

**PRESCRIBING INFORMATION  
PRODUCT MONOGRAPH**

**HUMATIN\*CAP**

**(Paromomycin Sulfate Capsules MANUFACTURER STANDARD)**

**250 mg Capsules**

**ANTIBIOTIC**



8250 Décarie Blvd, suite 110  
Montréal, QC  
Canada, H4P 2P5

DATE OF PREPARATION  
January 08, 2001

DATE OF REVISION:

Control No. 100197

**PRESCRIBING INFORMATION****HUMATIN\*****(Paromomycin Sulfate Capsules MANUFACTURER STANDARD)****250 mg Capsules****THERAPEUTIC CLASSIFICATION**

Antibiotic

**ACTION AND CLINICAL PHARMACOLOGY**

HUMATIN (Paromomycin Sulfate) is a broad spectrum aminoglycoside antibiotic produced by *Streptomyces rimosus var. paromomycinus*. The drug is structurally related to neomycin, streptomycin and kanamycin.

It is poorly absorbed after oral administration with almost 100% of the drug recoverable in the stool.

Paromomycin sulfate is considered a luminal or contact amebicide since it acts principally in the intestinal lumen.

Unlike tetracyclines, paromomycin is a direct-acting amebicide and is effective either in the presence or absence of bacteria.

Like other aminoglycosides, paromomycin is bactericidal and appears to inhibit protein synthesis in susceptible bacteria at the 30S segment of the ribosome.

Paromomycin sulfate has a broad spectrum of activity, including activity against protozoa, bacteria and cestodes.

Paromomycin sulfate is active against protozoa, especially *E. histolytica*. The drug is believed to act against both the trophozoite and encysted forms of *Entamoeba*.

Paromomycin sulfate has an antibacterial spectrum quite similar to that of neomycin and is bactericidal to many normal and pathogenic organisms in the gastrointestinal tract. Almost complete cross-resistance exists between paromomycin and kanamycin, neomycin and streptomycin.

### **INDICATIONS AND USAGE**

HUMATIN (Paromomycin Sulfate) is indicated for the treatment of intestinal amebiasis, acute and chronic.

(NOTE--It is not effective in extraintestinal amebiasis).

### **CONTRAINDICATIONS**

Individuals with a history of previous hypersensitivity reactions to HUMATIN (Paromomycin Sulfate). It is also contraindicated in intestinal obstruction.

### **PRECAUTIONS**

The use of HUMATIN (Paromomycin Sulfate), 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.

### **ADVERSE REACTIONS**

Nausea, abdominal cramps and diarrhea have been reported in patients using HUMATIN (Paromomycin Sulfate), on doses over 3 g daily.

### **DOSAGE AND ADMINISTRATION**

Adults and Children: Usual dose of HUMATIN (Paromomycin Sulfate) is 25 to 35 mg/kg body weight daily, administered in 3 doses with meals, for 5 to 10 days.

#### **Capsule Composition**

Each HUMATIN (Paromomycin Sulfate) capsule contains: paromomycin sulfate equivalent to paromomycin 250 mg. Non-medicinal ingredients: Each capsule contains: colloidal silica, magnesium stearate. Capsule shell: yellow iron oxide, black iron oxide, red iron oxide, gelatin and titanium dioxide.

**Stability and Storage Recommendations**

Store HUMATIN (Paromomycin Sulfate) at controlled room temperature 15 - 30°C. Protect from moisture.

**AVAILABILITY OF DOSAGE FORMS**

HUMATIN (Paromomycin Sulfate) capsules are available in the dosage strength of 250 mg per capsule.

Each capsule has a conic snap No1 brown cap and a yellow body with no print.

Available in bottles of 100.

**PHARMACEUTICAL INFORMATION****Drug Substance**

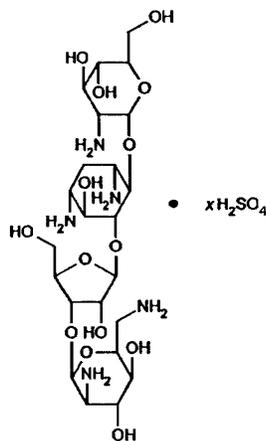
Proper Name: Paromomycin Sulfate

Chemical Name: *O*-2-amino-2-deoxy- $\alpha$ -D-glucopyranosyl-(1 $\rightarrow$ 4)-*O*-[*O*-2,6-diamino-2,6-dideoxy- $\beta$ -L-idopyranosyl-(1 $\rightarrow$ 3)- $\beta$ -D-ribofuranosyl-(1 $\rightarrow$ 5)]-2-deoxy-D-streptamine sulfate(salt).

Empirical Formula:  $C_{23}H_{45}N_5O_{14} \cdot xH_2SO_4$

Molecular Weight: 615.64 (Base)

Structural Formula:



Description: It is a white, amorphous, stable water-soluble product. Paromomycin Sulfate is the sulfate salt of an antibiotic substance or substances produced by the growth of *Streptomyces rimosus var. paromomycinus*, or a mixture of two or more such salts. It has a potency equivalent to not less than 675 µg of paromomycin (C<sub>23</sub>H<sub>45</sub>N<sub>5</sub>O<sub>14</sub>) per mg, calculated on the dried basis.