HIH13-01

Humatin®

成分

活性物質

Paromomycinum ut paromomycini sulfas。

賦形劑

無水二氧化矽膠體、硬脂酸鎂、二氧化鈦、黃色氧化鐵、黑色氧化鐵、紅色氧化鐵、明膠、蟲膠、丙二醇(E 1520)、simeticonum。

每單位藥物劑型和活性物質含量

硬膠囊。

1粒硬膠囊含有357.2毫克paromomycin sulfate (相當於250.0毫克paromomycin base)。白色至奶油色/淺黃色粉末，裝於附棕色蓋、黃色主體和白色«Parke-Davis»印記的膠囊中。

適應症/用途

肝昏迷前期和肝昏迷。

預防肝原性腦病變。

術前減少腸道菌叢。

絛蟲病。

急性、亞急性和慢性形式的腸道阿米巴性痢疾。

必須尊重關於適當使用抗生素的官方建議，尤其是預防抗生素抗藥性增加的施用建議。

用量/用法

常用劑量

在每種情況下，每天劑量應以6-8小時的間隔分次服藥。

肝昏迷前期和肝昏迷

根據臨床表現的嚴重性，成人和兒童每天每公斤體重接受35-75毫克paromomycin。治療時間：2-6天。

預防肝原性腦病變

每日750-1500毫克；治療的劑量和持續時間必須根據症狀的嚴重性而定。

術前減少腸道菌叢

建議在手術前兩天每天服用4.0 g Humatin。

對於順行浣腸，應在浣腸結束後1小時給予單一劑量8.0克。

絛蟲病

體重小於50公斤：75.0毫克/公斤體重；體重超過50公斤：4.0克。所需劑量可以單一劑量給藥或在一小時內服用。

急性、亞急性和慢性形式的腸道阿米巴性痢疾

成人：建議每天劑量：25 (-100)毫克/公斤體重，持續至少5天(至10天)。

兒童：建議每天劑量爲25-35毫克/公斤，持續至少5至10天。

建議將每天劑量分三次於餐後服用。

給藥途徑

Humatin硬膠囊與少量液體一起服用。

禁忌症

已知對paromomycin、胺基糖苷類抗生素或任何成分過敏的病人禁用paromomycin。嚴重腎功能不全、腸梗阻、腸阻塞和重症肌無力病人禁用paromomycin。Humatin不適用於傷寒或其他全身性沙門氏菌感染，因為實際上沒有任何藥物是由腸道吸收。出於同樣的原因，在腸外阿米巴性痢疾的情況下不應給予本藥品。懷孕或哺乳期間不得使用paromomycin。

警語和注意事項

應謹慎對患有腸道潰瘍性病灶的病人使用humatin，因為在這些情況下有時可能會發生非預期的吸收。即使paromomycin幾乎不被吸收，也應對輕度腎功能不全病人謹慎使用humatin。特別是在長期使用時，建議監測血清肌酸酐和尿液沉渣以及病人的聽力。關於長期治療(例如，作為肝原性腦病變的預防措施)，應時不時測試聽力，因為不能肯定地排除耳毒性作用。如有必要，必須停用本藥品。

交互作用

Digoxin的消化道吸收可能會受到paromomycinsulfate的干擾。建議在同時服用兩種物質時請謹慎使用。

懷孕、哺乳

懷孕

沒有針對動物或孕婦的研究。

懷孕期間禁用paromomycin。由於不能完全排除全身性影響，因此不能排除在第一孕期時的胚胎毒性/致畸風險，也不能排除第二和第三孕期的胎兒毒性風險。在整個懷孕期間都可能對聽力造成毒性損害。

