National Agency for Food & Drug Administration & Control

(NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

1. NAME OF THE MEDICINAL PRODUCT
Acithromac Suspension 125mg/5ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 5ml of reconstituted suspension contains:

- Amoxicillin trihydrate equivalent to 125mg Amoxicillin.

Excipients with known effect: None.

3. PHARMACEUTICAL FORM
Powder for Suspension.
Off-white to pale yellow granular powder that forms a uniform suspension upon reconstitution.

4. CLINICAL PARTICULARS
4.1 Therapeutic Indications

- Treatment of bacterial infections caused by amoxicillin-susceptible organisms, such as:
- Respiratory tract infections.
- Otitis media.
- Skin and soft tissue infections.
- Urinary tract infections.

4.2 Posology and Method of Administration
Posology:

- Children under 40kg: 20-40mg/kg/day in divided doses every 8 hours, depending on the severity of the infection.
- Adults and children over 40kg: Not applicable for this formulation.

Reconstitution Instructions:

- Add potable water to the powder up to the marked line on the bottle. Shake well to ensure uniform mixing.

Method of Administration:

- Oral use. Shake the bottle well before each use.

4.3 Contraindications

- Hypersensitivity to amoxicillin, penicillins, or any of the excipients.

4.4 Special Warnings and Precautions for Use

- Monitor for allergic reactions, especially in individuals with a history of penicillin allergy.
- Use with caution in patients with renal impairment.

4.5 Interaction with Other Medicinal Products

- May interact with anticoagulants (e.g., warfarin).
- Reduced efficacy when co-administered with bacteriostatic antibiotics (e.g., tetracyclines).

4.6 Fertility, Pregnancy, and Lactation

- Safe during pregnancy and lactation when used as prescribed.

4.7 Effects on Ability to Drive and Use Machines

- None reported.

4.8 Undesirable Effects

Common side effects:

- Gastrointestinal disturbances (e.g., diarrhea, nausea).
- Skin rashes or urticaria.

Rare side effects:

- Hypersensitivity reactions, including anaphylaxis.
- Hepatic dysfunction.

4.9 Overdose

- Symptoms: Gastrointestinal upset and crystalluria.
- Management: Symptomatic treatment, maintain adequate fluid intake, and monitor renal function.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

- Pharmacotherapeutic group: Penicillins with extended spectrum.
- Mechanism of Action: Amoxicillin inhibits bacterial cell wall synthesis, leading to bacterial lysis.

5.2 Pharmacokinetic Properties

- Absorption: Rapidly absorbed from the gastrointestinal tract.
- Metabolism: Partially metabolized in the liver.
- Excretion: Excreted primarily in the urine.

5.3 Preclinical Safety Data

No additional data relevant to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Talc
- Na CMC
- Na Benzoate
- Na citrate
- Mg Stearate
- Vanilla
- Citric Acid
- Starch
- Sugar

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 Years

6.4 Special Precautions for Storage

- Store the powder below 25°C in a tightly closed container.

6.5 Nature and Contents of Container

1 bottle per packets

6.6 Special Precautions for Disposal

- Dispose of unused medicine according to local regulations.

7. MARKETING AUTHORISATION HOLDER

AC Drugs Limited
Plot C5/C6, Old Airport Road, Emene, Enugu State, Nigeria

8. MARKETING AUTHORISATION NUMBER

(To be assigned by the regulatory authority)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

(To be completed upon authorization)

10. DATE OF REVISION OF THE TEXT

(Date to be added when applicable)