1.3.1

Summary of Product Characteristics (SmPC)

1. Name of the medicinal Product

1.1 Name of the medicinal Product

Azithromycin Tablets USP 500 mg

1.2 Strength

Each Film coated tablet contains:

Azithromycin USP (Dihydrate)

E.q to Anhydrous Azithromycin 500 mg

Excipients Q.S.

Colour: Titanium Dioxide BP

2. Qualitative and Quantitative Composition

2.1 Qualitative Declaration

Azithromycin Dihydrate USP

2.2 Quantitative Declaration

Sr. No.	Ingredients	Specifications	Label Claim (mg/Tablet)	Rational
1	Azithromycin Dihydrate Eq. to Anhydrous Azithromycin	USP	524.00 e.q. to 500.00	Antibacterial
2	Microcrystalline Cellulose (Plain)	BP	80.080	Diluent
3	Sodium Lauryl Sulphate	BP	2.000	Solubilizer
4	Pregelatinized Starch (Starch 1500)	BP	20.000	Binder
5	Croscarmellose Sodium	USP-NF	10.000	Disintegrant
6	Sodium Starch Glycolate (Type-A)	BP	15.000	Disintegrant
7	Microcrystalline Cellulose (PH 102)	BP	56.00	Lubricant
8	Croscarmellose Sodium	USP-NF	10.000	Glidant
9	Purified Talc	BP	10.00	Lubicant
10	Magnesium Stearate	BP	16.000	Lubricant
11	Colour White SC-SP 3180 (Spraycel)	IH	20.000	Colouring Agent

12	Purified Water	BP	Q.S.	Solvent

3. Pharmaceutical Form

Film Coated Tablets.

White to off-white coloured, capsule shaped, film coated tablets, embossed "500" on one side and plain on other side.

4. Clinical Particulars

4.1 Therapeutic Indications

Lower respiratory tract infections: Acute bacterial bronchitis, Community acquired pneumonia.

Upper respiratory tract infections: Acute sinusitis, Acute otitis media.

Uncomplicated skin and skin structure infections, Sexually transmitted diseases: Uncomplicated cervicitis, Uncomplicated Chlamydia infections and non-gonococcal urethritis. Pelvic Inflammatory Disease, Chlamydia trachomatis conjunctivitis and trachoma, Prevention of infection due to Mycobacterium avium-intracellulare Complex (MAC) disease.

4.2 Posology and Method of Administration

Adults: 500 mg once daily for 3 days or 500 mg on first day then 250 mg once daily for 4 days.

Child: Over 6 months: 10 mg /kg once daily for3 days.

Uncomplicated genital chlamydia! infections and non gonococcal urethritis, I gas a single dose.

4.3 Contraindications

Known hypersensitivity to azithromycin or any of the macrolide antibiotics. It should not be prescribed in patients with hepatic diseases.

4.4 Special Warnings and Special Precautions for Use

It should only be used in pregnant or lactating women where adequate alternatives are not available.

Use with caution in patients with renal dysfunction, hepatic dysfunction; hepatic impairment with or without jaundice. It may be accompanied by malaise, nausea, vomiting, abdominal colic, and fever; discontinue use if these occur. May mask or delay symptoms of incubating gonorrhoea or syphilis, so appropriate culture and susceptibility tests should be performed prior to initiating Azithromycin. Pseudomembranous colitis has been reported with use of macrolide antibiotics. Use caution in patients at risk of prolonged cardiac repolarization.

4.5 Interaction with other medicinal products and other forms of interaction

Cardiac glycosides, Colchicine, Nelfinavir, Warfarin, Ergot derivatives, Cyclosporin, Digoxin, Warfarin, Terfenadine.

4.6 Fertility, Pregnancy and Lactation

Pregnancy: Pregnancy Category B: Azithromycin should be used during pregnancy only if clearly needed.

Lactation: It 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

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable Effects

The majority of side-effects are gastrointestinal in origin with anorexia, nausea, abdominal discomfort (pain/cramps), flatulence, vomiting and diarrhoea. Hearing impairment including hearing loss, deafness and or tinnitus, interstitial nephritis and acute renal failure.

Cases of abnormal liver function including hepatitis and cholestatic jaundice. Reductions in neutrophil counts, Chest pain, malaena, nephritis, vaginitis, headache, vertigo, dizziness, convulsions, somnolence and fatigue. Allergic reactions including arthralgia, oedema, urticaria, rash, photosensitivity, angioedema and anaphylaxis. Less frequently, serious skin reactions including erythema multiforme, Stevens Johnson syndrome and toxic epidennal necrolysis, have occurred.

4.9 Overdose

Symptoms of overdose include nausea, vomiting, diarrhoea, and prostration. Gastric lavage and general supportive measures are indicated.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Antibacterial

Azithromycin acts by binding to the 50S ribosomal subunit of susceptible organisms, thus interfering with microbial protein synthesis. Nucleic acid synthesis is not affected.

5.2 Pharmacokinetic Properties

Following oral administration, azithromycin is absorbed from the gastrointestinal tract with an absolute bioavailability of 37% and half-life is 68 hours. The serum protein binding to it is variable in the concentration range, decreasing from 51% at 0.02 µg/ml to 7% at 2 µg/ml. 6% excreted unchanged in urine. In elderly patient, no dosage adjustment is necessary.

5.3 Preclinical Safety Data

Not Applicable

6 Pharmaceutical Particulars

6.1 List of Excipients

Microcrystalline Cellulose (Plain) BP
Sodium Lauryl Sulphate BP
Croscarmellose Sodium USP-NF
Pregelatinized Starch (Starch 1500) BP
Sodium Starch Glycolate (Type-A) BP
Microcrystalline Cellulose (PH 102) BP
Purified Talc BP
Magnesium Stearate BP
Colour White SC-SP 3180 Spraycel IH
Purified Water BP

6.2 Incompatibilities

None.

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Store below 30^0C. Protect from light.

6.5 Nature and Contents of Container

White to off-white coloured, capsule shaped, film coated tablets, embossed "500" on one side and plain on other side. 3 tablets are packed in Alu-Alu blister pack. 3 Blister packed in printed carton along with packaging insert.

6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Registrant (Marketing Authorization Holder And Manufacturing Site Addresses)

7.1 Name and Address of Marketing Authorization Holder

GENERICS AND SPECIALITIES LTD.

31, AWONIYI ELEMO STREET,

OFF LATEEF SALAMI STREET.

AJAO ESTATE, LAGOS,

NIGERIA.

E-mail: info@zolonhealthcare.com

7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited

Trimul Estate, Khatraj, Taluka: Kalol,

District: Gandhinagar Gujarat, India.

Telephone no.: +91-07949-135000

Fax: +91-02764-281809

Email: info@lincolnpharma.com

Website: www.lincolnpharma.com

7.3 Marketing Authorization Number

To be included after obtaining first registration.

7.4 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

8. Date of Revision of the Text

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9. Dosimetry (If Applicable)

Not Applicable

10. Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable