Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

Brand Name : **CLARITHROMYCIN TABLETS** **Generic Name** : Clarithromycin Tablets BP 250 mg		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:

PROPAN TABLETS (Clarithromycin Tablets BP 250 mg)

2. Qualitative and Quantitative Composition:

Each film coated tablet contains: Clarithromycin Tablets BP 250 mg

3. Pharmaceutical form:

Yellow coloured, circular, biconvex, film coated tablet.

4. Clinical particulars:

4.1 Therapeutic Indications:

Clarithromycin is a prescription drug used to treat a wide variety of bacterial infections. This medication can also be used in combination with anti-ulcer medications to treat certain types of stomach ulcers. It may also be used to prevent certain bacterial infections. Clarithromycin is known as a macrolide antibiotic. It works by stopping the growth of bacteria.

4.2 Posology and Method of Administration:

Clarithromycin is a prescription drug used to treat a wide variety of bacterial infections.

Dosage of Clarithromycin:

Adult and pediatric dosages:

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Oral suspension

- 125 mg/5 ml
- 250 mg/5 ml

Tablet

- 250 mg
- 500 mg

Tablet, extended release (adult dosage only, safety and efficacy not established in children)

- 500 mg

Dosing Considerations – Should be Given as Follows:

Acute Exacerbation of Chronic Bronchitis

Adults:

- 250-500 mg orally every 12 hours for 7-14 days
- Extended release: 1,000 mg orally once daily for 7 days

Pediatric:

- 15 mg/kg/day orally divided every 12 hours for 10 days

Acute Maxillary Sinusitis

Adult Dosage:

- 500 mg orally every 12 hours for 14 days
- Extended release: 1,000 mg orally once daily for 14 days

Pediatric Dosage:

- 15 mg/kg/day orally divided every 12 hours for 10 days

Mycobacterial Infection

Adult Dosage:

- 500 mg orally every 12 hours for 7-14 days
- Use with antimycobacterial drugs such as rifampin and ethambutol

Pediatric Dosage:

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Prophylaxis and treatment

- 7.5 mg/kg orally divided every 12 hours; individual dose not to exceed 500 mg
- Children under 20 months: safety of clarithromycin for mycobacterium avium complex not studied

Peptic Ulcer Disease

Adult Dosage:

- 500 mg orally every 8-12 hours for 10-14 days
- Administer as part of 2- or 3-drug combination regimen with bismuth subsalicylate, amoxicillin, H2 receptor antagonist, or proton pump inhibitor

Pharyngitis, Tonsillitis

- 250 mg orally every 12 hours for 10 days

Streptococcal Pharyngitis

Pediatric Dosage:

- 7 mg/kg orally every 12 hours for 10 days; individual dose not to exceed 500 mg

Community-Acquired Pneumonia

Adult Dosage:

- 250 mg orally every 12 hours for 7-14 days
- Extended release: 1,000 mg orally once daily for 7 days

Pediatric Dosage:

- 15 mg/kg/day orally divided every 12 hours for 10 days

Pertussis (off-label)

Adult dosage:

- 500 mg orally twice daily for 7 days

Pediatric Dosage:

- Infants under 1 month: safety and efficacy not established
- Infants 1-6 months: 7.5 mg/kg/dose orally every 12 hours for 7 days
- Infants over 6 months: 7.5 mg/kg/dose orally every 12 hours for 7 days

Skin/Skin Suture Infection

Adult Dosage:

- 250 mg orally for every 12 hours for 7-14 days

Pediatric Dosage:

- 15 mg/kg/day orally divided every 12 hours for 10 days

Endocarditis

Adult Dosage:

Prophylaxis

- 500 mg orally 30-60 minutes before surgical procedure

Pediatric Dosage:

Prophylaxis

- 15 mg/kg orally 30-60 minutes before surgical procedure; individual dose not to exceed 500 mg

Dosing Modifications

- Renal impairment (creatinine clearance under 30 ml/min): reduce normal dosage by 50%
- In combination with atazanavir: creatinine clearance 30-60 ml/min decrease dose by 50%; creatinine clearance under 30 ml/min, decrease dose by 75%

Method of administration : Oral.

4.3 Contraindications:

- Documented hypersensitivity
- Coadministration with pimozide, cisapride, ergotamine, and dihydroergotamine
- History of cholestatic jaundice or hepatic dysfunction associated with previous use of clarithromycin
- Coadministration with colchicine in patients with kidney (renal) or liver (hepatic) impairment
- Coadministration with HMG-CoA reductase inhibitors (statins) that are extensively metabolized by CYP3A4 (lovastatin, simvastatin), due to the increased risk of muscle disease (myopathy), including destruction of muscle tissue (rhabdomyolysis)

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4.4 Pregnancy and Lactation:

- Use clarithromycin during pregnancy with caution if benefits outweigh risks. Animal studies show risk and human studies are not available, or neither animal nor human studies were done
- Clarithromycin is excreted in breast milk; use with caution if breastfeeding. Consult your doctor

4.5 Warnings

- Discontinue clarithromycin immediately if signs and symptoms of hepatitis occur (loss of appetite, jaundice, dark urine, pruritus, or tender abdomen)
- This medication contains clarithromycin. Do not take Biaxin or Biaxin XL if you are allergic to clarithromycin or any ingredients contained in this drug
- In case of overdose, get medical help or contact a Poison Control Center immediately

5. Pharmacological properties:

5.1 Pharmacokinetic Properties:

Clarithromycin is a prescription drug used to treat a wide variety of bacterial infections. This medication can also be used in combination with anti-ulcer medications to treat certain types of stomach ulcers. It may also be used to prevent certain bacterial infections. Clarithromycin is known as a macrolide antibiotic. It works by stopping the growth of bacteria.

6. Pharmaceutical particulars:

6.1 List of Excipients:

Microcrystalline cellulose	BP
Maize starch	BP
Iso Propyl alcohol	BP
Poly Vinyl pyrrilidone K-30	BP
Purified talc	BP
Magnesium stearate	BP
Cross Carmellose Sodium	BP
Colloidal silicon dioxide	BP
Stearic Acid	BP
Sodium Starch Glycolate	BP
Methylene Dichloride	BP
Iso Propyl alcohol	BP
Colour Instacoat (IC-U-6198) Yellow	INH

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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:
14 tablets packed in one Blister. Such 1 blister packed in unit printed duplex board carton along with its package insert. Such cartons packed in export worthy shipper.

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.

8. Manufacturer:
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Vasai (E), Dist. Thane,
India.

9. Date of revision of the text :