

Humatin®

Composition

Active ingredient: Paromomycin sulfate
Excipients: excipients pro caps

Dosage form and quantity of active principle per unit

1 capsule contains 357.1 mg of paromomycin sulfate (equivalent to 250 mg paromomycin).

Uses

Management of hepatic pre-coma and coma;
Hepatic encephalopathy prophylaxis;
Pre-operative intestinal flora reduction;
Teniasis;
Intestinal amebiasis—acute, sub-acute and chronic
Official guidelines on proper usage of antibiotics should be followed, in particular any guideline on how to prevent an increase of antibiotics resistance.

Posology / How to use

Standard posology

Daily intake in divided doses, given at regular intervals, each intake at 6-8 hours apart

Hepatic pre-coma and coma

Depending on clinical outlook: 35 to 75 mg/kg body weight daily, for 2 to 6 days.

Hepatic encephalopathy prophylaxis

750-1000mg daily, posology and duration will be based on severity of symptoms

Pre-operative intestinal flora reduction

It is recommended to administer two days before surgery, 4.0g daily. In case of orthograde intestinal cleansing, 8.0g per dose 1 hour after the cleansing.

Teniasis

If body weight is less than 50kgs: 75.0mg/kg of body weight; if body weight is more than 50kgs: 4.0g of body weight. The intake can be administered in one dose or in divided doses over one hour.

Intestinal amebiasis—acute, sub-acute and chronic

Recommended daily intake: 25 (-100) mg/kg of body weight for a minimum of 5 days (up to 10 days).

Method of intake: Oral administration of Humatin capsules with some liquid.

Contraindications

Contraindicated in individuals with a history of previous hypersensitivity reactions to aminoglycoside antibiotics and in case of severe renal failure, intestinal obstruction, intestinal occlusion, pseudo-paralytic myasthenia gravis.

Humatin must not be used during pregnancy and breast-feeding.

Warnings and precautions

The drug should be used with caution in individuals with ulcerative lesions of the bowel to avoid inadvertent absorption.
Even though it is almost not absorbed, Humatin must be used with caution in individuals with mild renal failure, especially of intakes over a long period of time.
Constant observation of the patient's serum creatinine and urine sediments, as well as auditory acuity is necessary.
In case of long-lasting treatment, e.g. Hepatic encephalopathy prophylaxis, auditory acuity must also be controlled since ototoxic effect cannot be ruled out completely. If necessary, treatment should be stopped.

Drug interactions

Gastro-intestinal intake of digoxin may be affected by paromomycine sulfates. Caution should be used is case of simultaneous usage of these two drugs.

Pregnancy / breast feeding

No controlled studies in animal or pregnant woman are available.
Usage of paromomycine is not indicated during pregnancy. Because systemic effect cannot be entirely ruled out, embryotoxic / teratogenic risk during the 1st trimester and fetotoxic risk during the 2nd and 3rd trimesters cannot be ruled out. Toxic lesions of auditory system are possible throughout the pregnancy.
Because it is not yet fully certain some amount of the drug will not migrate to breast-milk, breast-feeding should be avoided during intake of the paromomycin.

Effect on driving and using of machinery

Because of its potential side-effects (vertigo, nausea), Humatin might alter capacity to focus. In case of undesirable side-effects, caution is to be used when driving or using heavy machinery.

Side effects

Infections and infestations
The use of this antibiotic may result in an overgrowth of non-susceptible organisms, including yeasts and fungi. Constant bacteriological observation of the patient is essential, appropriate measures should be taken if necessary.

Blood and lymphatic circulation

Eosinophilia cases have been reported

Metabolism and nutritional side effects

Malabsorption of xylose and saccharose, as well as abnormal lipid metabolism, have been reported.

Nervous system side effects

Cases of headaches and dizziness have been observed.

Gastrointestinal side effects

Frequent: Diarrhea.

Rare–Uncommon: nausea, vomiting, loss of appetite, abdominal discomfort, abdominal cramps.
Very rare: Pancreatitis.

Occurrence of diarrhea during, of after, treatment with paromomycin, especially if severe and lasting, can be symptomatic of a pseudo-membranous colitis caused by antibiotics, which should be immediately treated. In such an occurrence, antiperistaltics are contra-indicated.

