





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

	CLARITHROMYCIN TABLETSClarithromycin Tablets BP 250 mg	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:

PROPAN TABLETS (Clarithromycin Tablets BP 250 mg)

2. **Qualitative and Quantitative Composition:**

Each film coated tablet contains: Clarithromycin Tablets BP 250 mg

Pharmaceutical form: 3.

Yellow coloured, circular, biconvex, film coated tablet.

4. **Clinical particulars:**

4.1 **Therapeutic Indications:**

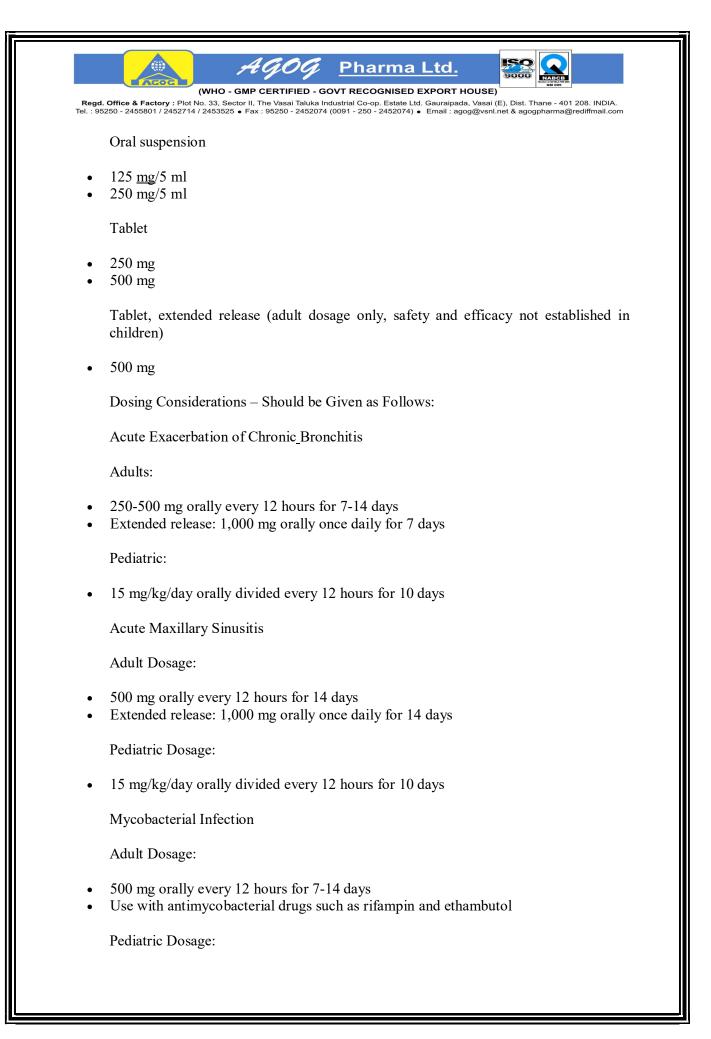
Clarithromycin is a prescription drug used to treat а wide varietv of bacterial infections. This medication can also be used in combination with antiulcer medications to treat certain types of stomach ulcers. It may also be used to prevent certain bacterial infections. Clarithromycin is known as a macrolide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

