1.16	Summary Product Characteristics (SPC)
1.16.1	Product Information

1. NAME OF THE MEDICINAL PRODUCT:

TRADE NAME : **SUMAMOX 200** (Azithromycin Oral Suspension USP 200mg/5ml)

INN : Azithromycin dihydrate

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of reconstituted suspension contains:

Azithromycin Dihydrate USP equivalent to

Anhydrous Azithromycin ….. 200mg

Excipients ….. Q.S.

Colour - Ponceau 4R

Flavoured Base

3. PHARMACEUTICAL FORM

Liquid dosage form (Powder for oral suspension)

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

INDICATIONS:

Azithromycin is indicated for the following bacterial infections induced by micro-organisms susceptible to azithromycin:

- Infections of the lower respiratory tract: acute bronchitis and mild to moderate community-acquired pneumonia
- Infections of the upper respiratory tract: sinusitis and pharyngitis/tonsillitis
- Acute otitis media
- Infections of the skin and soft tissue of mild to moderate severity e.g. folliculitis, cellulites, erysipelas
- Uncomplicated Chlamydia trachomatis urethritis and cervicitis.

4.2 Dosage and Administration

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For Pediatric Patients (Age: 6 month and above)

Sumamox for oral suspension (200mg/5ml.) can be taken with or without food.

Method of Reconstitution:

Add water in the bottle containing granules till the mark of 20 ml to get suspension, each containing 200 mg of azithromycin / 5 ml. Shake well to get uniform suspension.

Carefully shake the content of the bottle till formation of homogeneous suspension.

Dose Table for Sumamox Oral suspension 200mg/5ml.	
OTITIS MEDIA AND ACUTE BACTERIAL SINUSITIS (3 days therapy) (10mg/kg/day)	
Body weight in kg.	**Dose**
10-20	2.5 ml daily for 3 days
20-30	5 ml. daily for 3 days.
30-40	7.5 ml. daily for 3 days
40-50	10 ml. daily for 3 days
50 and above	12.5 ml. daily for 3 days
OTITIS MEDIA (30mg/kg ,Single dose therapy)	
5-10	3.75 ml. for 1 day
10-20	7.5 ml. for 1 day
20-30	15 ml. for 1 day
30-40	22.5 ml. for 1 day
40-50	30 ml. for 1 day
50 and above	37.5 ml. for 1 day
PHARYNGITIS/TONSILLITIS (12mg/kg/day)	
8-17	2.5 ml. daily for 5 days
17-25	5 ml. daily for 5 days
25-33	7.5 ml. daily for 5 days

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33-40	10 ml. daily for 5 days
40 kg and above	12.5 ml. daily for 5 days

Adults: in uncomplicated Chlamydia trachomatis urethritis and cervicitis, the dosage is 1,000 mg in one single oral dose.

For all other indications, the dosage is 1,500 mg, to be administered as 500 mg per day for three consecutive days. Alternatively, the same total dosage (1,500 mg) can also be given over a period of 5 days with 500 mg on the first day and then 250 mg on days 2 to 5.

To treat these patients other pharmaceutical forms are also available.

Elderly

No dose adjustments are required for elderly patients.

In the elderly the same dosage as for adults can be given.

Patients with renal impairment

No dose adjustment is necessary in patients with mild to moderate renal impairment (GFR 10- 80 ml/min)

Patients with hepatic impairment

A dose adjustment is not necessary for patients with mild to moderately impaired liver function (Child-Pugh class A or B).

4.3 Contraindications

SUMAMOX is contraindicated in patients with known hypersensitivity to azithromycin, erythromycin, any macrolide or ketolide antibiotic. Azithromicin is contraindicated in patients with a history of cholestatic jaundice/hepatic dysfunction associated with prior use of azithromycin.

4.4 Special warnings and special precautions for use

Warning

Hypersensitivity

Serious allergic reactions, including angioedema, anaphylaxis, and dermatologic reactions including Stevens Johnson Syndrome and toxic epidermal necrolysis have been reported rarely in patients on azithromycin therapy. Although rare, 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. The

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relationship of these episodes to the long tissue half-life of azithromycin and subsequent prolonged exposure to antigen is unknown at present.

If an allergic reaction occurs, the drug should be discontinued and appropriate therapy should be instituted. Physicians should be aware that reappearance of the allergic symptoms may occur when symptomatic therapy is 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.

Clostridium Difficile-associated diarrhea

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including SUMAMOX, 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*.

Precaution

General: Because azithromycin is principally eliminated via the liver, caution should be

exercised when azithromycin is administered to patients with impaired hepatic function. Due to the limited data in subjects with GFR <10 mL/min, caution should be exercised when prescribing azithromycin in these patients.

