For the use of only a Registered Medical Practitioner or a Hospital or a Laboratory

Not to be sold by retail without the prescription of a Registered Medical Practitioner

Prescribing Information

1. Generic Name

Azithromycin Oral Suspension IP
(Brand Name: AZIBEST® 100 mg / 200 mg Suspension)

2. Qualitative and Quantitative Composition

Each 5 ml contains:
Azithromycin IP as Dihydrate equivalent to Anhydrous Azithromycin ….. 100 mg / 200 mg.
Flavoured syrup base …… q.s.
Colour: Sunset Yellow FCF

3. Dosage Form and Strength

Dosage Form: Suspension.
Dosage Strength: Azithromycin 100 mg and 200 mg per 5 ml of suspension.

4. Clinical Particulars

4.1 Therapeutic Indication

AZIBEST Suspension is indicated in children above 6 months of age for the treatment of following infections when known or likely to be caused by susceptible strains of the microorganisms:

- Sinusitis.
- Otitis media.
- Community-acquired pneumonia.
- Pharyngitis/tonsillitis.
- Typhoid fever.

4.2Posology and Method of Administration

For oral administration in children above 6 months of age and weight below 45 kg (for paediatric use). Children over 45 kg of body weight should be given the adult dose.

Dosage Based on Body Weight

Usual Dose: 10 mg/kg once daily for 3 days. Alternatively, azithromycin can also be administered as 10 mg/kg as a single dose on day 1, followed by 5 mg/kg once a day for next 4 days (5-day regimen).
Pharyngitis/Tonsillitis: 12 mg/kg once daily for 5 days. Eradication of the bacteria is more significant at a daily dose of 20 mg/kg body weight.
Typhoid Fever: 20 mg/kg once a day for 5 to 7 days.

In children, for any indication, maximum daily dose of azithromycin should not exceed 500 mg.

Dosage Based on Age Group

Table: Dosage Recommendations for AZIBEST 100 mg / 5 ml Suspension

Age Group	**Usual Dosage** (10 mg/kg/day) For 3 Days	**Dosage in Typhoid Fever** (20 mg/kg/day) For 5 to 7 Days
6 to 12 Months	4 to 5 ml OD	8 to 10 ml OD
1 to 3 Years	5 to 7 ml OD	10 to 14 ml OD

Table: Dosage Recommendations for AZIBEST 200 mg / 5 ml Suspension

Age Group	**Usual Dosage** (10 mg/kg/day) For 3 Days	**Dosage in Typhoid Fever** (20 mg/kg/day) For 5 to 7 Days
6 to 12 Months	2 to 2.5 ml OD	4 to 5 ml OD
1 to 3 Years	2.5 to 3.5 ml OD	5 to 7 ml OD
4 to 6 Years	4 to 5 ml OD	8 to 10 ml OD
7 to 9 Years	5 to 6 ml OD	10 to 12 ml OD
10 to 12 Years	8 to 10 ml OD	16 to 20 ml OD

AZIBEST Suspension can be administered with or without food. Shake well before use.
Or, as prescribed by the physician.

4.3Contraindications

AZIBEST Suspension is contraindicated in the following:

- In patients with known hypersensitivity to azithromycin or to any other macrolide/ketolide class of drug or to any component of the formulation.
- In patients with a history of cholestatic jaundice or hepatic dysfunction associated with prior use of azithromycin.

4.4Special Warnings and Precautions for Use

Hypersensitivity: Serious allergic reactions, including angioedema, anaphylaxis, and dermatologic reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) have been reported rarely in patients on azithromycin therapy. Fatalities have been reported. Despite initially successful symptomatic treatment of the allergic symptoms, when symptomatic therapy was discontinued, the allergic symptoms recurred soon thereafter in some patients without further azithromycin exposure. These patients required prolonged periods of observation and symptomatic treatment. If an allergic reaction occurs, the drug should be discontinued and appropriate

therapy should be instituted. Allergic symptoms may reappear when symptomatic therapy has been discontinued.

Hepatotoxicity: Abnormal liver function, hepatitis, cholestatic jaundice, hepatic necrosis, and hepatic failure have been reported, some of which have resulted in death. Discontinue azithromycin immediately if signs and symptoms of hepatitis occur.

