Humatin (paromomycin sulfate) Capsule
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Description

Humatin is a broad spectrum antibiotic produced by *Streptomyces rimosus* var. *paromomycinus* . It is a white, amorphous, stable, water-soluble product supplied as capsules containing the equivalent of 250 mg paromomycin.

The capsule contains D&C yellow No. 10; FD&C blue No. 1; FD&C red No. 3; FD&C yellow No. 6; gelatin, NF; and titanium dioxide, USP.

Action

The *in vitro* and *in vivo* antibacterial action of paromomycin closely parallels that of neomycin. It is poorly absorbed after oral administration, with almost 100% of the drug recoverable in the stool.

Indications

Humatin is indicated for intestinal amebiasis—acute and chronic (NOTE —It is not effective in extraintestinal amebiasis); management of hepatic coma—as adjunctive therapy.

Contraindications

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

Precautions

The use of this antibiotic, as with other antibiotics, may result in an overgrowth of nonsusceptible organisms, including fungi. Constant observation of the patient is essential. If new infections caused by nonsusceptible organisms appear during therapy, appropriate measures should be taken.

The drug should be used with caution in individuals with ulcerative lesions of the bowel to avoid renal toxicity through inadvertent absorption.

Pediatric Use: See **Dosage and Administration** section.

Adverse Reactions

Nausea, abdominal cramps, and diarrhea have been reported in patients on doses over 3 g daily.

Dosage and Administration

Intestinal amebiasis: Adults and Pediatric Patients: Usual dose—25 to 35 mg/kg body weight daily, administered in three doses with meals, for five to ten days.

Management of hepatic coma: Adults: Usual dose—4 g daily in divided doses, given at regular intervals for five to six days.

How Supplied

Humatin Capsules, each containing paromomycin sulfate equivalent to 250 mg paromomycin, are supplied as follows

NDC 61570-529-10: Bottles of 100

Store at controlled room temperature 15°–30°C (59°–86°F).

Protect from moisture.

Rx only.

Prescribing Information as of November 2001.

Distributed by: Monarch Pharmaceuticals, Inc., Bristol, TN 37620

Manufactured by: Caraco Pharmaceutical Laboratories, Ltd., Detroit, MI 48202

Humatin (Paromomycin Sulfate)

PRODUCT INFO

Product Code	61570-529	**Dosage Form**	CAPSULE
Route Of Administration	ORAL	**DEA Schedule**	

INGREDIENTS

Name (Active Moiety)	Type	Strength
Paromomycin Sulfate (Paromomycin Sulfate)	Active	250 MILLIGRAM In 1 CAPSULE
D&C yellow No. 10	Inactive	
FD&C blue No. 1	Inactive	
FD&C red No. 3	Inactive	
FD&C yellow No. 6	Inactive	
gelatin	Inactive	
titanium dioxide	Inactive	

IMPRINT INFORMATION

Characteristic	Appearance	Characteristic	Appearance
Color	YELLOW (with a Brown Cap)	**Score**	
Shape	CAPSULE	**Symbol**	false
Imprint Code	M-529	**Coating**	false
Size	19mm		

PACKAGING

#	NDC	Package Description	Multilevel Packaging
1	61570-529-10	100 CAPSULE In 1 BOTTLE (1 BOTTLE)	None