

## PRODUCT LITERATURE

### WORMNIL TABLET 125 MG

#### Each tablet contains:

Pyrantel Pamoate 125 mg  
equivalent to Pyrantel USP

#### Preservatives

Sodium Benzoate BP 0.16% w/w

#### Description

Yellow, odourless and round flat tablet

#### Pharmacodynamics and Pharmacokinetics

None

#### Indication

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

#### Recommended Dose

10 mg/kg body weight, as a single dose

#### 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's tablet

#### Storage Conditions

Store below 30°C in a dry place, protected from direct light.

Keep away from reach of children.

#### Expiry Date

3 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.,

Pulau Pinang, Malaysia

#### Name and Address of Manufacturer:

**TERAPUTICS SDN. BHD.** (590500-W)

Lot 10 & 11, PERDA Industrial Park,

Lorong IKS Simpang Ampat B,

14100 Simpang Ampat, S.P.S.,

Pulau Pinang, Malaysia

#### Malaysian Drug Registration No. :

MAL19940589XC

#### Date of Revision:

25/07/2019