QT Prolongation / Cardiovascular Events: Prolonged cardiac repolarization and QT interval, imparting a risk of developing cardiac arrhythmia and torsades de pointes, have been seen during treatment with other macrolides. A similar effect with azithromycin cannot be completely ruled out in patients at increased risk for prolonged cardiac repolarization. Therefore as the following situations may lead to an increased risk for ventricular arrhythmias (including torsade de pointes) which can lead to cardiac arrest, azithromycin should be used with caution in patients (especially women and elderly patients) with ongoing pro-arrhythmic conditions such as:

- Patients with congenital or documented QT prolongation.
- Patients currently receiving treatment with other active substance known to prolong QT interval such as antiarrhythmics of Class IA (quinidine and procainamide) and Class III (dofetilide, amiodarone and sotalol), cisapride, and terfenadine.
- Patients with electrolyte disturbance, particularly in case of hypokalaemia and hypomagnesemia.
- Patients with clinically relevant bradycardia, cardiac arrhythmia or severe cardiac insufficiency.

Epidemiological studies investigating the risk of adverse cardiovascular outcomes with macrolides have shown variable results. Some observational studies have identified a rare short term risk of arrhythmia, myocardial infarction and cardiovascular mortality associated with macrolides including azithromycin. Consideration of these findings should be balanced with treatment benefits when prescribing azithromycin.

***Clostridium Difficile*-Associated Diarrhea (CDAD):** *Clostridium difficile*-associated diarrhea has been reported with use of nearly all antibacterial agents, including azithromycin, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon, leading to overgrowth of *C. difficile. Clostridium difficile* produces toxins A and B which contribute to the development of CDAD. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

Exacerbation of Myasthenia Gravis: Exacerbation of symptoms of myasthenia gravis and new onset of myasthenic syndrome has been reported in patients receiving azithromycin therapy.

Use in Sexually Transmitted Infections: Azithromycin, at the recommended dose, should not be relied upon to treat syphilis. Antibacterial agents used to treat non-gonococcal urethritis may mask or delay the symptoms of incubating syphilis. All patients with sexually transmitted

urethritis or cervicitis should have appropriate testing at the time of diagnosis; appropriate antibacterial therapy and follow-up tests should be initiated if infection is confirmed.

Antibiotic Resistance: Prescribing azithromycin in the absence of a proven bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Intolerance to Carbohydrates/Sugar: Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take azithromycin.

Ergot Derivatives: In patients receiving ergot derivatives, ergotism has been precipitated by co-administration 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 co-administrated.

Streptococcal Infections (Pharyngitis/Tonsillitis): Penicillin is usually the first choice for treatment of pharyngitis/tonsillitis due to *Streptococcus pyogenes.* Azithromycin is also effective against streptococcus, but can be used as an alternative to first-line therapy in individuals who cannot use first-line therapy.

4.5Drug Interactions

Drugs Metabolized by Cytochrome P450 Enzyme: Azithromycin does not interact significantly with the hepatic cytochrome P450 system. It is not believed to undergo the pharmacokinetic drug interactions as seen with erythromycin and other macrolides. Hepatic cytochrome P450 induction or inactivation via cytochrome-metabolite complex does not occur with azithromycin. Thus, azithromycin has no drug interactions with cytochrome P450 inducer or inhibitor drugs.

Ciclosporin: Caution should be exercised while concurrent administration of azithromycin with ciclosporin, as C_{max} and AUC of ciclosporin was found to be elevated. If co-administration of these drugs is necessary, ciclosporin levels should be monitored and the dose adjusted accordingly.

Nelfinavir: Co-administration of nelfinavir at steady-state with a single oral dose of azithromycin resulted in increased azithromycin serum concentrations. Although a dose adjustment of azithromycin is not recommended when administered in combination with nelfinavir, close monitoring for known adverse reactions of azithromycin, such as liver enzyme abnormalities and hearing impairment is warranted.

Warfarin: Spontaneous post-approval reports suggest that concomitant administration of azithromycin may potentiate the effects of oral anticoagulants such as warfarin, although the prothrombin time was not affected in the dedicated drug interaction study with azithromycin and warfarin. Prothrombin times should be carefully monitored while patients are receiving azithromycin and oral anticoagulants concomitantly.

