PRODUCT LITERATURE

WORMNIL SUSPENSION 250MG/5ML

Each 5 ml contains:
Pyrantel Pamoate
equivalent to Pyrantel USP 250 mg

Preservatives
Methyl Paraben 0.1% w/v
Propyl Paraben 0.01% w/v

Description
Yellow, viscous suspension with fruity odour and sweet taste.

Pharmacodynamics Properties
Pyrantel Pamoate binds to an ion channel that forms a nicotinic acetylcholine receptor on the body muscle of nematodes. Binding to the recognition site of this excitatory receptor induces entry of calcium which in turn leads to depolarization and spastic paralysis of the nematode muscle that can result in passive expulsion of the worm from the host's gastrointestinal tract. Because pyrantel causes paralysis of the worms prior to expulsion, they are typically expelled intact, which makes it useful as a tool for identifying all morphologic features of adult parasites. Such information may be useful for epidemiologic and clinical investigations

Pharmacokinetics Properties
Pyrantel is poorly and incompletely absorbed from the gastrointestinal tract, with a time to peak concentration of between 1 and 3 hours. The drug is partially metabolized in the liver and a small percentage is excreted in the urine while the majority is eliminated unchanged in the feces.

Indication
For the eradication of round worm, pin worm and hook worm, as a single or mixed infestation.

Recommended Dose
As a single dose

6 months – 2 years	:	2.5 ml – 5 ml
2 – 6 years	:	5 ml
6 – 12 years	:	10 ml
Above 12 years	:	15 ml

Route of administration
Oral.

Contraindication
Risk-benefit should be considered when the following medical problem exists
Hypersensitivity to pyrantel
Liver disease
Note: Worsening of pre-existing myasthenia gravis has been reported in one patient.

Warning and Precautions
Pregnancy/Reproduction
Pregnancy;
Adequate and well-controlled studies in humans have not been done. However, the use of pyrantel during pregnancy is not recommended.
Studies in animals have not shown that pyrantel causes adverse effects in the fetus.

Breast-feeding
Pyrantel is poorly and incompletely absorbed from the gastrointestinal tract and resulting maternal serum concentrations are low (0.05 to 0.13 mcg/mL). Therefore, it is unlikely that significant amounts of pyrantel would be excreted in breast milk. Problems in humans have not been documented. However, the Canadian manufacturer recommends discontinuing breast-feeding while on pyrantel therapy.

Pediatrics
Appropriate studies on the relationship of age to the effects of pyrantel have not been performed in children up to the age of 2. However, no pediatrics-specific problems have been documented to date.

Geriatrics
No information is available on the relationship of age to the effects of pyrantel in geriatric patients.

Interactions with Other Medicaments
Piperazine (may antagonize the anthelmintic effects of pyrantel; concurrent use is not recommended)

Pregnancy and Lactation.
Refer on Warning and Precautions sectioned.

Side Effects
Those indicating need for medical attention
Incidence rare

Hypersensitivity (skin rash)

Those indicating need for medical attention only if they continue or are bothersome
Incidence less frequent

CNS effects (dizziness; drowsiness; headache; irritability; trouble in sleeping)
gastrointestinal disturbances (abdominal or stomach cramps or pain; diarrhea ; loss of appetite; nausea or vomiting)

Symptoms and Treatment of Overdose
Clinical effects of overdose
The following effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate) - not necessarily inclusive:
Autonomic dysfunction (blurred vision; confusion; dizziness, faintness, or lightheadedness when getting up from a lying or sitting position sudden; sweating; unusual tiredness or weakness; irregular heartbeat)
muscle spasm, twitches, and weakness
prostration (extreme tiredness or weakness)
asphyxia (difficulty in breathing; loss of consciousness)

Treatment of overdose
There is no specific antidote for pyrantel overdose.
To decrease absorption - Early gastric lavage.
Supportive care - Maintaining an open airway and breathing, and maintaining blood pressure.
Patients in whom intentional overdose is confirmed or suspected should be referred for psychiatric consultation.

Packing
Packed in plastic container of 30 ml and 60 ml

Storage Conditions
Store below 30^{o}C in a dry place, protected from direct light.
Keep away from reach of children.

SHAKE WELL BEFORE USE

Expiry Date
2 years from date of manufacture

Product Registration Holder / Distributor:
ZONTRON PHARMACEUTICALS SDN.BHD. (445695-T)
Lot 10 & 11, PERDA Industrial Park,
Lorong IKS Simpang Ampat B,
14100 Simpang Ampat, S.P.S.,
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