

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF DRUG

Auréomycine SPECIA 3 PERCENT, ointment

2. Qualitative and quantitative composition

Chlortetracycline hydrochloride
3.0 g

Per 100 g of ointment.

excipients: Wool fat.

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

3. PHARMACEUTICAL FORM

Ointment.

4. CLINICAL DATA

4.1. Therapeutic indications

Skin infections caused by staphylococcus and streptococcus:

- impetigo and impetiginous dermatoses:
 - local treatment only in localized forms to fewer injuries
 - locally an adjunct in combination with systemic antibiotics adapted in the most extended forms;
- disinfection of mucocutaneous microbial deposits, in healthy carriers of staphylococci and after staphylococcal

Take into consideration the official recommendations of appropriate use of antibacterial agents.

4.2. Dosage and administration

- 2 or 3 applications per day.
- The treatment period will not exceed 8 days due to the risk of selecting resistant organisms.

4.3. Contraindications

- Hypersensitivity to any component in particular grease wool or lanolin.
- mastitis during lactation, due to the risk of ingestion of the product by the newborn. ([see section 4.6](#))

4.4. Special warnings and precautions

Special warnings

- in cases of streptococcal infection: A systemic antibiotics should be considered.
- Dermal sensitization may compromise subsequent use by the general route of an antibiotic of the same family.

Precautions

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

- risk of selection of resistant organisms during prolonged treatment.
- this form ointment is not suitable for treating weeping lesions, macerated, folds or leg ulcers.
- This medicine contains lanolin (wool fat) and can cause local skin reactions (eg eczema).

4.5. Interactions with other drugs and other forms of interaction

Not applicable.

4.6. Pregnancy and breast feeding

Do not use in case of mastitis during lactation, due to the risk of ingestion of the product by the newborn.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Side effects

- Possibility of allergic reaction on contact. The Lesions of eczema can spread away from treated areas.
- Risk of photosensitivity.

4.9. Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic: LOCAL ANTIBIOTIC

(D. Dermatology)

Chlortetracycline is an antibiotic of the cyclin family.

SPECTRUM OF ACTIVITY ANTI-BACTERIAL

Breakpoints separate susceptible strains of intermediate susceptibility strains and the latter from resistant:

S \leq 4 mg / l and R > 8 mg / l

The prevalence of acquired resistance may vary depending on the geography and time for certain species. It is therefore useful to have information on the prevalence of local resistance, particularly when treating severe infections. These data may provide an orientation of the probabilities of the sensitivity of a bacterial strain to this antibiotic.

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

Categories	frequency of resistance acquired in France (> 10%) (range)
SUSCEPTIBLE SPECIES	
Aerobic Gram-positive	
<i>Bacillus</i>	
enterococci	40-80%
<i>Staphylococcus metis</i>	70-80%
<i>Staphylococcus ori-R *</i>	20%
<i>Streptococcus AT</i>	

<i>Streptococcus B</i> <i>Streptococcus pneumoniae</i> Aerobic Gram-negative <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> anaerobic <i>Propionibacterium acnes</i>	80-90% 20-40% 20-40% 10% 10-30%
Categories	frequency of resistance acquired in France (> 10%) (range)
Other <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>	
RESISTANT SPECIES Aerobic Gram-negative <i>Acinetobacter</i> <i>Proteus mirabilis</i> <i>Proteus vulgaris</i> <i>Pseudomonas</i> <i>Serratia</i>	

* The methicillin resistance rate is about 30 to 50% of all staphylococci and found mainly in hospitals.

5.2. pharmacokinetic properties

Unspecified.

5.3. Preclinical safety data

Unspecified.

6. PHARMACEUTICAL DATA

6.1. List of excipients

Liquid paraffin, wool grease, Vaseline.

6.2. Incompatibility

Not applicable.

6.3. The duration of the conversation

3 years.

6.4. Special precautions for storage

Store at a temperature below 25 ° C.

6.5. Nature and contents of container

Tube 15 g aluminum closed with a polypropylene cap. Box 1

6.6. Special precautions for disposal and handling

No special requirements.

7. OPERATOR AND MANUFACTURER

OPERATOR TO INTERNATIONAL:

FRILAB SA
17, rue des Pierres du Niton
1207 Genève Suisse

MAKERS:

POLYMEDIC AMYOT D'INVILLE STREET, DISTRICT ARSALAN - CASABLANCA MOROCCO
VAMFARMA, OFFICINA DI COMAZZO 26833 (LO)5, VIA KENNEDY – ITALIE

8. DOSIMETRY

Not applicable.

9. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

CONDITIONS OF PRESCRIPTION AND DELIVERY

List I.