Antacids: In a pharmacokinetic study investigating the effects of simultaneous administration of antacid with azithromycin, no effect on overall bioavailability was seen, although peak serum concentrations were reduced by approximately 24%. In patients receiving both, azithromycin and antacids, the drugs should not be taken simultaneously.

Digoxin and Colchicine: Concomitant administration of macrolide antibiotics, including azithromycin, with P-glycoprotein substrates such as digoxin and colchicine, has been reported to result in increased serum levels of the P-glycoprotein substrate. Therefore, if azithromycin and P-glycoprotein substrates such as digoxin are administered concomitantly, the possibility of elevated serum digoxin concentrations should be considered. Clinical monitoring, and possibly serum digoxin levels, during treatment with azithromycin and after its discontinuation are necessary.

Ergot Derivatives: Due to the theoretical possibility of ergotism, the concurrent use of azithromycin with ergot derivatives is not recommended.

4.6Use in Special Populations

Pregnant Women

Pregnancy Category B. In animal studies, no evidence of harm to the fetus due to azithromycin was found. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, azithromycin should be used during pregnancy only if clearly needed.

Lactating Women

Azithromycin has been reported to be excreted in human breast milk in small amounts. Thus, caution should be exercised when azithromycin is administered to a nursing woman. Generally, azithromycin should not be used unless the physician feels that the potential benefits justify the possible risks to the infant.

Paediatric Patients

Safety and effectiveness of azithromycin has not been established in infants below 6 months old. AZIBEST Suspension can be administered in children above 6 months of age. For dosage, please refer ‘Posology and Method of Administration’ section.

Geriatric Patients

Elderly patients may be given the same dose as recommended for adults. No overall differences in safety or effectiveness were observed between elderly and younger subjects, and other reported clinical experience has not identified differences in response between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Since elderly patients can be patients with ongoing proarrhythmic conditions, a particular caution is recommended due to the risk of developing cardiac arrhythmia and torsades de pointes.

Renal Impairment Patients

Dose adjustment is not required in patients with mild to moderate renal impairment (glomerular filtration rate - GFR 10 to 80 ml/min). Caution should be exercised when azithromycin is administered to patients with severe renal impairment (GFR < 10 ml/min).

Hepatic Impairment Patients

Since azithromycin is metabolised 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.

4.7Effect on Ability to Drive and Use Machines

There is no evidence to suggest that azithromycin may have an effect on a patient's ability to drive or operate machinery. Adverse effects such as visual impairment and blurred vision may have an effect on a patient's ability to drive or operate machinery. If affected, patient should not drive a vehicle or operating machines.

4.8Undesirable Effects

Clinical Trials Experience

The most common treatment-related adverse reactions in adult patients receiving multiple-dose regimens of azithromycin were related to the gastrointestinal system with diarrhea/loose stools, nausea, dyspepsia, and abdominal pain being the most frequently reported.

Rare adverse reactions included the following:

Allergic: Rash, pruritus, photosensitivity, angioedema.

Cardiovascular: Palpitations, chest pain.

Gastrointestinal: Dyspepsia, flatulence, vomiting, melena, cholestatic jaundice.

General: Fatigue.

Genitourinary: Monilia, vaginitis, nephritis.

Nervous System: Dizziness, headache, vertigo, somnolence.

Post-Marketing Experience

The following adverse reactions have been identified during post-approval use of azithromycin. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Adverse reactions reported with azithromycin during the post-marketing period in adult and/or paediatric patients include:

Allergic: Arthralgia, edema, urticaria, angioedema.

Cardiovascular: Arrhythmias including ventricular tachycardia and hypotension. QT prolongation and torsades de pointes have also been reported rarely.

Gastrointestinal: Anorexia, constipation, dyspepsia, flatulence, vomiting/diarrhea, pseudomembranous colitis, pancreatitis, oral candidiasis, pyloric stenosis, tongue discoloration.

General: Asthenia, paresthesia, fatigue, malaise, anaphylaxis.

Genitourinary: Interstitial nephritis, acute renal failure, vaginitis.

Hematopoietic: Thrombocytopenia.

Liver/Biliary: Abnormal liver function, hepatitis, cholestatic jaundice, hepatic necrosis, hepatic failure.

