Product Name : **AZITHROSAFE SUSPENSION**			
CURRENT DATE & CORRECTION NUMBER	**OLD PRODUCTION FILE DATE**		**carton size:**
24-12-2020 C7	**NEW**	Front/ back	**L.150 x W.105**

L.150 x W.105

AZITHROSAFE SUSPENSION

(Suspension For the use of a Registered Medical Practitioner or Hospital or Laboratory only.)

Azithromycin Suspension 200 mg / 5ml

Composition:
Each 5 ml contains:

Azithromycin dihydrate Eq. to Azithromycin anhydrous USP	200 mg
Flavoured Syrupy base	q.s.
Colour : Approved Colour used.	

Description:

AZITHROSAFE SUSPENSION contains 200 mg of azithromycin (as Azithromycin dihydrate). Azithromycin is a 15 – membered ring azalide antibiotic active against gram positive & gram negative organism.

Indications:
AZITHROSAFE suspension is indicated for the treatment of the following infections, when caused by microorganisms sensitive to azithromycin

- acute bacterial sinusitis (adequately diagnosed)
- acute bacterial otitis media (adequately diagnosed)
- pharyngitis, tonsillitis
- acute exacerbation of chronic bronchitis (adequately diagnosed)
- mild to moderately severe community acquired pneumonia
- skin and soft tissue infections
- uncomplicated Chlamydia trachomatis urethritis and cervicitis

Dosage and administration:
Azithromycin should be taken at least one hour before or two hours after administration of food and antacid preparation.

In children under 45 kg body weight:

Azithrosafe Suspension should be used for children under 45 kg. There is no information on children less than 6 months of age. The dose in children is 10 mg/kg as a single daily dose for 3 days.

Up to 15 kg (less than 3 years): Measure the dose as closely as possible using the 5ml measuring cap provided.

For children weighing more than 15 kg, Azithrosafe Suspension should be administered using the measuring cap provided according to the following guidance:

15-25 kg (3-7 years): 5 ml (200 mg) given as 1 x 5 ml capful, once daily for 3 days.

26-35 kg (8-11 years): 7.5 ml (300 mg) given as 7.5 ml capful, once daily for 3 days.

36-45 kg (12-14 years): 10 ml (400 mg) given as 10 ml capful, once daily for 3 days.

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: No dosage adjustment recommendations can be made; azithromycin has not been studied in patients with impaired hepatic function.

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Direction for use:

SHAKE WELL BEFORE USE. Replace cap tightly immediately after each use.

Contraindications :

Hypersensitivity to Azithromycin or any of the macrolide antibiotics. Co–administration with ergot derivatives.

Drug Interactions:

- Caution is advised, when using azithromycin in conjuction with drugs like carbamazapine, corticosteroids, cyclosporin, digoxin, ergot alkaloids, Theophylline and warfarin.
- Azithromycin should be taken at least one hour before or two hours after administration of food and antacid preparation.

Use during pregnancy & lactation

Azithromycin is classified as FDA pregnancy risk category B. Animal data reveal no teratogenic effects. There are, however, no adequate and well-controlled studies in pregnant women. Because animal studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Azithromycin has not been studied for use during labor and obstetric delivery. Treatment should be given only if clearly needed. Or as directed by physician.

Use in Lactating Women:

Breast-feeding
There are no data on secretion in breast milk. As many drugs are excreted in human milk, azithromycin should not be used in the treatment of a lactating woman unless the physician feels that the potential benefits justify the potential risks to the infant .

Side Effects include :
dizziness, headache, diarrhoea, nausea, flatulence, vomiting and rash.

Overdose & Treatment

Adverse events experienced in higher than recommended doses were similar to those seen at normal doses. In the event of overdosage, general symptomatic and supportive measures are indicated as required.

Presentation
15 ml cup, bottle packed in carton with insert.

Storage Condition:
Store below 30°C in a dark place

KEEP MEDICINE OUT OF REACH OF CHILDREN

Manufactured in India by:
Enicar Pharmaceuticals Pvt. Ltd.
Plot No: J-214, 215,216, M.I.D.C., Tarapur,
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Manufactured For :
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