Brand Name : ERO-125 DRY SYRUP **Generic Name :** Erythromycin Estolate for Oral Suspension USP 125 mg / 5 ml	2021
Module 1 Administrative Information and Product Information **1.5** Product Information	**Confidential**

1.5 PRODUCT INFORMATION

1.5.1 Prescribing information (Summary of products characteristics)

SUMMARY PRODUCT CHARACTERISTICS

1. Name of drug product:

ERO-125 DRY SYRUP (Erythromycin Estolate for Oral Suspension USP 125 mg / 5 ml)

2. Qualitative and Quantitative Composition:

Each 5 ml of reconstituted suspension contains: Erythromycin Estolate USP ≡ to Erythromycin 125 mg

3. Pharmaceutical form:

White powder after reconstitution with water forms light pink coloured suspension on shaking.

4. Clinical particulars:

4.1 Therapeutic Indications:

Conjunctivitis, chlamydial
Genitourinary tract infections
Pneumonia chlamydial - Conjunctivitis in newborns, genitourinary tract infections during pregnancy, and pneumonia in infants caused by Chlamydia trachomatis.

Diphtheria - Diphtheria caused Corynebacterium diphtheria (as an adjunct to antitoxin).

Endocarditis, bacterial (prophylaxis)- Indicated in the prophylaxis of bacterial endocarditis in penicillin-allergic patients.

Erythrasma Gonorrhea caused by Neisseria gonorrhoeae. Legionnaires' disease - Legionnaires' disease caused by Legionella pneumophila.

Listeriosis - Listeriosis caused by Listeria monocytogenes. Otitis media, acute - Acute otitis media caused by Hemophilus influenzae (concurrently with sulfonamides).

Pertussis - Pertussis caused by Bordetella pertussis.

Pharyngitis, bacterial - Phyaryngitis caused by Streptococus epidemicus. (S.pyogenes) (group A beta hemolytic).

Pneumonia, mycoplasmal - Pneumonia caused by Mycoplasma pneumoiae (Eaton agent, PPLO).

Rheumatic fever (prophylaxis)- Long term rheumatic fever prophylaxis.
Skin and soft tissue infections - Skin and soft tissue infections caused by S. epidemicus (S. pyogenes) (group A beta hemolytic) and Staphylococcus aureus.

Acne vularis
Actinomtcosis
Anthrax
Burn wound infections
Chancroid
Diphtheria (prophylaxis)
Enterocolitis, campylobacter - Enterocolitis (including diarrhea) caused by Campylobacter fetus ssp jejuni.

Erysipelas
Erysipeloid
Granuloma inguinale
Lymphogranuloma venereum
Relapsing fever
Septicemia, bacterial - Parenteral erythromycins are used in the treatment of septicemia
Sinusitis
Skin infections, bacterial, minor
Trachoma.

4.2 Posology and Method of Administration:

Adults

The usual dosage is 250 mg every 6 hours. This may be increased up to 4g/day or more according to the severity of the inflection.

Paediatric patients

Age, weight, and severity of the infection are important factors in determining the proper dosage. The usual regimen is 30 to 50 mg/kg/day in divided doses. For more severe infections, this dosage may be doubled.

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If administration is desired on a twice-a-day scheduled in either adults or children, 1/2 of the daily dose may be given every 12 hours.

Twice-a-day dosing is not recommended when doses larger than 1 g daily are administered.

4.3 Contraindications:

Erythromycin is contraindicated in patients with known hypersensitivity to this antibiotic.

Erythromycin is contraindicated in patients taking terfenadine or astemizole.

4.4 Special Warnings and Precautions for Use :

Erythromycin is principally excreted by the liver. Caution should be exercised when Erythromycin is administered to patients with impaired hepatic function.

Prolonged or repeated use of Erythromycin may result in an overgrowth of nonsusceptible bacteria or fungi. If superinfection occurs, Erythromycin should be discontinued and appropriate therapy instituted.

When indicated, incision and drainage or other surgical procedures should be performed in conjunction with antibiotic therapy.

4.5 Interaction with other medicinal products, and other forms of interaction:

Erythromycin use in patients who are receiving high doses of theophylline may be associated with an increase in serum theophylline levels and potential theophylline toxicity. In case of therophylline toxicity and/or elevated serum theophylline levels, the dose of theophylline should be reduced while the patient is receiving concomitant Erythromycin therapy.

Concomitant administration of Erythromycin and digoxin has been reported to result in elevated digoxin serum levels. There have been reports of increased anticoagulant effects when erythromycin and oral anticoagulants were used concomitantly.

Concurrent use of Erythromycin and ergotamine or dihydroergotamine has been associated in some patients with acute ergot toxicity characterized by severe peripheral vasospasm and dysesthesia.

Erythromycin has been reported to decrease the clearance of triazolam and thus may increase the pharmacologic effect of triazolam.

The use of erythromycin in patients concurrently taking drugs metabolized by the cytochrome P450 system may be associated with elevations in serum erythromycin

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with carbamazepine, cyclosporine, hexobarbital and phenytoin, Serum concentrations of drugs metabolized by the cytochrome P450 system should be monitored closely in patients concurrently receiving Erythromycin.

Troleandomycin significantly alters the metabolism of terfenadine when taken concomitantly; therefore, observe caution when Erythromycin and terfenadine are used concurrently.

Patients receiving concomitant lovastatin and erythromycin should be carefully monitored; cases of rhabdomyolysis have been reported in seriously ill patients.

4.6 Pregnancy and Lactation:

There is no evidence that the use of erythromycin is hazardous in pregnancy though it does cross the placental barrier. However, asymptomatic elevation of transaminases may be more common and appeared in 10% of pregnant women taking erythromycin compared with 2% on placebo.

4.7 Effects on ability to drive and use machines:

Patients experiencing visual disturbances, dizziness, vertigo, somnolence, or other central nervous system disturbances while taking Erythromycin should refrain from driving or using machines.

4.8 Undesirable effects:

The most frequent adverse effects of oral Erythromycin preparations are dose related. They include nausea, vomiting, abdominal pain, diarrhea and anorexia. Symptoms of hepatic dysfunction and/or abnormal liver function test results may occur. Pseudomembranous colitis has been rarely reported in association with erythromycin therapy.

Occasional case reports of cardiac arrhythmias such as ventricular tachycardia have been documented in patients receiving Erythromycin therapy. There have been isolated reports of other cardiovascular symptoms such as chest pain, dizziness, and palpitations; however, a cause and effect relationship has not been established.

Allergic reactions ranging from urticaria and mild skin eruptions to anaphylaxis have occurred.

There have been isolated reports of reversible hearing loss occurring chiefly in patients with renal insufficiency and patients receiving high doses of Erythromycin.

4.9 Overdose:

Signs and Symptoms-symptoms of oral overdose of Erythromycin estolate may include nausea, vomiting, epigastric distress and diarrhea. The severity of the

epigastric distress and the diarrhea are dose related. Reversible mild acute pancreatitis has been reported. Hearing loss, with or without tinnitus and vertigo, may occur, especially in patients with renal or hepatic insufficiency.

5. Pharmacological properties:

5.1 Pharmacodynamic properties:

Erythromycin is effective against Gram-positive organisms, which accumulate much more drug than Gram-negative organisms. It is particularly effective against streptococci. The organisms affected by erythromycin, and the minimum inhibitory concentration involved, are shown in the Concentration-effect active against Clostridium spp. and Propionibacterium acne. Nocardia spp. have variable sensitivity to the drug. Gram-negative organisms other than those in TABLE 1 have variable susceptibility with useful activity being reported against some Brucella strains, Flavobacterium, and Pasteurella. Among Gram-negative anaerobes Helicobacter pylori and most strains of campylobacter jejuni are sensitive. Other organisms usually sensitive to erythromycin include Actinomyces, chlamydia spirochetes such as Borrelia burgdorferi, and mycoplasmas including Mycoplasma pneumoniae. Some opportunistic mycobacteria, including M. scrofulaceum and M. avium and M.fortuitum, are usually not.