Nervous System: Convulsions, dizziness/vertigo, headache, somnolence, hyperactivity, nervousness, agitation, syncope.

Psychiatric: Aggressive reaction, anxiety.

Skin/Appendages: Pruritus, erythema multiforme, Stevens-Johnson Syndrome, toxic epidermal necrolysis, DRESS, Acute Generalized Exanthematous Pustulosis (AGEP).
Special Senses: Hearing disturbances including hearing loss, deafness and/or tinnitus; taste/smell perversion and/or loss.

Laboratory Abnormalities
Significant abnormalities (irrespective of drug relationship) occurring during the clinical trials were reported as follows:

- **Incidence 1 to 2%:** Elevated levels of serum creatine phosphokinase, potassium, alanine aminotransferase (ALT), gamma-glutamyl transferase (GGT), and aspartate aminotransferase (AST).
- **Incidence < 1%:** Leukopenia, neutropenia, decreased platelet count, elevated levels of serum alkaline phosphatase, bilirubin, blood urea nitrogen (BUN), creatinine, blood glucose, lactate dehydrogenase (LDH), and phosphate.

When follow-up was provided, changes in laboratory tests appeared to be reversible.

4.9Overdose
Adverse events experienced in higher than recommended doses were similar to those seen at normal doses. The typical symptoms of an overdose with macrolide antibiotics include reversible loss of hearing, severe nausea, vomiting and diarrhoea. In the event of overdose, the administration of medicinal charcoal and general symptomatic treatment and supportive measures are indicated as required.

5. Pharmacological Properties
5.1 Mechanism of Action
Azithromycin is a macrolide class of antibiotic belonging to the azalide group. Azithromycin acts by binding to the 23S rRNA of the 50S ribosomal subunit of susceptible microorganisms inhibiting bacterial protein synthesis and impeding the assembly of the 50S ribosomal subunit. Inhibition of bacterial protein synthesis leads to bactericidal effect (death of bacteria).

5.2Pharmacodynamic Properties
Azithromycin is a macrolide class of antibacterial drug. Azithromycin concentrates mainly in phagocytes and fibroblasts (as demonstrated by *in vitro* incubation techniques), with the ratio of intracellular to extracellular concentration reported to be > 30 after one hour incubation. *In vivo* studies suggest that concentration in phagocytes may contribute to drug distribution to inflamed tissues.
Azithromycin has been shown to be active against most isolates of the following bacteria both *in vitro* and in clinical infections:
Aerobic Gram-Positive Microorganisms

- *Staphylococcus aureus.*
- *Streptococcus agalactiae.*
- *Streptococcus pneumonia.*
- *Streptococcus pyogenes.*

Aerobic Gram-Negative Microorganisms

- *Haemophilus influenza.*
- *Moraxella catarrhalis.*

Other Microorganisms

- *Chlamydia trachomatis.*

Azithromycin has been shown to be active *in vitro* and in the prevention and treatment of disease caused by the following microorganisms:

Mycobacteria

Mycobacterium avium complex (MAC) consisting of:

- *Mycobacterium avium.*
- *Mycobacterium intracellulare.*

The following *in vitro* data are available, but their clinical significance is unknown. Azithromycin exhibits *in vitro* minimal inhibitory concentrations (MICs) of 2.0 mcg/ml or less against most (≥ 90%) strains of the following microorganisms; however, the safety and effectiveness of azithromycin in treating clinical infections due to these microorganisms have not been established in adequate and well-controlled trials.

Aerobic Gram-Positive Microorganisms

- Streptococci (Groups C, F, G).
- Viridans group streptococci.