哺乳

由於尚不清楚該物質是否進入母乳，如果母親正在接受paromomycin的治療，則不得哺乳。

對駕駛及操作機械能力之影響

由於可能的副作用(眩暈、噁心)，paromomycin治療期間反應性可能會受損。因此，駕駛或操作機械時應謹慎。

不良作用

頻率約定

非常常見(≥1/10)、常見(≥1/100、<1/10)、不常見(≥1/1000、<1/100)、罕見(≥1/10000、<1/1000)，非常罕見(<1/10000)。

感染及寄生蟲感染

關於長期使用，不能排除抗藥性病原體(包括酵母菌和黴菌)過度增生的可能性。因此建議進行細菌檢查，以便採取相應的措施。

血液及淋巴系統異常

曾通報發生嗜酸性白血球增多症。

代謝及營養異常

曾通報發生木糖和蔗糖吸收不良，以及脂肪代謝異常。

神經系統異常

已觀察到頭痛、眩暈。

胃腸道異常

常見：腹瀉。

罕見：噁心、嘔吐、食慾不振、腹痛和痙攣。

非常罕見：胰臟炎。

如果在paromomycin治療期間或治療後出現持續嚴重的腹瀉，則其可能表現為抗生素相關性偽膜性大腸炎，需要立即治療。在這種情況下，禁止使用抑制蠕動的製劑。

皮膚和皮下組織異常

曾通報罕見的紅斑、蕁麻疹(過敏反應/交叉過敏)。在這種情況下，必須立即停止paromomycin治療並採取適當的緊急措施(例如抗組織胺類藥物)。

腎臟及泌尿系統異常

非常罕見：不明原因的血尿。

經腸道潰瘍性病灶而無意間吸收的paromomycin可能會導致腎臟損傷。

過量

到目前為止尚未曾通報關於過量的表徵，且因為由消化道吸收的量很微量，因此預期不會發生。

屬性/效應

ATC代碼

A07AA06

作用機轉

Paromomycin是Humatin中的活性物質，是一種腸道特異性胺基糖苷類抗生素，可對抗革蘭氏陰性和革蘭氏陽性、需氧和厭氧病原體。

與大多數胺基糖苷類抗生素一樣，其藉由將抗生素與細菌核醣體的30 S次單元相結合，抑制細菌蛋白質的生物合成。

Humatin大大減少了產氨腸道菌叢，因而減輕了肝臟的負擔。

由於其具有殺阿米巴作用，paromomycin經證明可用於治療腸道阿米巴痢疾。此外，此物質對絛蟲病(絛蟲感染)有效。

藥效學

無資訊。

臨床療效

無資訊。

藥物動力學

吸收

幾乎沒有paromomycin從消化道吸收。

分佈

無資訊。

代謝

無資訊。

排除

大多數口服劑量在糞便中似乎沒有發生變化；大約0.1%的每日劑量會存在尿液中。

特定病人族群的動力學

如果胃腸運動性受損或腸道有損傷或潰瘍，則有可能會吸收。任何吸收的藥物都會經由腎臟緩慢排出體外。如果腎功能不全，則可能會發生堆積。

臨床前資料

說到其他胺基糖苷類藥物，paromomycin可能具有耳毒性和腎毒性。其會導致肝臟酵素濃度升高以及血液相的毒性和過敏性改變。

其他資訊

對診斷方法的影響

在接受Humatin治療期間不得進行木糖吸收測試。

架貯期

若已超過容器上所聲明之到期日(«EXP»)，請勿使用本藥品。

儲存特別注意事項

以原始容器儲存在室溫(15-25°C)下，並置於兒童拿不到的地方。

保存在密閉容器中。

包裝

含250毫克的硬膠囊：16。

內文修訂日期

2021年3月。

LPD V007

This Artwork is property of :	
Type: Circular	Front Color
Product name: Humatin	K
Item code: HIH13-01	Back Color
Pharma code:	K
Size: 140x400 m/m	
Date(mm/dd/yy): 05/04/22 10:00	
Long Yih Printing Company TEL : (02) 77091988 0935874015	**WARNING:** Proof color may not reflect true Pantone color. Artworks may not be altered.