4.5 Interaction with other medicinal products and other forms of Interaction

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 side effects of azithromycin, such as liver enzyme abnormalities and hearing impairment, is warranted.

4.6 Pregnancy and lactation

There are no controlled data in human pregnancy. Animal studies failed to reveal evidence of fetotoxicity. Azithromycin should only be given during pregnancy when benefit outweighs risk.

Azithromycin is excreted into human milk. The manufacturer recommends that caution be used when administering azithromycin to nursing women.

4.7 Effects on ability to drive and use machines

It is necessary to take into account the clinical state of the patient and the profile of adverse reactions of Sumamox in assessing the patient's ability to drive or move vehicles.

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4.8 Undesirable effects

The types of side effects in pediatric patients were comparable to those seen in adults, with different incidence rates for the dosage regimens recommended in pediatric patients.

Most of the side effects leading to discontinuation were related to the gastrointestinal tract, e.g., nausea, vomiting, diarrhea, or abdominal pain.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term studies in animals have not been performed to evaluate carcinogenic potential. Azithromycin has shown no mutagenic potential in standard laboratory tests: mouse lymphoma assay, human lymphocyte clastogenic assay, and mouse bone marrow clastogenic assay. No evidence of impaired fertility due to azithromycin was found.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antibacterials for systemic use; macrolides.

ATC code: J01FA10

Azithromycin is a semi-synthetic macrolide antibiotic chemically related to erythromycin and clarithromycin. It is effective against a wide variety of bacteria organisms, such as Hemophilus influenzae, Streptococcus pneumoniae, Mycoplasma pneumoniae, Staphylococcus aureus, and mycobacterium avium, and many others. Azithromycin, like all macrolide antibiotics, prevents bacteria from growing by interfering with their ability to make proteins. It acts by binding to the 50S ribosomal subunit of susceptible microorganisms and, thus, interfering with microbial protein synthesis. Nucleic acid synthesis is not affected. Due to the differences in the way proteins are made in bacteria and humans, the macrolide antibiotics do not interfere with humans' ability to make proteins.

5.2 Pharmacokinetic properties

Azithromycin is acid-stable, so it can be taken orally with no need of protection from gastric acids. It is readily absorbed, but its absorption is greater on an empty stomach. Time to peak concentration in adults is 2.1 to 3.2 hours for oral dosage forms and after that dose, one to two hours after a dose

Due to its high concentration in phagocytes, azithromycin is actively transported to the site of infection. During active phagocytosis, large concentrations are released. The concentration of azithromycin in the tissues can be over 50 times higher than in plasma due to ion trapping and its high lipid solubility (volume of distribution is too high).

Azithromycin's half-life allows a large single dose to be administered and yet maintain bacteriostatic levels in the infected tissue for several days.

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Metabolism

Following a single dose of 500 mg, the half-life of azithromycin is 11–14 h. The longer half-life of 68 h is achieved only when multiple doses are consumed

Biliary excretion of azithromycin, predominantly unchanged, is a major route of elimination. Over the course of a week, approximately 6% of the administered dose appears as unchanged drug in urine.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, and carcinogenic potential.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sucrose(Sugar) BP
Croscarmellose Sodium BP
Xanthan Gum BP
Tribasic Sodium phosphate dodecahydrate USP
Sodium Lauryl Sulphate BP
Sodium Benzoate BP
Sodium Chloride BP
Colour Ponceau 4R IHS
Cherry Flavour IHS
Colloidal Silicon Dioxide(Aerosil 200) USP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the prepared suspension is 5 days if stored at temperature (15 - 25°C).

Shelf life of unopened bottle is 2 years.

6.4 Special precautions for storage

Shelf life of the prepared suspension is 5 days if stored at temperature (15 - 25°C).

Store at temperature NMT 25°C in a dry, protected from light place, away from children.

6.5 Nature and contents of container

SUMAMOX (Azithromycin 200 mg/5 ml powder for oral suspension) is packed 40 ml ambered colored glass bottle with 20 ml marking, sealed with crimped aluminum pp cap. Single bottle with a double dosing spoon 2.5/5.0 ml and Pack insert in a carton.

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6.6 Special precautions for disposal and other handling

No special requirements for disposal

7. MANUFACTURER (name, address, country)

Oxford Laboratories Pvt. Ltd

B/ 306, Crystal Plaza, New Link road,

Andheri (W), Mumbai- 400 053, INDIA.

8. MARKETING AUTHORIZATION HOLDER

Oxford Laboratories Pvt. Ltd

B/ 306, Crystal Plaza, New Link road,

Andheri (W), Mumbai- 400 053, INDIA.

9. DATE OF FIRST AUTHORIZATION

NA

10. DATE OF FINAL REVISION OF THE TEXT

NA

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