SUMMARY OF PRODUCT CHARACTERISTICS:

1. NAME OF MEDICAL PRODUCT:

Unibrol 250mg tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Aminosidine 250mg /tablet(as sulphate).

For full list of excipients please see section 6.1

3. PHARMACEUTICAL FORM:

Tablet .

White ,circular ,flat, bevel-edged tablets, embossed UCL on one side and scored on the reverse side.

4. CLINICAL PARTICULARS:

4.1 Therapeutic Indications:

Treatment of acute and chronic intestinal amoebiasis ,lambliasis, trichomoniasis, cryptosporidiosis, aminosidine has being tried parentally and topically for cutaneous leishmaniasis, prophylactic sterization in gastro-intestinal surgery and prophylactic treatment of coma hepaticum.

4.2 Posology and Route of Administration:

Intestinal amoebiasis ,lambliasis and trichomoniasis:

Adult :500mg daily for six days

Children :15mg/kg daily for six days

Prophylactic sterization in gastro-intestinal surgery

Adult 2gram daily for 3 days

Children 50mg/kg daily for 3 days

Prophylactic treatment of coma hepaticum.

Adult: 2gram daily

Children 50mg/kg daily

The dosage may be increased depending on severity ,duration of disease and physicians judgment.

Route of administration

Oral

4.3 Contraindications:

Paromomycin sulfate is contraindicated in individuals with a history of previous hypersensitivity reactions to it. It is also contraindicated in intestinal obstruction.

4.4 Special Warnings and Precautions for use:

Warnings

Neurotoxicity

Manifests as both auditory and vestibular ototoxicity, and primarily occurs in patients with pre-existing renal damage or with prolonged therapy. Partial or total irreversible deafness may continue to develop after drug is stopped. Other features of neurotoxicity include paraesthesia's, twitching, and seizures.

Nephrotoxicity

Usually reversible.

Paromomycin is teratogenic in pregnancy. Closely monitor renal and eighth nerve function in patients with suspected renal function impairment. Monitor peak and trough concentrations. Renal function impairment requires dosage adjustments.

4.5 Drug Interactions:

Digoxin

May reduce rate and extent of digoxin absorption; this may be offset by decreased digoxin metabolism.

Methotrexate

Decreased absorption of methotrexate.

Neuromuscular blockers

Increased action of both depolarizing and nondepolarizing neuromuscular blocking agents, may prolong need for respiratory support.

Neurotoxic, nephrotoxic, or ototoxic medications (eg, polypeptide antibiotics)

Additive adverse effects may occur with concurrent or sequential administration of medications with similar toxic profiles.

4.6 Pregnancy and Lactation:

There are no data linking the use of paromomycin to congenital malformations or fetal toxicity, although there are no controlled data in human pregnancy. In pregnant patients with symptomatic protozoan or tapeworm infections, paromomycin may be a therapeutic option. Paromomycin should only be given during pregnancy when there are no alternatives and benefit outweighs the risk. Paromomycin is poorly absorbed from the gastrointestinal tract; therefore, any excretion into breast milk is expected to be minimal.

4.7 Effects on ability to drive and use machines:

None

4.8Undesirable effects:

Common side effects of paromomycin sulfate include:

- nausea.
- vomiting.
- abdominal cramps.
- diarrhea, or.
- itching.

4.8 Over dosage:

Symptoms may include decreased urination; hearing loss; ringing in the ears; skin tingling or numbness.

5.0 PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Paromomycin is a broad spectrum aminoglycoside antibiotic produced by Streptomyces rimosus var. paromomycinus. The in vitro and in vivo antibacterial action of paromomycin closely parallels that of neomycin.

Mechanism of action:

Paromomycin inhibits protein synthesis by binding to 16S ribosomal RNA. Bacterial proteins are synthesized by ribosomal RNA complexes which are composed of 2 subunits, a large subunit (50s) and small (30s) subunit, which forms a 70s ribosomal subunit. tRNA binds to the top of this ribosomal structure. Paramomycin binds to the A site, which causes defective polypeptide chains to be produced. Continuous production of defective proteins eventually leads to bacterial death.

5.2: Pharmacokinetics:

Absorption

Bioavailability

Poorly absorbed from the GI tract.

Impaired GI motility or intestinal lesions or ulcerations may facilitate GI absorption.

Elimination

Elimination Route

Almost 100% of an oral dose is eliminated unchanged in faeces; any absorbed drug is slowly excreted in urine.

6. PHARMACEUTICAL PARTICULARS:

6.1list of excipients

a. Pregelatinised starch.
b. Sodium starch glycolate.
c. Colloidal silicon dioxide.
d. Microcrystalline cellulose.
e. Magnesium stearate.

6.2 Incompatibilities:

None

6.3 Shelf life:

3 Years.

6.4 Special precautions for storage:

Do not store above 30^0c.

Store in a dry place.

Protect from direct sunlight.

Keep all medicines out of reach of children.

6.5 Nature and contents of container:

ALU/ALU blister in process boxes .

Pack size :12 tablets and 24 tablets.

6.6 Special precautions for disposal:

Not applicable.

7. MARKETING AUTHORIZATION HOLDER:

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8. MARKETING AUTHORISATION NUMBER(S)

H2007/232

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION.

28th March 2007.
Retained annually.

10 DATE OF REVISION OF THE TEXT.

April 2020.