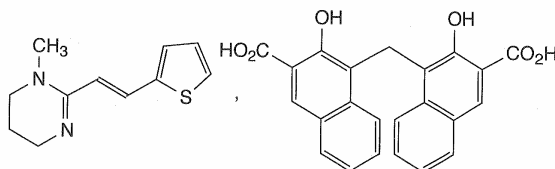


PRODUCT INFORMATION

Name of the Medicine

Active ingredient: Pyrantel (embonate)

Chemical name: 1,4,5,6-tetrahydro-1-methyl-2-[(e)-2-(2-thienyl)vinyl] pyrimidine 4,4' methylenebis (3-hydroxy-2-naphthoate). (1:1)



Molecular formula: $C_{11}H_{14}N_2S, C_{23}H_{16}O_6$

Molecular weight: 594.7

Description

A pale-yellow to yellow coloured, odourless, tasteless crystalline powder. Practically insoluble in water and methanol; soluble in dimethyl sulphoxide.

Each Anthel 125 tablet contains 125 mg of pyrantel. Anthel 125 tablets also contain the following inactive ingredients: disodium edetate, citric acid – anhydrous, ethylcellulose, sunset yellow FCF CI15985, sodium starch glycolate, magnesium stearate, silica - colloidal anhydrous, guar gum.

Each Anthel 250 tablet contains 250 mg of pyrantel. Anthel 250 tablets also contain the following inactive ingredients: disodium edetate, citric acid – anhydrous, ethylcellulose, cellulose – microcrystalline, sunset yellow FCF CI15985, sodium starch glycolate, magnesium stearate, silica - colloidal anhydrous, guar gum, starch - pregelatinised maize.

Pharmacology

A small proportion of a dose of pyrantel embonate is absorbed from the gastrointestinal tract. Up to about 7% is excreted as unchanged drug and metabolites in the urine but over half of the dose is excreted in the faeces.

Anthel is a single dose anthelmintic agent for the treatment of threadworm (*Enterobius vermicularis*), the common roundworm (*Ascaris lumbricoides*), and hookworm (*Necator americanus*, *Ancylostoma duodenale*) in children and adults. It acts against helminths as a neuro muscular blocking agent which has a paralysing effect resulting in eradication of the invading parasite population. The anthelmintic effect of pyrantel may be antagonised by piperazine.

Indications

Single dose treatment of threadworm, the common roundworm and hookworm infestations in children and adults.

The presence of an infestation in one member of a family or group of persons in close proximity may indicate unidentified infestations in other members. Anthel is recommended for all family or group members. Care must be taken that living quarters and clothing be rigorously cleaned in order to destroy helminth ova and thus prevent reinfection.

Contraindications

Anthel should not be administered to persons with acute liver disease.

Precautions

Use in Pregnancy (Category B2)

Although extensive animal studies have revealed no teratogenic effects, use of Anthel during pregnancy should be avoided where possible.

Australian categorisation definition of Category B2. Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of foetal damage.

Use in Lactation

Safety for the use of this drug during lactation has not been established.

Adverse Effects

Anorexia, nausea, vomiting, abdominal discomfort or cramps, diarrhoea, headache, dizziness, drowsiness, insomnia, fatigue and rash have been infrequently reported. Minor abnormalities of liver function have occasionally been associated with treatment.

Dosage and Administration

Paediatric and Adult. Dosage is based on body weight. The single dose should be administered on the basis of 10 mg pyrantel base/kg.

For Young Children. Tablet can be crushed and mixed with jam or honey before administering.

Anthel may be administered at any time of day and purging is not necessary prior to or during therapy

Presentation and Storage Conditions

Anthel 125, 125 mg pyrantel tablet: yellow, scored one side; bottles of 6 and 18.

Anthel 250, 250 mg pyrantel tablet: oblong, yellow, scored one side; bottles of 6.

Store below 30°C.

Poison Schedule of the Medicine

S2 – Pharmacy Medicine

Name and Address of the Sponsor

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Date of Approval

Approved by the Therapeutic Goods Administration on 18 February 2008.