Aerobic Gram-Negative Microorganisms

- *Bordetella pertussis.*
- *Campylobacter jejuni.*
- *Haemophilus ducreyi.*
- *Legionella pneumophila.*

Anaerobic Microorganisms

- *Bacteroides bivius.*
- *Clostridium perfringens.*
- *Peptostreptococcus species.*

Other Microorganisms

- *Borrelia burgdorferi.*
- *Mycoplasma pneumonia.*
- *Treponema pallidum.*
- *Ureaplasma urealyticum.*

5.3Pharmacokinetic Properties

Absorption: After oral administration, bioavailability of azithromycin is approximately 37%. Peak plasma levels are achieved 2 to 3 hours after taking azithromycin by oral route. Absorption is not affected by food.
Distribution: Orally administered azithromycin is widely distributed throughout the body. The concentrations of azithromycin measured in tissues are noticeably higher (as much as 50 times) than those measured in plasma, which indicates that azithromycin strongly binds to tissues. Azithromycin has been shown to penetrate into tissues in humans, including skin, lung, tonsil, and cervix. Extensive tissue distribution was confirmed by examination of additional tissues and fluids (bone, prostate, ovary, uterus, fallopian tube, stomach, liver, and gallbladder). Binding to plasma proteins varies according to plasma concentration and range from 12 to 52%. The mean volume of distribution at steady state is 31.1 l/kg.
Metabolism and Excretion: Approximately 12% of an intravenously administered dose of azithromycin is excreted unchanged in urine within the following 3 days. Biliary excretion of azithromycin, predominantly as unchanged drug, is a major route of elimination. Particularly high concentrations of unchanged azithromycin have been found in human bile. Also in bile, 10 metabolites of azithromycin were detected, which were formed through N- and O-demethylation, hydroxylation of desosamine and aglycone rings and cleavage of cladinose conjugate. The metabolites of azithromycin are not microbiologically active. The terminal plasma elimination half-life of azithromycin which closely reflects to the elimination half-life from tissues is 2 to 4 days (average 68 hours).

Pharmacokinetic Data in Paediatric Population

Pharmacokinetics has been studied in children aged 4 months to 15 years taking capsules, granules or suspension. At 10 mg/kg on day 1 followed by 5 mg/kg on days 2 to 5, the C_{max} achieved is slightly lower than adults. The t½ of 36 hours in the older children was within the expected range for adults.

6. Nonclinical Properties

6.1 Animal Toxicology

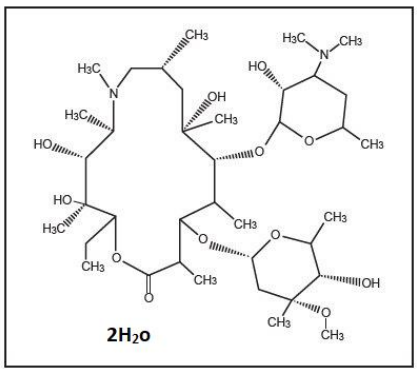
Toxicity: Phospholipidosis (intracellular phospholipid accumulation) has been observed in some tissues of mice, rats, and dogs given multiple oral doses of azithromycin. It has been demonstrated in numerous organ systems (e.g., eye, dorsal root ganglia, liver, gallbladder, kidney, spleen, and/or pancreas) in dogs and rats treated with azithromycin at doses which, expressed on the basis of body surface area, are similar to or less than the highest recommended adult human dose. This effect has been shown to be reversible after cessation of azithromycin treatment. Phospholipidosis has been seen in the rat (50 mg/kg/day dose) at the observed maximal plasma concentration of 1.3 mcg/ml (1.6 times the observed Cmax of 0.821 mcg/ml at the adult dose of 2 gram.) Similarly, it has been shown in the dog (10 mg/kg/day dose) at the observed maximal serum concentration of 1 mcg/ml (1.2 times the observed Cmax of 0.821 mcg/ml at the adult dose of 2 g).
Carcinogenesis: Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Mutagenesis: Azithromycin has shown no mutagenic potential in standard laboratory tests: mouse lymphoma assay, human lymphocyte clastogenic assay, and mouse bone marrow clastogenic assay.
Impairment of Fertility: No evidence of impaired fertility due to azithromycin was found in rats given daily doses up to 10 mg/kg (approximately 0.2 times an adult daily dose of 500 mg based on body surface area).
Reproductive Toxicity: In embryotoxicity studies in mice and rats no teratogenic effects were observed. Reproduction studies have been performed in rats and mice using oral administration at doses up to moderately maternally toxic dose concentrations (i.e., 200 mg/kg/day). These daily doses in rats and mice based on body surface area, are estimated to be 4- and 2-times, respectively, an adult daily dose of 500 mg. In the animal studies, no evidence of harm to the fetus due to azithromycin was found.

