susceptible microorganisms may occur.

4.9 Overdose

Opticyclin are for external use only, if you suspect someone has swallowed any of this preparation, contact your doctor or go to the accident and emergency department of your local hospital. Always take the tube with you, if possible, even if empty.

5. Pharmacological properties

5.1 Pharmacodynamic properties

This product is topical, and has very little absorption.

5.2 Pharmacokinetic properties

Opticyclin eye ointment contains tetracyclin which is a broad spectrum antibiotic. Tetracyclins are bacteriostatic in which they suppress protein synthesis by binding to the 30S bacterial ribosomal subunit, preventing the binding of aminoacyl tRNA to initial site on ribosome.

5.3 Preclinical safety data

Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

White petrolatum
Paraffin oil
Lanolin alcohol

6.2 Incompatibilities

None known.

6.3 Shelf life

Unopened: 36 months

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

5g Aluminum tube.

6.6 Special precautions for disposal and other handling

No special requirements

7. Marketing authorization holder

Marketing Authorization Holder and Manufacturer

Amman Pharmaceutical Industries

King Abdullah II Industrial State – Sahab – Amman- Jordan

8. Marketing authorization number(s)

08097/09911/NMR/2022

9. Date of first authorization/renewal of the authorization

Date of first authorization: Nov 12, 2022

Date of renewal of authorization:

10. Date of revision of the text

March.2017