140mm

400mm

Humatin®

Composition

Active substances

Paromomycinum ut paromomycini sulfas.

Excipients

Silica colloidalis anhydrica, magnesii stearas, titanii dioxidum, ferrum oxydatum flavum, ferrum oxydatum nigrum, ferrum oxydatum rubrum, gelatina, lacca, propylenglycolum (E 1520), simeticonum.

Pharmaceutical form and active substance quantity per unit

Hard capsule.

1 hard capsule contains 357.2 mg paromomycin sulfate (corresponding to 250.0 mg paromomycin base). White to cream coloured/light yellow powder in a capsule with brown cap, yellow body and white «Parke-Davis» imprint.

Indications/Uses

Hepatic pre-coma and coma.

Prophylaxis against hepatogenic encephalopathy.

Preoperative reduction of the intestinal flora.

Taeniasis.

Acute, subacute and chronic forms of intestinal amoebiasis.

Official recommendations for the appropriate use of antibiotics have to be respected, especially the application advices for prevention of increase of antibiotic resistance.

Dosage/Administration

Usual dosage

In each case, the daily dose should be taken in divided doses at 6-8 hourly intervals.

Hepatic pre-coma and coma

Depending on the severity of the clinical picture, adults and children receive 35-75 mg paromomycin per kg bodyweight daily. Duration of treatment : 2-6 days.

Prophylaxis against hepatogenic encephalopathy

750-1'500 mg a day ; the dose and duration of treatment must be oriented to the severity of the symptoms.

Preoperative reduction of the intestinal flora

It is recommended that 4.0 g of Humatin are given daily on the two days immediately before the operation.

With orthograde intestinal lavage, 8.0 g should be given as a single dose 1 hour after the end of the lavage.

Taeniasis

Body weight less than 50 kg : 75.0 mg/kg bodyweight ; bodyweight of more than 50 kg : 4.0 g. The required dose may be given as a single dose or taken within a period of one hour.

Acute, subacute and chronic forms of intestinal amoebiasis

Adults : Recommended daily dose : 25 (-100) mg/kg bodyweight for at least 5 days (till 10 days).

Children : recommended daily dose 25-35 mg/kg for at least 5 to 10 days.

It is recommended to take the daily dose in three intakes with the meals.

Mode of administration

Humatin hard capsules are taken with a little liquid.

Contraindications

Paromomycin is contraindicated with known hypersensitivity to paromomycin, aminoglycoside antibiotics or to any of the ingredients. Paromymicin is contraindicated in patients with severe renal insufficiency, intestinal obstruction, ileus and myasthenia gravis.

Humatin is not indicated in cases of typhoid fever or other systemic Salmonella infections, since practically none of the drug is absorbed from the intestinal tract. For the same reason, the product should not be given in cases of extraintestinal amoebiasis.

Paromomycin may not be used during pregnancy or lactation.

Warnings and precautions

Humatin should be used with caution in patients with ulcerative lesions of the intestinal tract, since unwanted absorption may sometimes occur in these cases.

Even though paromomycin is virtually not absorbed, Humatin should also be used with caution in patients with mild renal insufficiency. Especially with long-term use, it is recommended that serum creatinine and urinary sediments are monitored as well as the patient's hearing.

With long-term treatment e.g. as a prophylactic against hepatogenic encephalopathy, hearing should be tested from time to time, as an ototoxic effect cannot be ruled out with certainty. If necessary, the product must be discontinued.

Interactions

The gastrointestinal absorption of digoxin may be disturbed by paromomycinsulfate. Caution is advised in case of simultaneous administration of both substances.

Pregnancy, lactation

Pregnancy

No studies in animals or pregnant women are available.

The use of paromomycin is contraindicated during pregnancy. Since a systemic effect cannot be completely ruled out, an embryotoxic/teratogenic risk cannot be excluded in the first trimester neither a fetotoxic risk in the second and third trimesters. Toxic damage to hearing is possible during the entire pregnancy.

