COMBANTRIN® Tablet & Suspension
(Pyrantel Pamoate)

NAME OF THE MEDICINAL PRODUCT
COMBANTRIN®

QUALITATIVE AND QUANTITATIVE COMPOSITION
- Tablets containing 250 mg of Pyrantel base.
- Oral suspension containing 50 mg/ml of Pyrantel base.

PHARMACEUTICAL FORM
Tablet, Oral Suspension

THERAPEUTIC INDICATIONS
COMBANTRIN® (pyrantel pamoate) is specifically indicated for the treatment of infection with any of the following gastrointestinal parasites when these are present either alone or as a mixed infection.

1. Enterobius vermicularis (threadworm, pinworm)
2. Ascaris lumbricoides (roundworm)
3. Ancylostoma duodenale (hookworm)
4. Necator americanus (hookworm)
5. Trichostrongylus colubriformis and T. orientalis

COMBANTRIN® should be used for the treatment of infection with one or more of these parasites in both adults and children. It is well tolerated and will not stain the oral mucosa upon ingestion or the clothing by fecal contamination. The presence of an infection with any of the five parasites in one member of a family or group of persons in close proximity may indicate unidentified infection in other members. In these circumstances, COMBANTRIN® administration to all the family or group members is recommended. (Rigorous cleaning of living quarters and clothing to destroy helminthic ova will help prevent reinfection.)

POSOLOGY AND METHOD OF ADMINISTRATION
The recommended dose of COMBANTRIN® for the treatment of infections with Enterobius vermicularis, Ascaris lumbricoides, Ancylostoma duodenale, Necator americanus, Trichostrongylus colubriformis and T. orientalis is 10 mg of base per kilogram of patient body weight (maximum dose of 1g), administered orally as a single dose. A simplified dosage schedule based on weight follows:

<table>
<thead>
<tr>
<th>Weight</th>
<th>Tablets of 250mg</th>
<th>Oral Suspension (50mg/ml) Teaspoonful</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 12 kg*</td>
<td>-</td>
<td>1/2</td>
</tr>
<tr>
<td>12 to 22 kg</td>
<td>1/2-1</td>
<td>1/2-1</td>
</tr>
<tr>
<td>22 to 41 kg</td>
<td>1-2</td>
<td>1-2</td>
</tr>
<tr>
<td>41 to 75 kg</td>
<td>2-3</td>
<td>2-3</td>
</tr>
<tr>
<td>Adults over 75 kg</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

*Use in infants under 6 months is not recommended
For more severe infections of *Necator americanus*, the recommended dosage is 20 mg (base) per kilogram bodyweight administered as a single dose on each of two consecutive days, or 10 mg (base) per kilogram bodyweight administered as a single dose on each of three consecutive days.

Infection due to *Ascaris lumbricoides* alone can be successfully treated with a dose of 5 mg (base) per kilogram bodyweight administered as a single dose. A simplified dosage schedule for ascariasis based on weight follows:

<table>
<thead>
<tr>
<th>Weight</th>
<th>Tablets of 250mg</th>
<th>Oral Suspension (50mg/ml) Teaspoonful</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 12 kg*</td>
<td>-</td>
<td>1/4</td>
</tr>
<tr>
<td>12 to 22 kg</td>
<td>1/4-1/2</td>
<td>1/4-1/2</td>
</tr>
<tr>
<td>22 to 41 kg</td>
<td>1/2-1</td>
<td>1/2-1</td>
</tr>
<tr>
<td>41 to 75 kg</td>
<td>1-1 1/2</td>
<td>1-1 1/2</td>
</tr>
<tr>
<td>Adults over 75 kg</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

*Use in infants under 6 months is not recommended

In mass treatment programs for community control of *Ascaris lumbricoides* infestation alone, a single dose of 2.5 mg (base) per kilogram bodyweight can be used. A simplified dosage schedule based on weight follows:

<table>
<thead>
<tr>
<th>Weight</th>
<th>Tablets of 250mg</th>
<th>Oral Suspension (50mg/ml) Teaspoonful</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 12 kg*</td>
<td>-</td>
<td>1/8</td>
</tr>
<tr>
<td>12 to 22 kg</td>
<td>1/8-1/4</td>
<td>1/8-1/4</td>
</tr>
<tr>
<td>22 to 41 kg</td>
<td>1/4-1/2</td>
<td>1/4-1/2</td>
</tr>
<tr>
<td>41 to 75 kg</td>
<td>1/2-3/4</td>
<td>1/2-3/4</td>
</tr>
<tr>
<td>Adults over 75 kg</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

*Use in infants under 6 months is not recommended

Usage in Children
Use in infants under 6 months is not recommended because safety in this age group has not been established.