7. Description

AZIBEST 100 Suspension is Orange coloured, viscous suspension, 15 ml filled in amber PET bottle.
AZIBEST 200 Suspension is Orange coloured, viscous suspension, 15 ml filled in amber PET bottle.
AZIBEST 100 Suspension contains 100 mg of azithromycin per 5 ml for oral administration.
AZIBEST 200 Suspension contains 200 mg of azithromycin per 5 ml for oral administration.

Azithromycin dihydrate is the dihydrate form of azithromycin. Azithromycin is a semisynthetic macrolide class of antibiotic derived from erythromycin with anti-bacterial activity. Azithromycin dihydrate is a white crystalline powder.
Molecular Weight: 785 g/mol.
Molecular Formula: C38H72N2O12•2H2O.
Chemical Name: (2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-11-[(2S,3R,4S,6R)-4-(dimethylamino)-3-hydroxy-6-methyloxan-2-yl]oxy-2-ethyl-3,4,10-trihydroxy-13-[(2R,4R,5S,6S)-5-hydroxy-4-methoxy-4,6-dimethyloxan-2-yl]oxy-3,5,6,8,10,12,14-heptamethyl-1-oxa-6-azacyclopentadecan-15-one;dihydrate.
Structural Formula:



Inactive ingredients (excipients) of AZIBEST 100 Suspension contain Glycerin, Sucrose, Xanthan Gum, Sodium Methyl Paraben, Sodium Propyl Paraben, Sodium Hydroxide,

Polysorbate 80, Colloidal Silicon Dioxide, Propylene Glycol, Sodium Citrate, Aspartate, Menthol, Saccharin Sodium, Flavour Mango, Colour Sunset Yellow FCF, Di Phosphate Hydrogen Phosphate, Potassium Hydroxide & Purified Water. ……

Inactive ingredients (excipients) of AZIBEST 200 Suspension contain Glycerin, Sucrose, Xanthan Gum, Sodium Methyl Paraben, Sodium Propyl Paraben, Sodium Hydroxide, Polysorbate 80, Colloidal Silicon Dioxide, Propylene Glycol, Sodium Citrate, Aspartate, Menthol, Saccharin Sodium, Flavour Mango, Colour Sunset Yellow FCF, Di Phosphate Hydrogen Phosphate, Potassium Hydroxide & Purified Water. ……

8. Pharmaceutical Particulars

8.1 Incompatibilities

None known.

8.2Shelf-life

24 Months

8.3Packaging Information

15 ml bottle with measuring cup.

8.4Storage and Handling Instructions

Store at a temperature not exceeding 30°C. Protect from light and moisture.
Keep out of reach of children.

9. Patient Counseling Information

Administration Instructions to Patients / Caregivers

- Patients/caregivers should be counseled that antibacterial drugs should only be used to treat bacterial infections; not to use this medicine to treat infections caused by viruses.
- Patients/caregivers should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may decrease the effectiveness of the treatment and increase the likelihood of developing antibiotic resistance.
- Inform patients/caregivers that diarrhea is a common problem caused by antibacterial drugs which usually ends when the antibacterial is discontinued. Sometimes after starting treatment with antibacterials, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibacterial. If this occurs, patients should inform their physician as soon as possible.
- This medicine should be avoided in children below 6 months of age.
- Pregnant women and lactating mothers should consult their doctor before use of this medicine.

- Shake suspension well before each use.

10. Details of Manufacturer

Akums Drugs & Pharmaceuticals Ltd., Plot No. 22, Sector-6A, I.I.E., SIDCUL, Ranipur, Haridwar 249 403, Uttarakhand.

11. Details of Permission or License Number with Date

Azibest 100 mg Suspension: Mfg. Lic. No. : 129/UA/SC/P-2007 Date of FDA Product Permission: 15/01/2019. Azibest 200 mg Suspension: Mfg. Lic. No. : 129/UA/SC/P-2007 Date of FDA Product Permission: 15/01/2019.

12. Date of Revision

January 2022.

Marketed by:

EXCEL BLUE CROSS || EXCEL

Division of

BLUE CROSS LABORATORIES PVT LTD.

A-12, M.I.D.C., NASHIK-422 010.

Regd. Off.: Peninsula Chambers, G. K. Marg, Mumbai-400 013.