SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

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COMBIWORM TABLET

1. NAME OF THE MEDICINAL PRODUCT

Combiworm Tablet (Pyrantel Pamoate 125mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Pyrantel Pamoate	125mg

Excipients:

Nipagin (Methyl Paraben)	0.24mg
Nipasol (Propyl Paraben)	0.12mg
Dicalcium Phosphate	28.00mg
Corn Starch (Bulk)	73mg
Corn Starch (Paste)	30mg
Talcum	2.00mg
Magnesium Stearate	5.00mg
Sunset Yellow	0.55mg
Purified Water	q.s

3. PHARMACEUTICAL FORM

Tablet.

Orange circular shaped tablet with 'COMBIWORM' inscribed on one side and a breakline on the other side presented in a blister strips of 6 tablets. 12 of such blisters packed in a carton with insert

4. Clinical particulars

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

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.

Method of administration

For oral administration

4.3 Contraindications

Do not give to patients who are hypersensitive to pyrantel or 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. It has very occasionally been possible to observe a small and transient rise in SGOT.

Paediatrics: Combiworm 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.

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Pregnancy and Lactation

There are no controlled studies in animals or pregnant women. This potential outweighs the risk to the foetus. Combiworm 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 Combiworm is not needed

4.7 Effects on ability to drive and use machines

No corresponding study has been carried out

4.8 Undesirable 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

4.9 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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: PO2CC01

Mechanism of action: Pyrantel, the active ingredient in Combiworm, 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*:** Combiworm 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.

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

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

5.1 Pharmacokinetic properties

After oral administration of Combiworm, 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 Combiworm is very weak. Plasma levels of pyrantel are minimal (0.05 to 0.13µg/ml) and are reached within 1 to 3 hours.

5.2 Preclinical safety data

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Nipagin (Methyl Paraben)

Nipasol (Propyl Paraben)

Dicalcium Phosphate

Corn Starch (Bulk)

Corn Starch (Paste)

Talcum

Magnesium Stearate

Sunset Yellow

Purified Water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in the original package in order to protect from light

Do not store above 30°C

6.5 Nature and contents of container <and special equipment for use, administration orimplantation>

Blister strips of 12 x 6 tablets packed in a cardboard carton.

6.6 Special precautions for disposal <and other handling:

Not applicable

7. APPLICANT/MANUFACTURER:

Vitabiotics Nigeria Limited
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Oregun Industrial Estate,
Ikeja, Lagos,
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