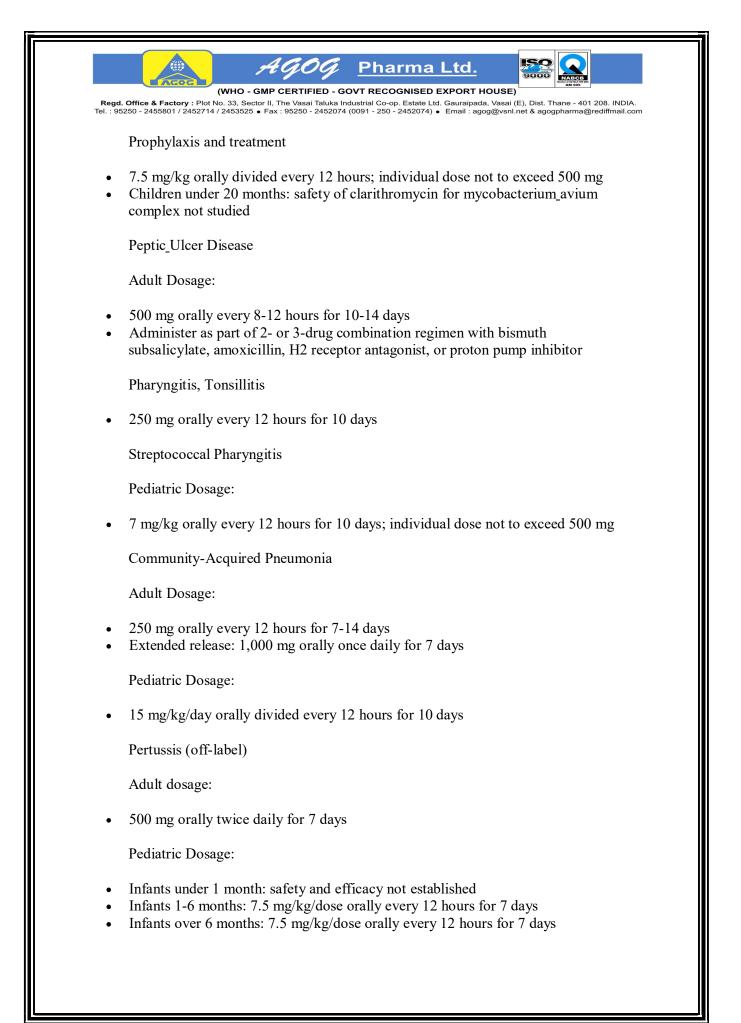
4.2 **Posology and Method of Administration:**

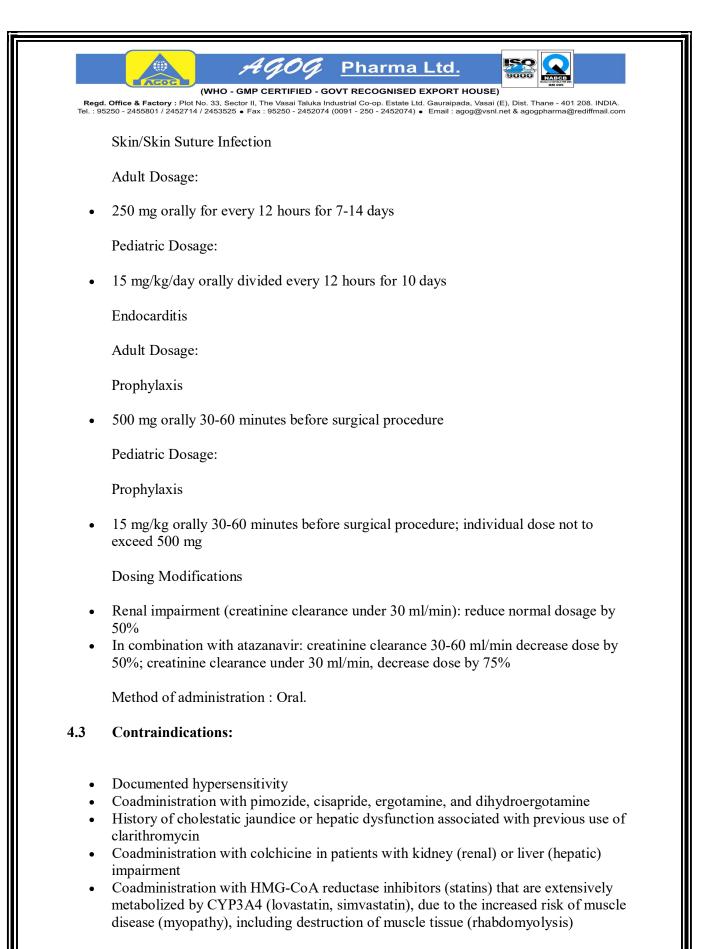
Clarithromycin is a prescription drug used wide variety to treat а of bacterial infections.

Dosage of Clarithromycin:

Adult and pediatric dosages:









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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 wide variety а of bacterial infections. This medication can also be used in combination with antiulcer 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:** AGOG PHARMA LTD. Plot No. 33, Sector II,

The Vasai Taluka Industrial Co-Op. Estate Ltd., Gauraipada, Vasai (E), Dist. Thane, India.

9. Date of revision of the text :