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TECHNICAL DATA SHEET

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93339-CLINDAMYCIN HCL.

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

1.1. Identification of the substance or preparation

Name: Clindamycin hcl

Bulk code: 93339

1.2. Synonyms

(7S)-7-Chloro-7-deoxylincomycin hydrochloride.

2. DESCRIPTION.

Appearance: Crystalline powder

Colour: White

3. COMPOSITION/INFORMATION ON COMPONENTS

Formula: $C_{18}H_{34}Cl_2N_2O_5S$

CAS: 21462-39-5

EC: 244-398-6

Molecular weight: 461.5 g/mol

4. PHYSICO-CHEMICAL DATA

See detailed specifications in analysis report.

Solubility: Very soluble in water, poorly soluble in ethanol (96°).

Melting point: 141-143

5. PROPERTIES/USES

ACTIVE PHARMACEUTICAL INGREDIENT

Clindamycin is a lincosamide antibacterial agent with a primarily bacteriostatic action against gram-positive aerobes and many anaerobic bacteria.

Clindamycin is a chlorinated derivative of the lincosamide antibacterial agent lincomycin. It is a mainly bacteriostatic drug used to treat serious anaerobic infections, in particular those caused by *Bacteroides fragilis*. Clindamycin is also used for some gram-positive infections caused by pneumococci, staphylococci (including methicillin-resistant forms) and streptococci. However, because of its potential to cause pseudomembranous colitis, it is usually used only when alternative medications are not

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suitable.

It can be used to treat (either alone or with other antibacterial agents) liver abscess, actinomycosis, biliary tract infections, staphylococcal infections of the bones and joints, diphtheria carrier status, endophthalmitis, gas gangrene, various gynaecological infections including bacterial vaginosis, endometritis and pelvic inflammatory disease, intra-abdominal infections, including secondary peritonitis, streptococcal pharyngitis (usually to treat carrier status), severe respiratory tract infections, including empyema and pneumonia (especially pulmonary abscess), septicaemia and soft tissue infections involving extensive colonisation with streptococci or anaerobic bacteria, such as necrotising fasciitis. It is used in the prophylaxis of endocarditis in patients who are allergic to penicillin, in the prevention of perinatal streptococcal infections and with other drugs for the prophylaxis of surgical infection. It can be used as part of a multi-drug regimen to treat inhaled and gastrointestinal anthrax.

Clindamycin has antiprotozoal activity and has been used, generally with other antiprotozoal agents, for various infections, including babesiosis, malaria and toxoplasmosis. It can also be used with primaquine to treat Pneumocystis pneumonia.

It is also used in acne vulgaris therapy.

6. DOSAGE

Orally:

- 150–300 mg every 6 hours administered as capsules. These should be taken with a glass of water. Doses are expressed in terms of base; 1.1 g Clindamycin hydrochloride is equivalent to 1 g Clindamycin. For severe infections, the dose may be increased to up to 450 mg every 6 hours.

Topical use:

- 1% in the form of aqueous solutions, gels, emulsions and pastes.

7. REMARKS

STORAGE:

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

Keep away from all heat sources, including direct sunlight. Open flame. Ignition sources.

8. BIBLIOGRAPHY.

"Martindale. The Extra Pharmacopoeia". 37th Edition. Ed. The Pharmaceutical Press. London. (2011).