SHALZIN

(Azithromycin Tablets USP 500 mg)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Shalzin (Azithromycin Tablets USP 500 mg)

1.1 (INVENTED) NAME OF THE MEDICINAL PRODUCT

Shalzin (Azithromycin Tablets USP 500 mg)

1.2 STRENGTH

Strength per tablet:

Azithromycin USP (as dihydrate) equivalent to Azithromycin

(Anhydrous)…….500 mg

1.3 PHARMACEUTICAL FORM

Solid dosage form (Tablet-Oral Route)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredient	**Quantity per Tablet (mg)**
Azithromycin USP (as dihydrate) equivalent to Azithromycin (Anhydrous)	500.00
Maize Starch BP	175.50
Sodium starch glycolate BP	12.00
Methyl paraben BP	0.300
Propyl paraben BP	0.200
Magnesium Stearate BP	13.00
Colloidal Anhydrous Silica BP	5.00
Purified Talc BP	7.00
Croscarmellose Sodium BP	10.00
Tabcoat TC White 1000 IH (Composition of Tabcoat TC White 1000, Hypromellose, Titanium Dioxide, Talc & Polyethylene Glycol)	20.00

Note: BP = British Pharmacopoeia

IH = In House Specifications

USP = United States Pharmacopoeia

3. PHARMACEUTICAL FORM

Tablet- White capsule shaped film coated tablet having embossing ‘AZI 500‘on one side and ‘SHALINA’ on other side.

SHALZIN

(Azithromycin Tablets USP 500 mg)

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Shalzin is indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below.

Adults Patients

- Acute bacterial sinusitis due to Haemophilus influenzae, Moraxella catarrhalis or Streptococcus Pneumonia.
- Pharyngitis/tonsillitis caused by Streptococcus pyogenes.
- Uncomplicated skin and skin structure infections due to Staphylococcus aureus, Streptococcus Pyogenes, or Streptococcus agalactiae. Abscesses usually require surgical drainage.
- Urethritis and cervicitis due to Chlamydia trachomatis or Neisseria gonorrhoeae.
- Genital ulcer disease in men due to Haemophilus ducreyi (chancroid).
- Community-acquired pneumonia due to Chlamydia pneumoniae, Haemophilus influenzae, Mycoplasma pneumoniae or Streptococcus pneumoniae in patients appropriate for oral therapy.
- Acute bacterial exacerbations of chronic obstructive pulmonary disease due to Haemophilus Influenzae, Moraxella catarrhalis or Streptococcus pneumoniae.

Paediatric Patients

- Acute otitis media caused by Haemophilus influenzae, Moraxella catarrhalis or Streptococcus Pneumoniae.
- Pharyngitis/tonsillitis caused by Streptococcus pyogenes.
- Community-acquired pneumonia due to Chlamydia pneumoniae, Haemophilus influenzae, Mycoplasma Pneumoniae or Streptococcus pneumoniae in patients appropriate for oral therapy.
- Skin & skin structure infections: Folliculitis, furuncles, carbuncles, impetigo, pyoderma, infected ulcer, Infected dermatitis, cellulitis, & erysipelas due to Staphylococcus aureus, S. pyogenes or S. agalactiae.

4.2 Posology and method of administration

Food does not affect the absorption of **SHALZIN** (Azithromycin tablets USP 500 mg) and it can be administered without regard to meals.

Adults Patients

Upper and lower respiratory tract infections, skin and soft tissue infections and Otitis media: 500 mg once daily for 3 days. Uncomplicated sexually transmitted diseases caused by Chlamydia trachomatis: Single 1g dose. Use in the elderly: Normal adult dosage is recommended.

4.3 Contraindications

SHALZIN Tablets are contraindicated in patients with known hypersensitivity to Azithromycin, any macrolide or ketolide antibiotic.

4.4 Special warnings and precautions for use

General: Because Azithromycin is principally eliminated via the liver, caution should be exercised when **SHALZIN** 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.

Usage in Pregnancy & Lactation: Pregnancy Category B: There are no adequate and well-controlled studies in pregnant women. Clinical experience and published studies suggest that azithromycin in pregnancy is safe and effective in uncomplicated chlamydial infection. Azithromycin should only be given during pregnancy and lactation when benefit outweighs risk.

4.5 Interaction with other medicinal products and other forms of interaction

Human clinical and pharmacokinetic studies have shown no major drug-drug interactions between azithromycin and numerous other agents: carbamazepine, theophylline, midazolam, terfenadine, cetirizine, atorvastatin, Trimethoprim / Sulfamethoxazole, sildenafil, zidovudine, fluconazole or cimetidine. The extent of absorption of azithromycin was unaffected by concurrent administration of antacids.

4.6 Pregnancy and lactation

Pregnancy Category B: There are no adequate and well-controlled studies in pregnant women. Clinical experience and published studies suggest that azithromycin in pregnancy is safe and effective in uncomplicated chlamydial infection. Azithromycin should only be given during pregnancy and lactation when benefit outweighs risk.

4.7 Effects on ability to drive and use machines

No study on the effects on the ability to drive and use machines has been achieved. However, the possibility of undesirable effects such as dizziness and convulsions should be taken into account when carrying out these activities.

4.8 Undesirable effects

Allergic: Rash, pruritus, photosensitivity and angioedema.

Cardiovascular: Arrhythmias including ventricular tachycardia and hypotension.

There have been rare reports of QT prolongation and torsades de pointes.

Gastrointestinal: Anorexia, constipation, dyspepsia, flatulence, vomiting/diarrhoea.

Genitourinary: Interstitial nephritis, vaginitis. Nervous System: dizziness/vertigo, headache, somnolence, nervousness, agitation.