Lactation

Since it is unclear whether the substance enters breast milk, the child should not be nursed if the mother is being treated with paromomycin.

Effects on ability to drive and use machines

Due to the possible side effects (vertigo, nausea) the reactivity may be impaired during paromomycin therapy. Therefore, caution should be excercised while driving or operating machinery.

Undesirable effects

Frequency conventions

Very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1'000, <1/100), rare (≥1/10'000, <1/1'000), very rare (<1/10'000).

Infections and infestations

With long-term use, the possibility of overgrowth of resistant pathogens (including yeasts and fungi) cannot be ruled out. Bacteriological checks are therefore recommended so that the corresponding measures may be introduced.

Blood and lymphatic system disorders

Eosinophilia has been reported.

Metabolism and nutrition disorders

Malabsorption of xylose and sucrose, and abnormal fat metabolism has been reported.

Nervous system disorders

Headache, vertigo has been observed.

Gastrointestinal disorders

Common : diarrhoea.

Rare-uncommon : nausea, vomiting, loss of appetite, abdominal pain and cramps.

Very rare : pancreatitis.

If persistent, serious diarrhea occurs during or after therapy with paromomycin, it may be expression of an antibiotic-associated pseudomembraneous colitis, which requires immediate treatment. Peristalsis-inhibiting preparations are contraindicated in such cases.

Skin and subcutaneous tissue disorders

Rarely exanthema, urticaria has been reported (allergic reactions/crossallergy). In such cases, therapy with paromomycin must be withdrawn immediately and appropriate emergency measures (e.g. antihistamines) taken.

Renal and urinary disorders

Very rare : unexplained hematuria.

Renal damage may occur with inadvertent absorption of paromomycin through ulcerative lesions of the intestinal tract.

Overdose

Manifestations of overdose have not been reported to date, and are not to be expected because of the very slight absorption from the gastrointestinal tract.

Properties/Effects

ATC code

A07AA06

Mechanism of action

Paromomycin, the active substance in Humatin, is an intestinal-specific aminoglycoside antibiotic that acts against Gram-negative and Gram-positive, aerobic and anaerobic pathogens.

Like the majority of aminoglycoside antibiotics, it acts by inhibiting bacterial protein biosynthesis, through binding of the antibiotic to the 30 S subunits of the bacterial ribosomes.

The ammonia-forming intestinal flora is greatly reduced by Humatin and the load on the liver thus lessened.

Because of its amoebicidal effects, paromomycin has proved of use in the treatment of intestinal amoebiasis.

In addition, the substance is effective in cases of taeniasis (tape worm infestation).

Pharmacodynamics

No information.

Clinical efficacy

No information.

Pharmacokinetics

Absorption

Practically no paromomycin is absorbed from the gastrointestinal tract.

Distribution

No information.

Metabolism

No information.

Elimination

Most of an oral dose appears unchanged in the faeces ; approximately 0.1% of the daily dose is found in the urine.

Kinetics in specific patient groups

There is a possibility of absorption if gastrointestinal motility is impaired or there is injury or ulceration of the intestine. Any absorbed drug is slowly excreted via the kidneys. Accumulation may occur if renal function is impaired.

Preclinical data

As for other aminoglycosides, paromomycin may be ototoxic and nephrotoxic. It can lead to increased levels of liver enzymes and to toxic and allergic alterations of the hemogram.

Other information

Effects on diagnostic methods

A xylose absorption test should not be performed during treatment with Humatin.

Shelf life

Do not use this medicine after the expiry date («EXP») stated on the container.

Special precautions for storage

Store at room temperature (15-25°C) in original container and out of reach of children.

Keep in tightly closed container.

Authorisation number

Packs

Hard capsules containing 250 mg : 16.

Marketing authorisation holder

Date of revision of the text

March 2021.

LPD V007