SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PRODUCT

Azimax-250 Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS	**PER TABLET (MG)**
Azithromycin dihydrate	262.05 (equivalent to Azithromycin 250 mg)

For excipients, see 6.1

3. PHARMACEUTICAL FORM

Tablet

4. CLINICAL PARTICULARS

Therapeutic indication

Azithromycin is indicated for the treatment of the following infections when known or likely to be due to one or more susceptible microorganisms:

- Bronchitis
- Community-acquired pneumonia
- Sinusitis
- Pharyngitis/ tonsillitis
- Otitis media
- Skin and soft tissue infections
- Uncomplicated genital infections due to Chlamydia trachomatis

4.2 Posology and Method of administration

Oral.

Azimax-250 Tablet should be given as a single daily dose. It can be taken with or without food.

Children over 45 kg body weight and Adults, including elderly patients: The total dose of azithromycin is 1500 mg which should be given over three days (500 mg once daily). In uncomplicated genital infections due to Chlamydia trachomatis, the dose is 1000 mg as a single oral dose.

In children under 45 kg body weight: Azimax-250 tablet is not suitable for children under 45 kg.

Renal impairment:

No dose adjustment is necessary in patients with mild to moderate renal impairment (GFR 10 – 80 ml/min). Caution should be exercised when azithromycin is administered to patients with severe renal impairment (GFR < 10 ml/min)

Hepatic impairment:
Since azithromycin is metabolized in the liver and excreted in the bile, the drug should not be given to patients suffering from severe liver disease. No studies have been conducted regarding treatment of such patients with azithromycin.

Contraindication

- This medication should not be used when the patient is hypersensitive to azithromycin or other macrolides.
- Risk-benefit should be considered when hepatic function impairment exists because biliary excretion is the major route of elimination.

Warnings and precautions

- As with erythromycin and other macrolides, rare serious allergic reactions, including angiodema and anaphylaxis (rarely fatal), have been reported. Some of these reactions with azithromycin have resulted in recurrent symptoms and required a longer period of observation and treatment.
- Since liver is the principal route of elimination for azithromycin, the use of azithromycin should be undertaken with caution in patients with significant hepatic disease.
- In patients receiving ergot derivatives, ergotism has been precipitated by coadministration of some macrolide antibiotics. There are no data concerning the possibility of an interaction between ergot and azithromycin. However, because of the theoretical possibility of ergotism, azithromycin and ergot derivatives should not be coadministered.
- As with any antibiotic preparation, observation for signs of superinfection with non-susceptible organisms, including fungi is recommended.
- In patients with severe renal impairment (GFR<10ml/min) a 33% increase in systemic exposure to azithromycin was observed.
- Prolonged cardiac repolarization and QT interval, imparting a risk of developing cardiac arrhythmia and torsades de pointes, have been seen in treatment with other macrolides. A similar effect with azithromycin cannot be completely ruled out in patients at increased risk for prolonged cardiac repolarization.

Drug Interactions

- Concurrent use with aluminium and magnesium containing antacids will decrease the peak serum concentration in clinical trials; azithromycin should be administered at least 1 hour before or 2 hours after antacids.
- Concurrent use with theophylline has been associated with increased in the serum concentrations of theophylline.
- Concurrent use with warfarin has been associated with increased anticoagulant effects.
- Concurrent use with macrolide antibiotics has been associated with increased serum concentrations of digoxin, carbamazepine, terfenadine, cyclosporine, hexobarbital and phenytoin.
- Concurrent use with ergotamine or dihydroergotamine has been associated with acute ergot toxicity characterized by severe peripheral vasospasm and dysesthesia.
- Concurrent use with triazolam has been associated with a decrease in the clearance of triazolam, which may increase its effects.

4.6 Pregnancy and lactation

Use during pregnancy

Adequate and well-controlled studies in humans have not been done; azithromycin should be used during pregnancy only if adequate alternatives are not available.

Use during lactation

It is not known whether azithromycin is excreted in human milk, caution should be exercised when azithromycin is administered to a nursing woman.

4.7 Effects on ability to drive and use machines

NOT APPLICABLE

4.8 Main Side/ Adverse Effects

Gastrointestinal disturbances are the most frequent adverse effect but are usually mild. Transient elevations of liver enzyme values have been reported and, rarely, cholestatic jaundice. Rashes, headache and dizziness may occur. Transient alterations in neutrophil counts have been seen in patients receiving azithromycin.

4.9 Overdose

Clinical effects of overdose: Adverse events experienced in higher than recommended doses were similar to those seen at normal doses.

Treatment of overdose: In the event of overdosage, general symptomatic and supportive measures are indicated as required.

5. PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Azithromycin is an azalide antibiotic, part of the macrolide family of antibacterials. It binds to the 50S ribosomal subunit of the 70S ribosome of susceptible organisms, thereby inhibiting RNA-dependent protein synthesis.

Pharmacokinetic properties

Following oral administration, azithromycin is rapidly absorbed and widely distributed throughout the body; bioavailability is approximately 37%. The time taken to peak plasma levels is 2-3 hours. The plasma terminal elimination half-life closely reflects the tissue depletion half-life of 2 to 4 days. Protein binding varies with concentration: very low to moderate; approximately 7% at 1 µg/mL, to 50% at 0.02 to 0.05µg/mL.

Azithromcyin concentrates intracellularly, resulting in tissue concentrations 10 to 100 times higher than those found in plasma or serum. Azithromcyin is highly concentrated in phagocytes and fibroblasts. Biotransformation occurs in liver, in which approximately 35% metabolized by demethylation. Over 50% of the dose is eliminated through biliary excretion as unchanged drug.

Preclinical Safety Data

NOT APPLICABLE

6. PHARMACEUTICAL PARTICULARS

List of excipients

Croscarmellose Sodium
Sodium Lauryl Sulfate
Magnesium Stearate
Pregelatinised Starch
Dicalcium Phosphate Dihydrate
Talc
Propylene Glycol
Titanium Dioxide
Hydroxypropyl Methylcellulose
Isopropyl Alcohol
Purified water

Incompatibilities
NOT APPLICABLE

Shelf life
3 years from date of manufacture

Special precaution for storage
Store below 30˚C. Protect from moisture.

Nature and contents of container

Blister Pack

Type	:	Push-through blister pack; the package consists of a white opaque themoformable plastic material and a heat-sealable lacquered backing material.
Material	:	Thermoformable plastic material : Polyvinyl Chloride (PVC) Backing Material : Aluminium Foil

Instructions for use and handling <and disposal>
NOT APPLICABLE

7. MARKETING AUTHORISATION HOLDER

Name	:	HOVID Bhd.
Address	:	121, Jalan Tunku Abdul Rahman, (Jalan Kuala Kangsar) 30010 Ipoh, Perak, Malaysia

Manufacturer Name:

Manufacturer	:	Hovid Bhd.
Address	:	Lot 56442, 71/2 Miles , Jalan Ipoh/Chemor, 31200 Ipoh, Perak, Malaysia

8. NUMBER (S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS
HOV/MAL/099

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
2017

10. DATE OF REVISION OF THE TEXT
Dec 2020