

LYMECYCLINE

Product Type: Tetracycline Antibiotic

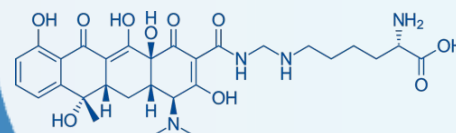
CAS Number: 992-21-2

Common Indications: Treatment of moderate to severe acne

Product Status: Commercial

Available Grades: Non-Micronized

Structural formula:



Our API Lymecycline is manufactured in accordance with cGMP and stringent international quality standards. Our quality control follows every stage from development of analytical methods to the control of manufacturing process.

Lymecycline is a semisynthetic tetracycline antibiotic formed of a molecule each of tetracycline, the amino-acid L-lysine, and formaldehyde. In contrast to the customarily used tetracyclines, Lymecycline is claimed to be much more soluble, to be stable throughout physiological pHs, to have improved oral absorption, enhanced tissue penetration, and slower elimination than tetracycline.

After administration, it is converted to tetracycline in the gastrointestinal tract before being absorbed. These properties suggest important advantages for lymecycline.

Lymecycline was demonstrated to be an efficacious and well-tolerated treatment for acne vulgaris.



CHARACTERISTICS AND THERAPEUTIC USE AS A DRUG

Lymecycline is an **antibiotic with bacteriostatic action** that acts by inhibiting protein synthesis. It has a broad spectrum against Gram-positive and Gram-negative germs, especially Rickettsiae, Mycoplasma pneumoniae, Chlamydia sp, Vibrio Cholerae, Bacteroides sp, Brucella sp, etc. It is used in the treatment of:

- Otolaryngological and dental infections
- Respiratory infections
- Urethritis (non-gonococcal)
- Gastrointestinal infections
- Genitourinary infections
- Skin and soft-tissue infections
- Brucellosis (associated with streptomycin)
- Typhoid typhus, psittacosis



FINISHED DOSAGE FORMS

ORAL:

Capsule: 250 and 500 mg



ADVANTAGES

EFFICACY:

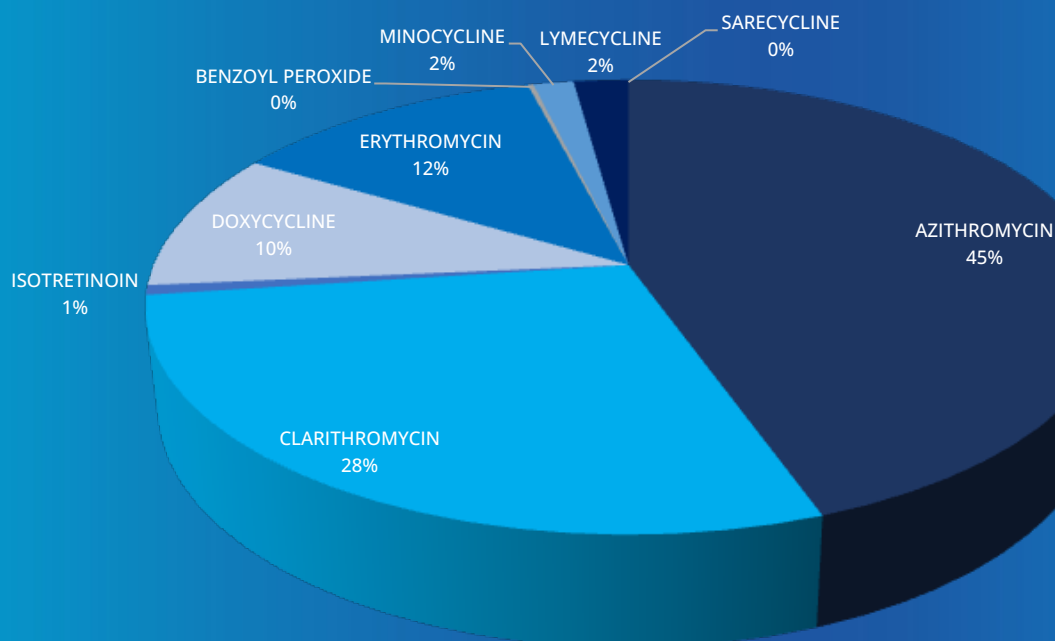
- Bacteriostatic action over a wide range of bacteria.
- Good safety profile and is generally well tolerated.
- Best cost-effectiveness in several European countries.

SAFETY:

- It is rapidly and completely absorbed in the gastrointestinal tract, mainly in the small intestine, and reaches its maximum concentration in the blood within three to six hours.
- Parenterally it is optimally absorbed.



