SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAMENT

COMBIFRINIL®

Galenic forms, composition and presentation
Chewable tablet: 250mg of Pyrantelum pro compresso. Excipients: Mannitol, Sodium Saccharin, Povidone K 29-32, isopropyl alcohol, purified water, blackcurrant flavour, caramel flavour (Ethylvanillinum, vanillinum and alia), Colloidal Silica (Aerosil 200), Magnesium Stearate.
Box of 3 chewable tablets.

Oral suspension: 50mg of Pyrantelum pro 1 ml. Sorbitol solution 70%, Sodium Benzoate, Lecithin, Polysorbate 80, Glycerin, Aluminium Magnesium Silicate, Sodium CMC, Sodium Saccharin, Blackcurrant flavour, caramel flavour (Ethylvanillinum, vanillinum and alia).
15ml bottle.

Indications/suitability for use
Single or mixed pinworm infections (Enterobius vermicularis), roundworms (A. lumbricoides) and hookworms (Ankylostoma duodenale, Necator americanus).

Dosage/directions for use
The average dose is 10mg/kg body weight single dose, i.e.:

Weight/age	Chewable tablet (250mg)	Oral suspension (50 mg/ml) 5ml measuring cup
Up to 12 kg ½ to 2 years old	1/2 tablet	1/2 (2,5 ml)
12-22 kg 2 to 6 y/o	1	1 (5ml)
22-41 kg 6 to 12 y/o	2	2 (10 ml)
41- 85 kg Children over 12 y/o and adults	3	3 (15 ml)
adults 85kg and over	4	4 (20 ml)

The dose may be administered at once, during or after a meal.

In case of severe infestation with hookworms (daily elimination of over 4000 eggs per gram of stool), a double dose should be prescribed and administered for 1 to 3 consecutive days.

In the case of oxyurosis, with a view to definitive parasitic eradication, impose rigorous hygiene measures and also treat the environment.

Contraindication
Do not give to patients who are hypersensitive to pyrantel or any of the excipients according to the composition.

Warnings and precautions
Administer with caution to subjects with impaired liver function. It has very occasionally been possible to observe a small and transient rise in SGOT.

Paediatrics: Combifrinil should not be administered to children of under 6 months of age, as the safety of this medication has not been studied in this age group.

Interactions
Since piperazine has a antagonistic mechanism to pyrantel, these two drugs should not be administered simultaneously.

Pregnancy, breastfeeding
There are no controlled studies in animals or pregnant women. This potential outweighs the risk to the foetus. Combifrinil should not be used during pregnancy unless absolutely necessary.

The extent to which pyrantel pamoate passes into breast milk is unknown. Therefore, breastfeeding women should give up if Combifrinil is not needed.

Effect on driving ability and use of machinery
No corresponding study has been carried out

Side effects

Metabolism and nutritional disorders

Occasionally (0.1-1%): anorexia.

Psychiatric disorders

Occasionally (0.1-1%): insomnia.

CNS disorders

Frequently (1-10%): headache.

Occasionally (0.1-1%): drowsiness.

Cases of vertigo have also been reported.

Gastrointestinal disorders

Frequently (1-10%): abdominal cramps, diarrhoea, nausea, vomiting.

Hepatobiliary disorders

Frequently (1-10%): transient increase of transaminases.

Dermatological and subcutaneous disorders

Occasionally (0.1-1%): rash.

Overdose
Because of its low absorption rate, plasma concentrations are low. An overdose, even a significant one, usually only leads to some digestive disorders and some mild and transient CNS disorders (fatigue, dizziness).
There is no specific antidote for treating such overdoses. If necessary, supportive symptomatic treatment should be applied.

Properties/Effects
ATC Code: PO2CC01

Mechanism of action: Pyrantel, the active ingredient in Combifrinil, blocks nerve conduction at the neuromuscular level. It works by paralyzing the worms so that they detach from the intestinal wall and are then eliminated in stools.

Pharmacodynamics: Combifrinil kills sensitive helminths without lysing them. Thus, their elimination is carried out without irritating the intestinal wall, nor stimulating their migration towards the skin, nor provoking any toxic phenomenon due to a lysis of the parasites.

Combifrinil is active in the intestinal lumen on mature and immature forms of susceptible helminths. Migrating larvae in the tissues are not affected.

Combifrinil is suitable for single-dose treatment of pinworms, roundworms and hookworms.

Pharmacokinetics
After oral administration of Combifrinil, over 50% of the product is excreted unchanged via stools. Less than 7% are found in the urine in unchanged form and in the form of metabolites. The intestinal resorption of Combifrinil is very weak. Plasma levels of pyrantel are minimal (0.05 to 0.13µg/ml) and are reached within 1 to 3 hours.

Preclinical data
There is no relevant specific data for the use of the preparation.

Special remarks

Stability: Please consult the expiry date on the packaging (3 years)

Storage considerations: Combifrinil tablet and suspension should be stored in their original packaging at a temperature below 30°C.

Holder and operator of the authorisation
Frilab SA, CH -1207 Geneva - Switzerland

Manufacturers:
TABLET: HELIOS PHARMACEUTICALS, Village Malpur, Baadi, Solan district, India
SUSPENSION: SANPRAS HEALTHCARE PVT. LTD. AT: PLOT NO.- 81, STICE, MUSAL GAON, SINNAR-422 112