

94113 - ERYTHROMYCIN**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.****1.1. Identification of the substance or preparation.**

Name: Erythromycin

Bulk code: 94113

1.2. Synonyms.

Erithromycinum; Ermycine; Erythromycin A; Erythromycin base.

2. DESCRIPTION

Appearance: Powder or crystals

Colour: White or yellowy white (powder) and colourless or slightly yellow (crystals)

Smell: Odourless or almost odourless

Somewhat hygroscopic.

3. COMPOSITION/INFORMATION ON COMPONENTS.Formula: $C_{37}H_{67}NO_{13}$

CAS: 114-07-8

Molecular weight: 733.9 g/mol

4. PHYSICO-CHEMICAL DATA.

See detailed specifications in the certificate of analysis.

Solubility: Slightly soluble in water (solubility decreases when the temperature increases).

Soluble in alcohol; soluble in chloroform, methanol and diluted hydrochloric acid.

Melting point: Approximately 135°C.**5. PROPERTIES/USES.**

ACTIVE PHARMACEUTICAL INGREDIENT.

This is a bacteriostatic antibiotic from the group of broad-spectrum macrolides that are most active against gram-positive bacteria, although it is also active against some gram-negative, actinomycetes, mycoplasma, spirochetes, chlamydia, rickettsia and certain mycobacteria.

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It is used to treat a wide variety of infections, including bronchitis, serious enteritis caused by *Campylobacter*, chancre, diphtheria, Legionnaire's disease and other infections caused by *Legionella*, neonatal conjunctivitis, whooping cough, pneumonia, even Mycoplasmatales and other atypical pneumonias like streptococcal infections and sinusitis.

When associated with neomycin, it is used in the prophylaxis of surgical infections in intestinal surgery patients.

It is used as an alternate medicine for individuals allergic to penicillin in certain medical conditions, including anthrax, prophylaxis of endocarditis, leptospirosis, otitis media, normally associated with a sulphonamide like sulfafurazole, pharyngitis, prevention of rheumatic fever and skin infections caused by staphylococcus and streptococcus bacteria.

Furthermore, it has been used in cases of syphilis in patients who are allergic to penicillin, although its efficacy is doubtful.

It is also used as a treatment alternative to tetracycline when treating infections caused by chlamydia, such as epididymitis, lymphogranuloma venereum, gonococcal urethritis, chlamydia pneumoniae, psittacosis, Q fever and trachoma, pelvic inflammatory disease and tularaemia.

It is used to treat severe acne both orally and topically.

6. DOSAGE.

Orally:

- Enteric capsules and tablets (erythromycin is destroyed in gastric acid environments) in doses of 1-2 g/day, divided into 2-4 intakes, which may be increased in serious infections to 4 g per day, also in several intakes. As foods interfere with its absorption, they must be taken a minimum of half an hour before meals. In paediatric patients, the usual dose is around 30-50 mg/kg of weight per day, although it may be doubled in serious infections; in infants and children younger than 2 years old, doses of 500 mg/day, several times, are recommended, while in children aged 2-8 years old 1 g is given per day, divided into several intakes.

Topical use:

- Solutions at 2%.

7. REMARKS.

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.



GUINAMA. Laboratory distributing raw materials for the pharmaceutical and cosmetics industries.

Type of Document:

THECNICAL DATA SHEET

Review date:

13.09.2022

Version:

6.0

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STORAGE:

Store at room temperature ($25\pm 2^{\circ}\text{C}$), in a cool, dry place, away from sunlight, in a hermetically sealed container.

8. BIBLIOGRAPHY.

Pharmaceutical Monographs. COF Alicante, 1998.

"Martindale. The Extra Pharmacopoeia". 30th Edition. Ed. The Pharmaceutical Press. London. (1993).