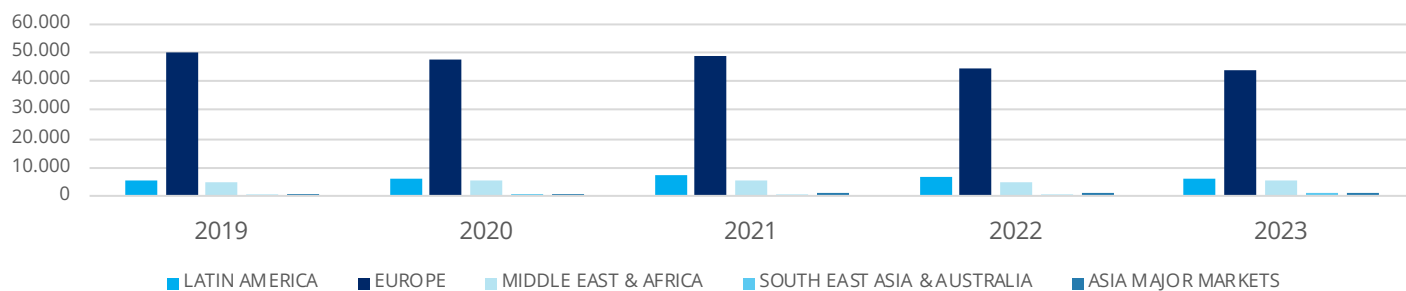
MARKET STATUS



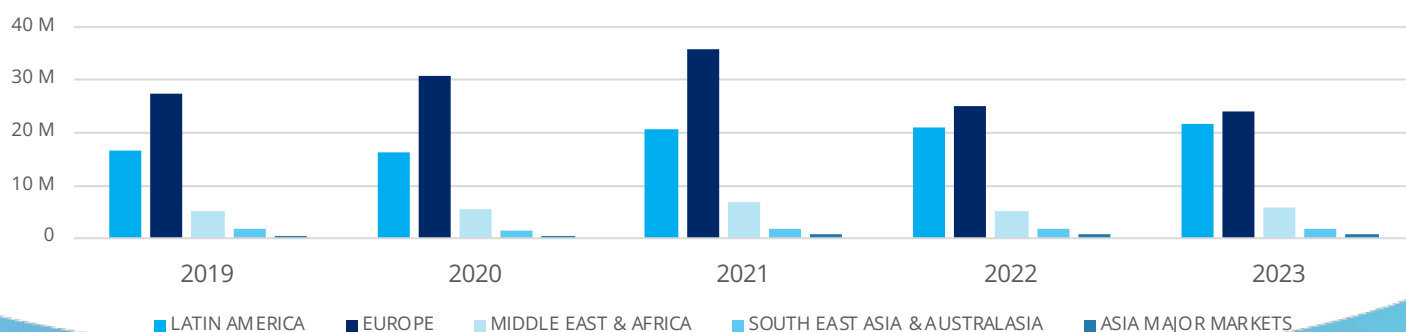


MARKET STATUS

API CONSUMPTION (kg)



SALES FDF 2022-2023



OUR API

KEY POINTS:

- 52,4 M USD global market sales in 2021.
- Global consumption of 272 MT.
- Well established market.
- Few API manufacturers to cover worldwide demand.

DOCUMENTATION:

- CEP available
- CoA available
- MSDS available

Other information:

- **Self life:** 36 months
- **Storage conditions:** The product is stored at a temperature not exceeding 8°C in airtight containers protected from light ($5 \pm 3^\circ\text{C}$).
- **Container closure system:** Bag 50 g. Double polyethylene bag heat sealed inside a hermetic metallic drum.
- **Samples available.**

Supply:

- We have a long lasting strategic commitment to this product that ensures continuity and security of supply.

LYMECYCLINE

PATENT PROTECTION



OFF



OUR API

CONTRACT MANUFACTURER:

Cipan, our facility located in Portugal with more than 75 years of experience in the API synthesis business (Chemical and Fermentation).

CIPAN started its activity in 1963. The plant site is located in Castanheira do Ribatejo, approximately 40 kilometers North of Lisbon. Since 2016, CIPAN is a company of the SUANFARMA Group.

Cipan develops and manufactures products in accordance with cGMP and stringent international quality standards.

Cipan's standards are regularly verified through audits conducted by clients and international authorities.

Relevant Certifications: EU and FDA GMPs, ISO 14001: 2015.

Relevant Information:

- Own european facility: CIPAN. Portuguese facility with over 50 years of API fermentation and organic synthesis expertise.
- EU-GMP certificate.
- FDA certificate.
- Plant successfully audited by European and American customers.
- CEP for other products available.
- Competitive price.
- Large scales API organic semi-synthesis units.
- Installed fermentation capacity in excess of 850.000 liters.



MORE INFORMATION

FOR MORE INFORMATION PLEASE CONTACT:

NARCIS BRUGADA (humanapis@suanfarma.com)

HUMAN API BUSINESS UNIT DIRECTOR