Brand Name : AGOMYCIN SUSPENSION **Generic Name :** Erythromycin Estolate Oral Suspension USP		2021
Module 1 **1.5**	Administrative Information and Product Information Product Information	**Confidential**

1.5 PRODUCT INFORMATION

1.5.1 Prescribing information (Summary of products characteristics)

SUMMARY PRODUCT CHARACTERISTICS

1. Name of drug product:

AGOMYCIN SUSPENSION (Erythromycin Estolate Oral Suspension USP)

2. Qualitative and Quantitative Composition:

Each 5 ml contains: Erythromycin Estolate USP equivalent to Erythromycin (125 mg)

3. Pharmaceutical form:

Light orange coloured thick, uniform suspension on shaking.

4. Clinical particulars:

ERYTHROMYCIN ESTOLATE

4.1 Therapeutic indications

Erythromycin Estolate is used for upper respiratory tract infection. Acute pneumonia. Vaginitis due to chlamydia trachomatis, Impetigo. Wound and burn infections. Infected eczema. Acne vulgaris. Sycosis vulgaris.

4.2 Posology and method of administration

Posology

250 mg. 6 hrly by oral, the dose may be doubled for severe infections.
Gonorrhoea : 500 mg. 6 hrly for 6-7 days
Syphillis : 1 g 6 hrly. For 10-15 days (30 days in late Syphillis)
Prophylaxis against streptococci : 250 mg. 12 hrly.

Children : 7.5-25 mg/kg. body wt. 12 hrly.
The dose can be doubled if required in severe cases or as directed by the physician.

This medication may be taken with food or milk if stomach upset occurs. Shake liquid well before using. Antibiotics work best when the amount of medicine in your body is kept at a constant level. Do this by taking the medication at evenly spaced intervals throughout the day and night. Continue to take this medication until the full prescribed amount is finished even if symptoms disappear after a few days. Stopping the medication too early may allow bacteria to continue to grow resulting in a relapse of the infection.

Method of administration

For oral administration only

4.3 Contraindications

Carbamazepine, Cyclosporine, Theophylline,certain Benzodiazepines (e.g.,midazolam, triazo lam), warfarin, felodipine (a calciumchannelblocker), Cisapride, Corticosteroids (e.g., prednis one), Digoxin,Ergotamine containing medications, Sildenafil, certain live vaccines, disopyramide, Phenytoin, all other antibiotics, certain "statin" drugs used to treat high cholesterol (e.g., atorvastatin, lovastatin, simvastatin).

Other drugs besides erythromycin which may affect the heart rhythm (QTc prolongation in the EKG)include dofetilide, pimozide, quinidine, sotalol, procainamide,and sparfloxacin amo ng others. QTc prolongation can infrequently result in serious, rarely fatal, irregular heartbeats. Consult your doctor or pharmacist for details. Ask for instructions about whether you need to stop any other QTc-prolonging drugs you may be using in order to minimize the risk of this effect. This drug may interfere with the effectiveness of birth control pills. Discuss using other methods of birth control with your doctor. Do not start or stop any medicine without doctor or pharmacist approval.

4.4 Special warnings and precautions for use

Erythromycin estolate may cause liver problems. This medication must not be used if you already have liver problems. Stop using this drug and notify your doctor immediately if you develop: nausea, vomiting, dark urine, yellowing of the eyes or skin, fever, severe stomach/abdominal pain, unusual fatigue. Tell your doctor your medical history, especially of: liver disease/jaundice, allergies (especially drug allergies). Use of this medication for prolonged or repeated periods may result in a secondary infection (e.g., oral, bladder or vaginal yeast infection) Caution is advised when this drug is used in infants. Though very unlikely to happen, a stomach problem called IHPS (infantile hypertrophic pyloric stenosis) has been noted. Contact your child's doctor immediately if the child has persistent vomiting or increased irritability. This drug should be used only if clearly needed during pregnancy. Small amounts of drug do appear in breast milk, so consult your doctor before breast-feeding.