Its action is bacteriostatic or bactericidal depending on the organism and the concentrations achieved. Recommended doses range from 1 to 4 g daily depending on the severity of infection. Erythromycin resistance a as result of mutation is uncommon and unstabel. In staphylococci continuously exposed to subinhibitory concentrations it may extend to other macrolides as well. Constitutive resistance may also be generalized to include Iincosamides. The frequency of staphylococci resistance ranges from 5 to 46% in different countries. In general, the prevalence of resistant strains is closely associated with the prevalence of erythromycin in combination with other antibiotics are unpredictable. The synthesis of penicillinase is variably affected, resulting in synergy or antagonism with susceptible β-lactams. The listericidal effects of penicillins, rifampin, and gentamicin are antagonized. Erythromycin is synergistic with sulfonamides against Haemophilus influenzae.

5.2 Pharmacokinetic Properties:

Absorption

Orally administered Erythromycin is readily and reliably absorbed.

Distribution

Readily to most body fluids except cerebrospinal fluid (CSF); crosses the placenta, also.

Liver, bile, and spleen – Highest concentrations.

Pleural and ascitic fluid	–	Adequate concentrations.
Prostatic and seminal fluid	–	33% of plasma concentrations.
Cerebrospinal fluid (CSF)	–	2 to 13% of plasma concentrations.
Middle ear	–	Variable.
Fetal plasma	–	5 to 20% of maternal plasma concentrations.
Vol_D	=	0.72 liter per kg.

Protein binding

Base	–	High
Stearate	–	Very high

Metabolism

Hepatic (free drug); partially, to inactive metabolites; may accumulate in patients with severe hepatic disease.

Erythromycin is dissociated to free drug in the gastrointestinal tract.

Half-life

Normal renal function	–	1.4 to 2 hours.
Impaired renal function	–	4.8 to 6 hours.

Time to peak serum concentration

1 to 4 hours (oral)

Excretion

Hepatic; primarily by hepatic concentration and excretion into the bile.

Renal, by glomerular filtration; 2 to 5% excreted unchanged following oral administration; 10 to 15% excreted unchanged following intravenous administration.

Fecal; small amounts

Breast milk; may exceed maternal serum concentrations.

In dialysis-Dialysis does not remove significant amounts of Erythromycins from the blood.

5.3 Pre-clinical safety data:

There is no evidence for embryotoxicity in the rat or rabbit though no data for the estolate are available. Mutagenicity and carcinogenicity test have not been carried out.

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In dosage, erythromycin at plasma concentrations of over 20 mg.1 prolonged the cardiac actions potential. At higher concentrations (100-200 mg.1-1) early after depolarizations, which may herald arrhythmias, were observed.

6. Pharmaceutical particulars:

6.1 List of Excipients:

Sucrose	BP
Citric Acid	BP
Sodium carboxy methyl cellulose	BP
Colour erythrosine supra	Inhouse
Colloidal anhydrous silica	BP
Purified talc	BP
Essence pineapple powder	Inhouse

6.2 Incompatibilities:

None Reported

6.3 Shelf-Life:

36 months from the date of manufacture.

6.4 Special Precautions for Storage:

Store in a cool, dry and dark place. Protect from light.

6.5 Nature and Contents of Container:

100 ml amber coloured pet bottle with PP cap packed in a unit printed duplex board carton along with its package insert.

6.6 Special precautions for disposal:

None reported.

7. Registrant:

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8. Manufacturer:

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9. Date of revision of the text: