SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

FOR

BENDEX SUSPENSION

1. NAME OF THE MEDICINAL PRODUCT

BENDEX SUSPENSION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml Suspension contains:

250mg Pyrantel base (as Pyrantel Pamoate BP).

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Oral Liquid Suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Bendex suspension is indicated for the treatment of infection with any of the following gastrointestinal parasites when these are present either alone or as a mixed infestation.

- Enterobius vermicularis (threadworm, pinworm)
- Ascaris lumbricoides (roundworm)
- Ancylostoma duodenal (hookworm)
- Necator americanus (hookworm)
- Trichostrongylus colubriformis and orientalis

Bendex suspension is recommended for the treatment of infection with one or more of these parasites in both adults and children. 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 such cases, administration of Bendex to all the family or group members is recommend. (It may also be necessary to carry out proper cleaning of living quarters and clothing to destroy helminthic ova and thus prevent reinfection).

4.2 Posology and method of administration

Oral administration only

Shake well before use.
The recommended dose of Bendex suspension for the treatment of infections with Enterobius vermicularis. Ascaris lumbricoides, Ancylostoma duodenale, Necator americanus, Trichostrongylus colubriformis and orientalis is 10 mg of base per kilogram of patient body weight, administered orally as a single dose. A simplified dosage schedule, based on the above and on estimated weights at various ages is as follows:

Age of Patient	Weight	Oral Liquid Suspension
6 months to 2 years	less than 12kg	2.5ml
2 to 6 years	12 to 22kg	5ml
6 to 12 years	22 to 41kg	10ml
Aver 12 years	41 to 75kg	15ml
Adult	Over 75kg	20ml

For more severe infestation of Necator americanus, the recommended dosage is 20 mg (base) per kilogram body weight 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 body weight administered as a single dose.
A simplified dosage schedule for Ascariasis based on the above and on estimated weights at various age is as follows:

Age of Patient	Weight	Oral Liquid Suspension
6 months to 2 years	less than 12kg	1.25ml
2 to 6 years	12 to 22kg	2.5ml
6 to 12 years	22 to 41kg	5ml
Aver 12 years	41 to 75kg	7.5ml
Adult	Over 75kg	10ml

In mass treatment programmes directed against Ascaris lumbrrcoldes infestation alone, a single dosage of 2.5mg (base) per kilogram body weight can be used. A simplified dosage schedule base on preceding and on estimated weight at various age as follow:

Age of Patient	Weight	Oral Liquid Suspension
6 months to 2 years	less than 12kg	0.625ml
2 to 6 years	12 to 22kg	1.25ml
6 to 12 years	22 to 41kg	2.5ml
Aver 12 years	41 to 75kg	3.75ml
Adult	Over 75kg	5ml

4.3 Contraindications

Although animal reproductive studies have not demonstrated any teratogenic effects.
Bendex has not been studied in pregnancy. Use in pregnancy should be avoided, unless in the Judgment of the Physician it is essential for the health of the patient

.

4.4 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.
Abdominal cramps, nausea, vomiting, diarrhea, headache or dizziness sometimes occur after taking this drug. If any of these conditions persist, consult a physician.
Keep this and all medications out of reach of children.
In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately. If you are pregnant or have liver disease, do not take this product unless directed by a physician.

4.5 Interaction with other medicinal products and other forms of interaction

Acrivastine	Acrivastine may decrease the excretion rate of Pyrantel which could result in a higher serum level.
Acyclovir	Acyclovir may decrease the excretion rate of Pyrantel which could result in a higher serum level.
Adefovir dipivoxil	Adefovir dipivoxil may decrease the excretion rate of Pyrantel which could result in a higher serum level.
Agomelatine	The risk or severity of CNS depression can be increased when Agomelatine is combined with Pyrantel.
Albutrepenonacog alfa	Pyrantel may decrease the excretion rate of Albutrepenonacog alfa which could result in a higher serum level.
Alclofenac	Alclofenac may decrease the excretion rate of Pyrantel which could result in a higher serum level.
Aldesleukin	Aldesleukin may decrease the excretion rate of Pyrantel which could result in a higher serum level.
Alfentanil	The risk or severity of CNS depression can be increased when Alfentanil is combined with Pyrantel.
Alimemazine	The risk or severity of CNS depression can be increased when Alimemazine is combined with Pyrantel.
Allopurinol	Allopurinol may decrease the excretion rate of Pyrantel which could result in a higher serum level.

4.6 Fertility, pregnancy and lactation

Pregnancy

Although animal reproductive studies have not demonstrated any teratogenic effects. Bendex has not been studied in pregnancy. Use in pregnancy should be avoided, unless in the Judgment of the Physician it is essential for the health of the patient. There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

4.7 Effects on ability to drive and use machines

When using Pyrantel, patients may experience the following side effects:
Central nervous system: Dizziness, headache, insomnia. Alcohol can increase the side effects of Pyrantel which can seriously hamper the patients' ability to drive and use machinery.

4.8 Undesirable effects

When using Pyrantel, patients should pay attention to the following issues:
Use Pyrantel with caution in people with impaired liver function. Use caution when administering Pyrantel to malnourished or severely anemic patients. Ideally, patients who are dehydrated, anemic or malnourished should receive supportive treatment prior to administration of pyrantel. The drug can cause some toxicity in children and adults including increased alcohol concentration, lactic acidosis, convulsions and respiratory depression

4.9 Overdose

Symptoms of a Pyrantel overdose include: Difficulty breathing, seizures, muscle spasms, or severe muscle weakness. When an overdose occurs, the patient should immediately go to the nearest medical facility for timely treatment

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pyrantel pamoate and its analogs act by causing depolarizing neuromuscular blockade and by blocking acetylcholinesterase, which result in spastic paralysis and muscle contracture, respectively, and allow expulsion of the worms.

5.2 Pharmacokinetic properties

Pyrantel Pamoate has a neuromuscular blocking effect on susceptible helminthes. By this action, it 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 helminthes. The normal migratory stages of worms are unaffected. Pyrantel Pamoate is poorly absorbed from the gastrointestinal tract. More than fifty percent is excreted unchanged in the feaces following oral administration; less than seven percent is found in the urine unchanged and in the form of metabolites.

5.3 Preclinical safety data

No additional data of relevance.

6. Pharmaceutical particulars

6.1 List of Excipients:

S. No	Composition	Reference
1.	Glycerin	**BP**
2.	Sucrose	**BP**
3.	Methyl Paraben	**BP**
4.	Propyl Paraben	**BP**
5.	Sodium CMC	**BP**
6.	Polysorbate 80	**BP**
7.	Citric Acid ** Monohydrate	**BP**
8.	Citric Acid anhydrous	**BP**
9.	Sodium Citrate	**BP**

10.	Tartrazine Yellow	**IHS**
11.	Pineapple Flavour	**IHS**
12.	Purified Water (to)	**BP**

6.2 Incompatibilities
None known.

6.3 Shelf life
Shelf life before opening – 36 months

6.4 Special precautions for storage
Store below 30°C. Protect from light

6.5 Nature and contents of container

30ml Amber glass bottle with ROPP cap containing 15ml of Bendex Suspension

6.6 Special precautions for disposal and other handling
None.

7. APPLICANT/MANUFACTURER

Unique Pharmaceuticals Limited
Km 38, Abeokuta Road, Sango-Ota, Ogun State, Nigeria.
Tel: +234 8097421000
Email: mail@uniquepharm.com