General: Asthenia, paresthesia, fatigue, malaise.

4.9 Symptoms of Overdosage & Treatment

Symptoms of overdose include nausea, vomiting & diarrhoea. Treatment is supportive and symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Macrolide Antibiotics, ATC code: J01FA10

Mechanism of action

SHALZIN (Azithromycin tablets USP 500 mg) acts by binding to the 50S ribosomal subunit of susceptible microorganisms, thus interfering with microbial protein synthesis. Azithromycin concentrates in phagocytes and fibroblasts as demonstrated by in vitro incubation techniques. Using such methodology, the ratio of intracellular to extracellular concentration was >30 after one hour incubation. In vivo studies suggest that concentration in phagocytes may contribute to drug distribution to inflamed tissues.

SHALZIN (Azithromycin tablets USP 500 mg) has been shown to be active against most isolates of the following micro-organisms, both in vitro and in clinical infections. Aerobic and facultative gram-positive microorganisms Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus agalactiae, Streptococcus pyogenes. Aerobic and facultative gram-negative microorganisms Haemophilus influenzae, Moraxella catarrhalis, Neisseria gonorrhoeae, Haemophilus ducreyi. "Other" microorganisms Chlamydia pneumoniae, Chlamydia trachomatis, Mycoplasma pneumoniae.

N.B. Beta-lactamase production has no effect on Azithromycin activity.

Pharmacodynamic effects:

Azithromycin is an azalide, derived from the class of macrolide antibiotics.

SHALZIN (Azithromycin tablets USP 500 mg) acts by binding to the 50S ribosomal subunit of susceptible microorganisms, thus interfering with microbial protein synthesis. Azithromycin concentrates in phagocytes and fibroblasts as demonstrated by in vitro incubation techniques. Using such methodology, the ratio of intracellular to extracellular concentration was >30 after one hour incubation. In vivo studies suggest that concentration in phagocytes may contribute to drug distribution to inflamed tissues.

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influenzae, Moraxella catarrhalis, Neisseria gonorrhoeae, Haemophilus ducreyi. "Other" microorganisms Chlamydia pneumoniae, Chlamydia trachomatis, Mycoplasma pneumoniae.

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5.2 Pharmacokinetic properties

SHALZIN (Azithromycin tablets USP 500 mg) is more stable than erythromycin at gastric pH.

• The pharmacokinetic profile of **SHALZIN (**Azithromycin tablets USP 500 mg) reflects a rapid and extensive uptake from the circulation into intracellular compartments, followed by slow release.

• **SHALZIN** (Azithromycin tablets USP 500 mg) **l**evels in pulmonary macrophages, polymorph nuclear leukocytes, tonsillar tissue, and genital or pelvic tissue remain increased for extended periods, with a mean tissue half-life of 2 to 4 days. This feature allows single dose therapy for STDs and 3 to 5 day regimens for skin, soft tissue, and some respiratory infections.

Absorption: The absolute bioavailability of **SHALZIN** (Azithromycin tablets USP 500 mg) is 38%.

Distribution: The serum protein binding of **SHALZIN** (Azithromycin tablets USP 500 mg) is variable depending upon the serum concentration, decreasing from 51% at 0.02 µg/mL to 7% at 2 µg/mL.

Metabolism & Excretion: Most of an absorbed dose of **SHALZIN** (Azithromycin tablets USP 500 mg) is eliminated unchanged, principally in the feces, and no metabolite is thought to have appreciable antimicrobial activity. Urinary excretion of the unchanged drug seems to be a minor elimination route, with less than 7% of a 500-mg dose recovered in the urine after 24 hours. Terminal elimination half-life = 68 hours.

5.3 Preclinical safety data

In high-dose animal studies, giving concentrations of active substances 40 times higher than expected in clinical practice, azithromycin was noted to cause reversible phospholipidosis, generally without consequences

Toxicological properties. There is no evidence that it is in the interest of the normal use of azithromycin in humans.

Carcinogenic potential:

Long-term studies in animals have not been carried out to assess the potential carcinogen.

Mutagenic potential:

Azithromycin showed no mutagenic potential in laboratory tests standard: the mouse lymphoma test, human clastogenic test lymphocyte and marrow bone metabolism of clastogenic assay.

Reproductive Toxicity:

No teratogenic effects were observed in animal studies of the embryo in Mouse and rat. In the rat, azithromycin doses of 100 and 200 mg / kg body weight have led to slight delays in fetal ossification

and maternal weight. In post-natal studies in rats / peri, mild treatment with azithromycin 50 mg / kg / day and above were observed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch BP, Sodium Starch Glycolate BP, Methyl Paraben BP, Propyl Paraben BP, Purified Talc BP, Magnesium Stearate BP, Colloidal Anhydrous Silica BP, Cross Carmellose Sodium BP, Tabcoat TC White 1000 IH.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months (3 Years)

6.4 Special precautions for storage

Do not store above 30°C. Protect from sunlight and moisture. Keep out of reach of children.

6.5 Nature and contents of container

Blister: - 3 Tablets

Inner Carton: - 1 x 3 Tablets

Outer Carton: - 10 x 1 x 3 Tablets

6.6 Special precautions for disposal and other handling

No special requirement

7. MARKETING AUTHORISATION HOLDER

SHALINA HEALTHCARE NIGERIA LIMITED

19, Fatai Atare Road (way), Matori, Mushin, Lagos,

Nigeria,

Tel: +2348107539933

Email: theophilus.adimoha@shalina.com

8. MARKETING AUTHORISATION IN OTHER COUNTRIES

Product is registered in Ghana, Kenya, & Zambia.