CONTRAINDICATIONS
Pyrantel pamoate is contraindicated in patients with known hypersensitivity to this drug or to any of the inert ingredients.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Pyrantel pamoate should be used with caution in patients with pre-existing hepatic dysfunction, as minor transient elevations of the SGOT have occurred in a small percentage of patients.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
Piperazine: The anthelmintic effects of pyrantel and piperazine may be antagonized when pyrantel and piperazine are used concomitantly.³

PREGNANCY AND LACTATION
Usage in Pregnancy
Although animal reproductive studies have not demonstrated any teratogenic effects, pyrantel pamoate has not been studied in the pregnant patient. Accordingly, pyrantel pamoate should be given to a pregnant woman only if the potential benefits justify the potential risk to the patient or fetus.

**Usage in Nursing Mothers**
It is not known whether pyrantel pamoate is excreted in breast milk; nursing should be discontinued if use of this drug is deemed essential.

**EFFECTS ON ABILITY TO DRIVE AND USE MACHINES**
The effect of pyrantel pamoate on the ability to drive and operate heavy machinery has not been studied. There is no evidence to suggest that pyrantel pamoate may affect these abilities.

**UNDESIRABLE EFFECTS**
Clinical experience has shown COMBANTRIN® to be extremely well tolerated. Side effects, if encountered, usually relate to the gastrointestinal tract.
- **Gastrointestinal Disorders:** abdominal cramps, diarrhea, nausea, vomiting
- **Metabolism and Nutrition Disorders:** anorexia
- **Nervous System Disorders:** dizziness, drowsiness, headache
- **Psychiatric Disorders:** insomnia
- **Skin and Subcutaneous Tissue Disorders:** cold sweats\(^1\), hot sweats\(^1\), rash, pruritus\(^2\), urticaria\(^2\)

**OVERDOSE**
**Signs and Symptoms of Overdosage:** No toxic effects attributable to pyrantel pamoate overdose have been observed.

**Treatment of Overdosage:** There is no specific antidote for treatment of overdosage with pyrantel pamoate. Treatment is symptomatic and supportive.

**PHARMACOLOGICAL PROPERTIES**

**PHARMACODYNAMIC PROPERTIES**
Pyrantel pamoate is an anthelmintic agent highly effective against infections due to pinworm (*Enterobius vermicularis*), roundworm (*Ascaris lumbricoides*), hookworm (*Ancylostoma duodenale* and *Necator americanus*), and *Trichostrongylus colubriformis* and *T. orientalis*. Pyrantel pamoate has some activity against whipworm (*Trichuris trichiura*).

Pyrantel pamoate exercises a neuromuscular blocking effect on susceptible helminths. By virtue of its action, pyrantel pamoate immobilizes ascarides and brings about their expulsion without producing excitation or stimulating migration of the affected worms. Within the intestinal tract, pyrantel pamoate is effective against mature and immature forms of susceptible helminths. The normal migratory stages of worms are unaffected.

**PHARMACOKINETIC PROPERTIES**
Pyrantel pamoate is poorly absorbed from the gastrointestinal tract. Following a single oral pyrantel dose of 11 mg/kg, peak plasma concentrations of 50-130 ng/ml occur within 1-3 hours. More than 50% is excreted unchanged in the feces following oral administration; less than 7% is found in the urine unchanged and in the form of metabolites.
PRECLINICAL SAFETY DATA

Chronic Toxicity: 60 rats each received daily doses of 100, 300 or 600 mg per kg body weight over a period of 13 weeks. No gross or microscopic changes attributable to pyrantel pamoate were observed.

Pyrantel pamoate was administered to beagle dogs in daily doses of 100, 300 or 600 mg per kg body weight over a period of 13 weeks. Elevated serum transaminases were found in 5 dogs after 13 weeks. A slight and apparently dose-dependent lymphocytosis was observed in dogs after 13 weeks. There were no histopathologic changes attributable to the drug.

Teratogenesis: There was no effect on fertility, reproduction, organogenesis, parturition or lactation in rats or organogenesis in rabbits receiving pyrantel pamoate at dosage levels of 25 or 250 mg/kg body weight.

PHARMACEUTICAL PARTICULARS

List of excipients
- **Tablets**: Alginic Acid, Corn starch, Orange Dye, Magnesium Stearate & Sodium Lauryl Sulfate
- **Suspension**: Veegum, Lecithin Soya, Polysorbate 80, Sodium Benzoate, Povidone, Citric Acid Anhydrous, Antifoam emulsion, Sorbitol Solution, Glycerin, Imitation Caramel Current Flavor

INCOMPATIBILITIES

Not applicable

SHELF LIFE
- Tablet: 36 Months
- Suspension: 24 Months

SPECIAL PRECAUTIONS FOR STORAGE

Avoid exposure to heat and sun light

NATURE AND CONTENTS OF CONTAINER
- Tablet: PVC/ Aluminium foil blister cards
- Suspension: 10 mL amber glass bottle with pilfer proof caps and PVC liner
REFERENCES


   http://csi.micromedex.com/DKS/DATA/MT/MTM805-v.HTM?Top=Yes