PRESCRIBING INFORMATION
Including Patient Medication Information

HUMATIN*

(Paromomycin Sulfate Capsules MANUFACTURER STANDARD)

250 mg Capsules

ANTIBIOTIC

ERFA
Canada 2012 Inc.

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

DATE OF PREPARATION
January 08, 2001

DATE OF REVISION: 25-Jan-2019

Control No. 216065

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).

To reduce the development of drug-resistant microorganisms and maintain the effectiveness of HUMATIN* and other antimicrobial drugs, HUMATIN* should be used only to treat infections that are proven or strongly suspected to be caused by susceptible microorganisms. When culture and susceptibility information are available, they should be considered in selecting or modifying antimicrobial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

CONTRAINDICATIONS

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

PRECAUTIONS

Susceptibility/Resistance

Development of Drug Resistant Organisms

Prescribing HUMATIN* in the absence of a proven or strongly suspected microbial infection is unlikely to provide benefit to the patient and risks the development of resistant organisms.

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 coni-snap No1 brown cap and a yellow body with no print.

Available in bottles of 100.

PHARMACEUTICAL INFORMATION

Drug Substance

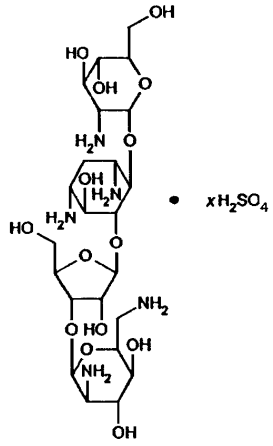
Proper Name: Paromomycin Sulfate

Chemical Name: *O*-2-amino-2-deoxy-α-D-glucopyranosyl-(1→4)-*O*-[*O*-2,6-diamino-2,6-dideoxy-β-L-idopyranosyl-(1→3)-β-D-ribofuranosyl-(1→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 ($C_{23}H_{45}N_5O_{14}$) per mg, calculated on the dried basis.

Patient Medication Information

HUMATIN*

Paromomycin Sulfate Capsules

Read this carefully before you start using HUMATIN*. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about HUMATIN*.

What is HUMATIN* used for?

HUMATIN* is used to treat infections of intestines that are caused by certain parasites.

Drugs like HUMATIN* only treat certain infections. They do not treat viral infections.

How does HUMATIN* work?

HUMATIN* contain an antibiotic. It works by killing or stopping the growth of parasites that cause disease.

What are the ingredients in HUMATIN*?

Medicinal ingredients: paromomycin sulfate

Non-medicinal ingredients: black iron oxide, colloidal silica, gelatin, magnesium stearate, red iron oxide, titanium dioxide, yellow iron oxide.

HUMATIN* come in the following dosage form:

As capsules containing paromomycin sulfate equivalent to 250 mg paromomycin.

Do not use HUMATIN* if you:

- are allergic to paromomycin sulphate
- have an intestinal blockage

To help avoid side effects and ensure proper use, talk to your healthcare professional before you use HUMATIN**.** Talk about any health conditions or problems you may have, including if you:

- are allergic to any other antibiotic
- have ulcers in your bowels
- are pregnant or planning to become pregnant
- are breastfeeding or planning to breastfeed

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take HUMATIN*:

- Swallow HUMATIN* capsules with water.
- Take HUMATIN* with your meals.
- Follow all instructions given to you by your healthcare professional.
- Although you may feel better early in treatment, HUMATIN* should be used exactly as directed.
- Misuse or overuse of HUMATIN* could lead to the growth of microorganisms that will not be killed by HUMATIN* (resistance). This means that HUMATIN* may not work for you in the future.
- Do not share your medicine.

Usual dose of HUMATIN*:

- Your healthcare professional will decide how much HUMATIN* you will be given.
- The dose you are given will be based on your body weight.
- You will take it three times a day with your meals.
- Your healthcare professional will tell you for how long you should take HUMATIN*.

Overdose:

If you think you have used too much HUMATIN*, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

- If you miss a dose of HUMATIN*, take it as soon as you remember.
- If it is almost time for your next dose, skip the missed dose and take your next scheduled dose.
- Never take a double dose to make up for a missed dose.

What are possible side effects from using HUMATIN*?

These are not all the possible side effects you may feel when taking HUMATIN*. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- nausea
- abdominal cramps
- diarrhea.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store HUMATIN* at room temperature (15 to 30°C). Protect from moisture.

Keep out of reach and sight of children.

If you want more information about HUMATIN*:

- Talk to your healthcare professional
- Find the full prescribing information that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (http://hc-sc.gc.ca/index-eng.php); the manufacturer's website (www.eci2012.net), or by calling 1-800-931-3133.

This leaflet was prepared by ERFA Canada 2012 Inc.

Last revision date: 25-Jan-2019