SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

COMBIFRINIL®

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chewable tablet : 250 mg of Pyrantelum pro compresso .

Oral suspension : 50 mg of Pyrantelum pro 1 ml.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Chewable tablets or oral suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Simple or mixed pinworm infestations (Enterobius) vermicularis), roundworms (A. lumbricoides) and hookworms (Ankylostoma duodenale , Necator americanus).

4.2 Posology and method of administration

Posology
The average dose is 10 mg/kg of body weight as a single dose, i.e.:

Weight/age	Tablets chewable (250mg)	Oral suspension (50 mg/ml) 5 ml measuring scoop
Until12 kg ½ to 2 years	1/2 tablet	1/2 (2.5 ml)
12-22 kg 2 to 6 years old	1	1 (5ml)
22-41 kg 6 to 12 years old	2	2 (10 ml)
41-85 kg children over 12 years and older	3	3 (15 ml)
adults 85 kg and more	4	4 (20 ml)

Method of administration
The dose can be administered all at once, during or after a meal.

In cases of severe hookworm infestation (daily egg excretion exceeding 4000 eggs per gram of stool), a double dose should be prescribed and administered for 1 to 3 consecutive days.

In cases of pinworm infection, with a view to definitive parasitic eradication, rigorous hygiene measures must be imposed and those in close contact with the infected person must also be treated.

4.3 Contraindications

Do not administer to patients hypersensitive to pyrantel or to any of the excipients according to the composition.

4.4 Special warnings and precautions for use

Administer with caution to subjects with impaired liver function. A minimal and transient elevation of SGOT has rarely been observed.

Population pediatric :

Combifrinil should not be given to children under 6 months of age, as the safety of this drug has not been studied in this age group.

4.5 Interactions with other medicinal products and other forms of interaction

Since piperazine has a mechanism of action antagonistic to that of pyrantel, these two drugs will not be administered simultaneously.

4.6 Fertility, pregnancy and breastfeeding

Pregnancy
No controlled studies are available in animals or pregnant women. The potential benefits outweigh the risk to the fetus. Combifrinil should therefore not be used during pregnancy unless absolutely necessary.

Breastfeeding
It is unknown to what extent pyrantel pamoate passes into breast milk. Therefore, breastfeeding women should avoid it unless the use of Combifrinil is essential.

4.7 Effects on the ability to drive vehicles and use machinery

No corresponding studies have been carried out

4.8 Undesirable effects

Metabolic and nutritional disorders
Occasionally (0.1–1%): anorexia.

Psychiatric disorders
Occasionally (0.1–1%): insomnia.

CNS disorders
Frequently (1–10%): headaches.
Occasionally (0.1–1%): drowsiness.
Cases of dizziness have also been reported.

Gastrointestinal disorders
Frequently (1–10%): abdominal cramps, diarrhea, nausea, vomiting.

Hepatobiliary disorders
Frequently (1–10%): transient increase in transaminases.

Dermatological and subcutaneous disorders
Occasionally (0.1–1%): skin rash.

4.9 Overdose

Due to its low absorption rate, plasma concentrations are low. Even a significant overdose generally only results in minor digestive disturbances and some mild, transient CNS disorders (fatigue, dizziness).
There is no specific antidote to treat such an overdose. Symptomatic supportive treatment will be administered if necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic class: Antiparasitic products, insecticides and repellents, 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 the stool.

Pharmacodynamics :
Combifrinil kills susceptible helminths without lysing them. Therefore, their elimination occurs without irritating the intestinal wall, stimulating their migration to the skin, or causing toxic effects due to parasite lysis.

Combifrinil is active in the intestinal lumen against both mature and immature forms of susceptible helminths. Larvae migrating in tissues are not affected.

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

5.2 Pharmacokinetics properties

Following oral administration of Combifrinil , more than 50% of the product is excreted unchanged in the feces. Less than 7% is recovered in the urine, both unchanged and as metabolites.
Intestinal absorption of Combifrinil is very low. Plasma levels of pyrantel are minimal (0.05 to 0.13 μg/ml) and are reached within 1 to 3 hours.

5.3 Preclinical safety data

There is no specific data relevant to the use of the preparation.

6. PHARMACEUTICALS PARTICULARS

6.1 List of the excipients

Chewable tablets : Mannitol, Sodium Saccharin, Povidone K 29-32, Isopropyl Alcohol, purified water, blackcurrant flavouring, caramel flavouring (Ethylvanillinum , vanillinum and related compounds), Colloidal Silica (Aerosil 200), Magnesium Stearate .

Oral suspension : Sorbitol solution 70%, Sodium Benzoate, Lecithin , Polysorbate 80, Glycerin , Aluminum Magnesium Silicate, Sodium CMC, Sodium Saccharin, Blackcurrant flavor, caramel flavor (Ethylvanillinum , vanillinum et alia).

6.2 Incompatibilities

Without object.

6.3 Shelf life

Please check the expiry date on the packaging (3 years)

6.4 Special precautions for storage

Combifrinil tablets and suspension should be stored in their original packaging, at a temperature below 30°C.

6.5 Nature and contents of container

Chewable tablets : Box of 3 chewable tablets.

Oral suspension : 15 ml bottle.

6.6 Special precautions for disposal and handling

Any unused medicinal product or waste material should be disposed of in accordance with local regulations.

7. MARKETING AUTHORISATION HOLDER OPERATOR AND MANUFACTURERS

Holder and operator of the authorization
Frilab SA,
1207 Geneva
Swiss

Manufacturers :
Tablets : HELIOS PHARMACEUTICALS, Village Malpur , Baadi , Distt . Solan (HP) – India
Oral suspension : Sanpras Healthcare Pvt . Ltd. At: Plot No.- 81, STICE, Musalgaon , Tal. Sinnar , District Nashik, 422 112 Maharashtra State, India

8. DATE OF REVISION OF THE TEXT

July 28, 2022

9. DOSIMETRY

Without object.

CONDITIONS FOR PRESCRIPTION AND DISPENSING

Non-prescription medication