4.5 Interaction with other medicinal products and other forms of interaction

Many potentiate action of carbamazepine, cyclosporine, theophylline warfarin. Increases serum digoxin levels, reduces therapeutic effect of penicillins terfenidine and asthemizole increase the risk the adverse effect on the heart.

4.6 Pregnancy and Lactation

Pregnancy: Safe
Lactation : Contraindicated

4.7 Undesirable effects

May cause stomach upset, diarrhea, loss of appetite, nausea, vomiting and stomach cramps the first few days as your body adjusts to the medication. If these symptoms persist or become severe, inform your doctor. Notify your doctor if any of the following rare side effects occur: dark urine, pale stools, severe stomach pain, unusual tiredness or weakness, yellowing of the eyes or skin. In the unlikely event you have an allergic reaction to this drug, seek medical attention immediately. Symptoms of an allergic reaction include: rash, itching, swelling, dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

5. Pharmacological properties:

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Macrolide Antibiotic

ATC code : J01FA01

Mechanism of action : Erythromycin displays bacteriostatic activity or inhibits growth of bacteria, especially at higher concentrations. By binding to the 50s subunit of the bacterial rRNA complex, protein synthesis and subsequent structure and function processes critical for life or replication are inhibited. Erythromycin interferes with aminoacyl translocation, preventing the transfer of the tRNA bound at the A site of the rRNA complex to the P site of the rRNA complex. Without this translocation, the A site remains occupied, thus the addition of an incoming tRNA and its attached amino acid to the nascent polypeptide chain is inhibited. This interferes with the production of functionally useful proteins, which is the basis of this antimicrobial action.

Erythromycin increases gut motility by binding to Motillin receptor, thus it is a Motillin receptor agonist in addition to its antimicrobial properties.

5.2 Pharmacokinetic properties

Absorption, Distribution, Elimination

Erythromycin is easily inactivated by gastric acid; therefore, all orally administered formulations are given as either enteric-coated or more-stable salts or esters, such as erythromycin ethylsuccinate. Erythromycin is very rapidly absorbed, and diffuses into most tissues and phagocytes. Due to the high concentration in phagocytes, erythromycin is actively transported to the site of infection, where, during active phagocytosis, large concentrations of erythromycin are released.

Metabolism

Most of erythromycin is metabolised by demethylation in the liver by the hepatic enzyme CYP3A4. Its main elimination route is in the bile with little renal excretion, 2%-15% unchanged drug. Erythromycin's elimination half-life ranges between 1.5 and 2.0 hours and is between 5 and 6 hours in patients with end-stage renal disease. Erythromycin levels peak in the serum 4 hours after dosing; ethylsuccinate peaks 0.5-2.5 hours after dosing, but can be delayed if digested with food.

Erythromycin crosses the placenta and enters breast milk. The American Association of Pediatrics determined erythromycin is safe to take while breastfeeding. Absorption in pregnant patients has been shown to be variable, frequently resulting in levels lower than in nonpregnant patients.

6. Pharmaceutical particulars:

6.1 List of Excipients:

Erythromycin as Erythromycin Estolate USP 31	USP
Sorbitol 70 %	BP
Methyl Paraben Sodium	BP
Propyl Paraben Sodium	BP
Colloidal Silicon Dioxide	BP
Sodium Benzoate	BP
Sucrose	BP
Propylene Glycol	BP
Xanthane Gum	BP
Glycerine	BP
Citric Acid Monohydrate	BP
Sodium Citrate	BP
Colour Sunset Yellow Supra	INH
Oil Orange Sweet Excellent	INH

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:
Pet amber colour 100 ml bottle

6.6 Special precautions for disposal:
None reported.

7. Registrant:

AGOG PHARMA LTD.
Plot No. 33, Sector II,
The Vasai Taluka Industrial
Co-Op. Estate Ltd., Gauraipada,
Vasai (E), Dist. Thane, India.

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9. Date of revision of the text: