

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

AUREOMYCIN SPECIA 3%, ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlortetracycline hydrochloride 3.0 g
Per 100g of ointment.

Excipient with known effect : wool fat (lanolin).

For the full list of excipients, [see section 6.1](#).

3. PHARMACEUTICAL FORM

Ointment.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Skin infections due to staphylococcus and streptococcus:

- impetigo and impetiginized dermatoses :
 - treatment only in localized forms with a small number of lesions
 - as an adjunct local treatment in combination with appropriate systemic antibiotic therapy in the most extensive forms;
- disinfection of cutaneous and mucosal microbial reservoirs, in healthy carriers of staphylococci, and after staphylococcal infection, particularly furunculosis.

Official recommendations regarding the appropriate use of antibacterial agents should be taken into account.

4.2. Posology and method of administration

Posology

2 or 3 applications per day.

The duration of treatment will not exceed 8 days due to the risk of selecting resistant germs.

Method of administration

Cutaneous route.

4.3. Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1, in particular to wool fat (lanolin).

Breast infections may occur during breastfeeding due to the risk of ingestion of the product by the newborn. ([see section 4.6](#))

4.4. Special warnings and precautions for use

Special warnings

In the event of a streptococcal infection, systemic antibiotic therapy should be considered.

Skin sensitization may compromise the subsequent systemic use of an antibiotic from the same family.

Precautions for use

Due to the risk of photosensitivity, avoid exposure to solar or artificial UV radiation.

Risk of selecting resistant germs in case of prolonged treatment.

This ointment form is not suitable for the treatment of oozing, macerated lesions, lesions of the folds, or leg ulcers.

This medicine contains lanolin (wool fat) and may cause local skin reactions (e.g., contact dermatitis).

4.5. Interactions with other medicinal products and other forms of interaction

Not applicable.

4.6. Fertility, pregnancy and breastfeeding

Pregnancy

Not applicable.

Breastfeeding

Do not use in case of breast infections during breastfeeding, due to the risk of ingestion of the product by the newborn.

4.7. Effects on the ability to drive vehicles and use machinery

Not applicable.

4.8. Undesirable effects

There is a possibility of allergic contact eczema. Eczema lesions may spread to areas distant from the treated areas.

Risk of photosensitivity.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals report any suspected adverse reactions via the FRILAB reporting system - Website: www.frilab.ch/pharmacovigilance .

4.9. Overdose

No cases of overdose have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic class : LOCAL ANTIBIOTIC THERAPY , ATC code: D06AA02

Chlortetracycline is an antibiotic in the tetracycline family.

SPECTRUM OF ANTIBACTERIAL ACTIVITY

The critical concentrations separate susceptible strains from strains with intermediate susceptibility, and the latter from resistant strains:

$S \leq 4 \text{ mg/l}$ et $R > 8 \text{ mg/l}$

The prevalence of acquired resistance can vary geographically and over time for certain species. Therefore, information on local resistance prevalence is useful, especially for treating severe infections. This data can only provide guidance on the likelihood of a bacterial strain's susceptibility to that antibiotic.

When the variability in resistance prevalence in France is known for a bacterial species, it is indicated in the table below:

Categories	Frequency of acquired resistance in France (> 10%) (extreme values)
<u>SENSITIVE SPECIES</u> Gram-positive aerobes <i>Bacillus</i> Enterococci Methicillin-susceptible <i>Staphylococcus</i> Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) <i>Streptococcus A</i> <i>Streptococcus B</i> <i>Streptococcus pneumoniae</i> Gram-negative aerobes <i>Branhamella catarrhalis</i> <i>Brucella</i> <i>Escherichia coli</i> <i>Haemophilus influenzae</i> <i>Klebsiella</i> <i>Neisseria gonorrhoeae</i> <i>Pasteurella</i> <i>Vibrio cholerae</i> Anaerobes <i>Propionibacterium acnes</i>	 40-80% 70-80% 20% 80-90% 20-40% 20-40% 10% 10-30%
<u>Others</u> <i>Borrelia burgdorferi</i> <i>Chlamydia</i> <i>Coxiella burnetii</i> <i>Leptospira</i> <i>Mycoplasma pneumoniae</i> <i>Rickettsia</i> <i>Treponema pallidum</i> <i>Ureaplasma urealyticum</i>	
<u>RESISTANT SPECIES</u> Gram-negative aerobes <i>Acinetobacter</i> <i>Proteus mirabilis</i> <i>Proteus vulgaris</i> <i>Pseudomonas</i> <i>Serratia</i>	

* The resistance frequency methicillin infection accounts for approximately 30 to 50% of all staphylococci and is found mainly in hospital settings.

5.2. Pharmacokinetic properties

Not specified.

5.3. Preclinical safety data

Not specified.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Liquid paraffin, wool grease, petroleum jelly.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years.

6.4. Special storage precautions

Store at a temperature below 25°C.

6.5. Nature and contents of container

15g aluminum tube closed with a polypropylene cap.
Box of 1 tube.

6.6. Special precautions for disposal and handling

Any unused medication or waste must be disposed of in accordance with the applicable regulations.

7. MARKETING AUTHORISATION HOLDER AND OPERATOR

FRILAB SA
17 RUE DES PIERRES DU NITON
1207 GENEVA - SWITZERLAND

8. MANUFACTURER

POLYMEDIC
AMYOT D'INVILLE STREET, ARSALANE DISTRICT
CASABLANCA - MOROCCO

9. DATE OF REVISION OF THE TEXT

January 2024

10. DOSIMETRY

Not applicable.

11. INSTRUCTIONS FOR THE PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

CONDITIONS FOR PRESCRIPTION AND DISPENSING

List I.