APPROVED
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INSTRUCTION
for medical use

PYRANTEL

Composition:
active substance: pyrantel pamoate;
1 tablet contains pyrantel pamoate equivalent to pyrantel 250 mg;
excipients: povidone, amylum maidis, croscarmellose sodium, microcrystal cellulose, magnesium stearate, colloidal anhydrous silicon dioxide.

Pharmaceutical form. Tablets.
General physical and chemical properties: capsule-shaped yellow tablets with the breakline on one side.

Pharmacotherapeutic group. Anti parasitic agents, insecticulor, insectifuge
Anti helmint agents. Code ATX P02C C01.

Pharmacological properties.
Pharmacodynamics.
Pyrantel is an antihelmint agent. Active against *Enterobius vermicularis*, *Ascaris lumbricoides, Ancylostoma duodenale* and *Necator americanus*. Pyrantel causes neuro-muscular blockade paralyzing the helmints so that they are excreted through the intestinal peristalsis with stool. Pyrantel is an active against sensitive and mature forms of immature helmints. There is no effect on larvae of helments that migrate through tissues.
Pharmacokinetics.
Intestinal resorption of pyrantel is very low. After using the drug, plasma concentration is very low (0,05-0,13 mg / ml) and reaches its maximum within 1-3 hours. Up to 93% of the drug is excreted unchanged in the stool. Less than 7% found in the urine in unchanged and as metabolites.

Clinical characteristics.
Indications.
Enterobiasis, ascaridiasis, ancylostomiasis.

Contraindications.
Hypersensitivity to any components of the drug.

Interaction with other medicinal products and other forms of interactions.
Do not use with piperazine, which is an antagonist of anthelmintic action of pyrantel.

Administration details.
In case of hepatic failure it is recommended to reduce the dosage.
Enterobiasis: to prevent reinfection, strict hygienic measures should be taken: the perianal area should be cleaned daily, the fingernails should be cleaned several times a day. Children's fingernails should be cut short. The underwear and pyjamas should be changed regularly. Prevent combing hair. It is recommended to treat the whole family simultaneously, because the infection is often without symptoms.

Usage during pregnancy and lactation.
In the absence of teratogenic effects in animals Pyrantel congenital malformations in humans are not expected. Currently, clinically was not confirmed congenital malformations or fetotoxicity effects of pyrantel. However, monitoring the use of pyrantel during pregnancy is insufficient to exclude all possible risks. Thus, the drug can be used during pregnancy only if it is absolutely necessary after careful evaluation of the benefit for female/risk to the fetus, which is determined by the physician. Therefore the absence of published studies about the undesired effect of pyrantel on children who are breastfed and despite on the very low absorption of the drug pyrantel, the use of the drug is possible, if it is necessary, after consultation with the physician.

Effects on ability to drive and operate machinery.
The adverse reactions of the nervous system, can sometimes be observed in the treatment by pyrantel may influence the reaction rate while driving and ability to work on other machines.

Administration and dosage.
The drug may be taken at any time, there is no need to abstain from food and take purgative agents before taking the drug.
Enterobiasis and ascaridiasis.
While the treatment of enterobiasis and ascaridiasis usually the dosage is 10 mg/kg to 12 mg/kg single-use.
Children from 6 years: 1 tablet per 20 kg of body weight as single dose.
Adults with body weight less than 75 kg: 3 tablets as single dose.
Adults with body weight more than 75 kg: 4 tablets as single dose.
In case of enterobiasis, to full excreted parasites, strict hygienic measures should be taken, and the whole family should be treated simultaneously. To avoid repeated autoinfection it is recommended to take repeated dose 3 weeks after the first intake.
Ancylostomiasis.
In endemic areas in case of contamination *Necator americanus* or massive invasion *Ancylostoma duodenale* the dosage is 20 mg/kg per day (1 or 2 doses) during 2-3 days.
Children from 6 years: 1 tablet per 10 kg of body weight per day.
Adults with body weight less than 75 kg: 6 tablets per day.
Adults with body weight more than 75 kg: 8 tablets per day.
In case of temper contamination with *Ancylostoma duodenale* (which usually occurs in non-endemic areas), it may be enough to take 10 mg/kg as single dose.

Children.
Prescribe to children aged 6 years. Children under 6 years is desirable to use the drug in the form of suspension.

Overdose.
Due to the low coefficient of absorption, plasma drug concentrations are low. Overdose causes some gastrointestinal disorders (such as nausea, vomiting, diarrhea) and minor temporary disorders of the central nervous system (such as asthenia, dizziness, headache). Sometimes overdose increases the level of liver transaminases (AST). Specific antidotes are unknown.

Immediate gastric lavage is recommended, as well as monitoring of functions of the respiratory and cardiovascular systems. The treatment is symptomatic.

Adverse reactions.
Gastrointestinal tract: epigastric pain, abdominal pain, nausea, vomiting, diarrhea, anorexia; abdominal cramps, tenesmus.
Hepatobiliary system: decreased or temporary increased liver transaminase level.
Nervous system: headache, dizziness, somnolence, increased fatigue, insomnia, fatigue.
Skin and subcutaneous tissue: skin rash, itching, urticaria.
Immune system: hypersensitivity reactions.

Shelf-life. 3 years.

Storage conditions.
Store below 25 °C in the original pack.
Keep it out of reach of children.

Package.
3 tablets are in a blister, 1 blister is in a carton package.

Conditions of supply.
Without prescription.

Manufacturer.
Kusum Healthcare Pvt Ltd.

Address:
SP-289 (A), RIICO Industrial area, Chopanki, Bhiwadi, Dist. Alwar (Rajasthan), India.

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