Cutaneous and sub-cutaneous tissues side effects

Rarely, cases of exanthema and urticaria have been reported (allergic reaction/contact allergy). In such cases, treatment must be stopped immediately and adequate emergency measures must be implemented (e.g. administering of antihistamines)

Renal and urinary side effects

Very rare: Non-explained hematuria.
Renal symptoms might appear after inadvertent absorpion of paromomycin thru ulcerative lesions of the bowel.

Overdose

Overdose reactions have not been reported to this day, because of the very low level of absorption thru gastrointestinal tract, therefore there is no reason to apprehend this occurrence.

Properties / effects

Code ATC: AC07AA06

Pharmacodynamics / Action

Paromomycin, the active ingredient of Humatin, is an aminoglyside antibiotic for action on the bowels, it is efficient against Gram-negative and Gram-positive germs, as well as against aerobic and anaerobic germs.
As with other aminoglycoside antibiotics, its action is to inhibit biosynthesis of bacterial proteins. This action results in targeting of 30s bacteria ribosomal subunits.
Humatin greatly decreases the ammoniacogen intestinal flora, relieving the liver.
Due to its amebiacid action, paromomycin proved to be effective in treating intestinal amebiasis. Furthermore, it has also proven to be effective in case of teniasis (tapeworm infection)

Pharmacokinetics

Paromomycin is almost not absorbed thru gastrointestinal tract. Most of the oral dose is recoverable in the feces; about 0.1% of the daily dose is found in urine. In cases of gastrointestinal motility disorders, or of ulcerative lesions of the intestine, there is a possibility of absorption. The absorbed fraction will be slowly eliminated thru the kidneys. In case of renal disorder, a build up is possible.

Preclinical data

As with other aminoglyside, paromomycin can also have ototoxic and nephrotoxic effects and provoke a rise in hepatic enzymes and a toxic or allergic alteration of the blood composition.

Notes

Impact on diagnosis
During Humatin treatment, xylose absorpion test should not be run.

Stability

The drug should not be used beyond the date shown on the packaging with the wordings “Exp.”

Storage

Humatin capsules must be stored at controlled room temperature 15°–25°C

Authorization number

25229 (Swissmedic)

Authorization holder
Pfizer SA, Zurich.

Date update date (Switzerland)
August 2006

Humatin®

成分

主要活性元素：Paromomycin sulfate

賦形劑：賦形劑前膠囊

制劑形態和每單位的主要活性元素

1 膠囊內含 357.1 毫克 Paromomycin sulfate (相當於 250.0 毫克 Paromomycin)

適應症

肝昏迷；
肝性腦病的預防；
減少手術前的腸道菌量；
條蟲病；
急性、亞急性和慢性腸道阿米巴感染症。
應遵守官方規定之抗生素正確用法，以避免對抗藥性之增加。

使用劑量／方法

常用劑量

每日劑量應該間隔 6-8 小時分次服用。

肝昏迷

每日依體重施以 35-75 毫克／公斤的劑量。
治療期限：2-6 天。

肝性腦病變的預防

每日 750-1500 毫克；視症狀的嚴重性調整治療劑量和期限。

減少手術前的腸道菌量

在手術前二天建議每日服用 4.0 公克。若是進行腸道灌洗，在灌洗結束 1 小時後一次服用 8.0 公克。

條蟲病

體重低於 50 公斤者：依體重施以 75.0 毫克 /公斤；
體重高於 50 公斤者：4.0 公克。可以一次或每間隔 1 小時分多次服用所需要的劑量。

急性、亞急性和慢性腸道阿米巴感染症

每日建議劑量：依體重施以 25(-100)毫克／公斤，最少連續 5 日(最多 10 日)。

正確服用方法

Humatin 膠囊配開水口服。

禁忌

對 aminoglycoside 類抗生素過敏者、腎衰竭、腸阻塞及假性麻痺性重症肌無力，不得使用 Humatin。
懷孕和哺乳期間不得使用 Humatin。

注意事項

對腸道羅息潰瘍性病變之病患，應該謹慎使用 Humatin，因為可能會造成意外之腸道吸收。
即使 Humatin 幾乎不能被吸收，對於輕微腎功能異常的患者仍應該謹慎使用 Humatin。特別是長期用藥時，更需要監督血清肌酸酐、尿液沈渣和聽力。
長期治療時，例如預防肝性腦病變時，也必需定期追蹤聽力，因為此藥可能具有耳毒性。如有不適，應停止用藥。

干擾

可能會干擾 digoxin 在腸胃道的吸收。同時服用此兩種藥物時應特別留心。

懷孕／哺乳

無動物實驗或懷孕婦女相關的研究資料。
懷孕期間禁止使用 Humatin。第一孕期時致畸胎的風險及第二、第三孕期時危害胎兒的風險無法排除。懷孕時使用也可能造成聽力受損。
由於不確定藥物是否會進入母乳內，所以在哺乳期間應該停止使用 Humatin。

駕駛和機器操作能力的影響

Humatin 產生的潛在不良反應(頭暈、噁心)可能會降低集中力。因此，駕駛或操作機器時應該特別謹慎。

副作用

感染

長期服用此藥時，可能會導致對此藥不具感受性的微生物增生(包括真菌或黴菌的入侵)。建議持續監控，以便必要時採取進一步的治療。

血液和淋巴循環

曾經有嗜酸性白血球增多症的病例被報告。

新陳代謝和營養吸收不良

曾有木糖和蔗糖吸收不良的病例被報告。
曾有血脂代謝異常的病例被報告。

神經系統

曾觀察到使用者出現頭疼和暈眩。

腸胃道

常見的：腹瀉。
少見的 – 偶而的：噁心、嘔吐、食慾不振、胃痛、腹部痙攣。
十分罕見的：胰臟炎。

Humatin 治療期間或之後出現腹瀉，特別是嚴重而持久的腹瀉，可能是抗生素引起的假膜性結腸炎，應該立即治療。此時，不能使用抑制腸道蠕動的藥物。

皮膚或皮下組織

少見，曾經有數例皮疹和蕁蕁疹的病例被報告(過敏反應)。若發生應該立即停止治療，並採取相關的緊急措施（如服用抗組織胺藥物）。

腎臟和泌尿系統

十分少見：不明原因的血尿。
經由腸道的潰瘍意外吸收 Humatin 後可能危害腎臟。

用藥過量

至目前為止無用藥過量之案例，因為經由腸胃道吸收的量極少，因此無需擔憂。

特性／功效

ATC 編號：A07AA06

藥劑學／作用原理

Humatin 主要成份 paromomycin 是 aminoglycoside 類的抗生素，主要作用於腸道，能有效對抗革蘭氏陰性菌、好氧和厭氧細菌。
如一般 aminoglycoside 類的抗生素，此藥能抑制細菌蛋白質的合成。因為該抗生素能附著於細菌的核糖體。

Humatin 大大降低腸道產生 ammonia 的細菌量並減少肝臟的負擔。
因其抗阿米巴原蟲的作用，Humatin 可有效治療腸道阿米巴感染症。且也可以用來對抗條蟲病(條蟲感染)。

藥物代謝

Humatin 幾乎不會在腸胃道中被吸收。絕大部份的劑量口服後會原封不動地經由糞便排出；每日約有 0.1%的劑量會出現在尿液中。腸胃運動機能障礙、腸道受損或潰瘍的患者，才可能吸收此藥。被吸收的劑量只能透過腎臟慢慢被排除。當腎臟功能有障礙時，就有可能會在體內累積。

前臨床資料

和其他 aminoglycoside 類一樣，有耳毒性和腎毒性，並造成肝指數上升及改變血液的中毒和過敏結構。

特別備註

診斷方式的影響

使用 Humatin 治療期間，不要進行木糖吸收試驗

穩定性

請在藥罐註明之有效期限內使用該藥品。有效期限以«Exp.»標示。

保存方式

Humatin 膠囊應該在常溫下保存(15-25°C)。

許可字號

25229 (Swissmedic)。

許可證持有人	代理商
輝瑞藥廠，蘇黎世。	FARMA MONDO SA
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