ROMYCIN (Eye Drops)

AZITHROMYCIN DIHYDRATE USP

Compositions:
Each ml sterile Eye Drops contains Azithromycin Dihydrate USP equivalent to Azithromycin 10 mg.

Pharmacology:
Azithromycin is a macrolide antibiotic. It acts by binding to the 50 S ribosomal subunit of susceptible bacteria.

Dosage And Administration:
Children less than one year of age: Not recommended. Children of one year of age and adults: Instill 1 drop in affected eye(s) twice daily for the first 2 days then once daily for the next 5 days.

Contraindications:
Hypersensitivity to any component of the preparation.

Warning And Precaution:
Romycin (Azithromycin) Eye Drops is indicated for topical ophthalmic use only and should not be administered systemically, injected subconjunctivally, or introduced directly into the anterior chamber of the eye.

Side Effects:
Eye irritation, contact dermatitis, corneal erosion, dry eye, punctate keratitis etc.

Use in Pregnancy and Lactation:
Pregnancy: Pregnancy Category B. In the animal studies, no evidence of harm to the fetus due to Azithromycin was found. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, Azithromycin should be used during pregnancy only if clearly needed. Lactation: It is not known whether Azithromycin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Azithromycin is administered to a nursing woman.

Drug Interaction:
Drug interaction studies have not been conducted with Romycin (Azithromycin) Eye Drops.

Overdosage:
Sign and symptoms of overdose may be similar to side effects as described above

Storage:
Store unopened bottle under refrigeration at 2°C to 8°C. Once the bottle is opened, store at 'C° to 25°C for up to 14 days. Discard after the 14 days of opening.

Packing:
Romycin Eye Drops: Each Plastic Dropper bottle contains 2.5 ml sterile eye drops.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.