SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:

1.1 Brand Name : **Kikverm Suspension**
1.2 Generic Name : Mebendazole Oral Suspension USP 100 mg
1.3 Strength : Mebendazole USP 100mg/5ml
1.4 Pharmaceutical Form : Suspension

2. QUALITATIVE & QUANTITATIVE COMPOSITION:

Each 5ml. contains:
Mebendazole USP 100 mg
Flavoured base q.s.
Colour: Sunset Yellow WS

3. PHARMACEUTICAL FORM

Suspension
Orange coloured, flavoured, palatable suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Kikverm Suspension is indicated for the treatment of Threadworm infection, Whipworm infections & Hookworm infections.

4.2 Posology and method of administration

- **Threadworm infections:**
  Child 2–17 years: 100 mg for 1 dose, if reinfection occurs, second dose may be needed after 2 weeks. **Adult:** 100 mg for 1 dose, if reinfection occurs, second dose may be needed after 2 weeks.
- **Whipworm infections & Hookworm infections:**
  Child 2–17 years: 100 mg twice daily for 3 days. **Adult:** 100 mg twice daily for 3 days.
- **Roundworm infections:**
  Child 2–17 years: 100 mg twice daily for 3 days, alternatively 500 mg 1 dose.
  Adult: 100 mg twice daily for 3 days, alternatively 500 mg 1 dose.

4.3 Contraindications

Mebendazole is contraindicated in patients with known hypersensitivity to benzimidazole class of compounds.

4.4 Special warnings and special precautions for use

Not recommended in the treatment of children under 2 years.

Hepatic Impairment: Mebendazole may undergo extensive hepatic metabolism; use with caution as systemic exposure may be increased.

4.5 Interaction with other FPPs and Other forms of Interaction

Concomitant treatment with Cimetidine may inhibit the metabolism of Mebendazole in the liver, resulting in increased plasma concentrations of the drug. Concomitant use of Mebendazole and Metronidazole should be avoided.

4.6 Pregnancy and lactation

Patients who think they are or may be pregnant should not take Mebendazole Suspension. Amount present in milk too small to be harmful, thus it is not advisable to breast feed, following administration of Mebendazole Suspension.

4.7 Effects on ability to drive and use machines

Mebendazole Suspension has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Common or very common: Abdominal pain. **Uncommon:** Diarrhoea, flatulence. **Rare:** Alopecia, convulsions, dizziness, hepatitis, neutropenia, rash, Stevens-Johnson syndrome toxic, epidermal necrolysis, urticaria.

4.9 Overdose & Treatment

In patients treated at dosages substantially higher than recommended or for prolonged periods of time, in the event of accidental over-dosage, abdominal cramps, nausea, vomiting and diarrhoea may occur. There is no specific antidote. Activated charcoal may be given if considered appropriate.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-helminthic

Mechanism of action:

Mebendazole causes degenerative alterations in the tegument and intestinal cells of the worm by binding to the colchicine-sensitive site of tubulin, thus inhibiting its polymerization or assembly into microtubules. The loss of the cytoplasmic microtubules leads to impaired uptake of glucose by the larval and adult stages of the susceptible parasites, and depletes their glycogen stores.

5.2 Pharmacokinetic properties

Less than 10% of orally administered Mebendazole is absorbed. The absorbed drug is protein-bound (> 90%), rapidly converted to inactive metabolites (primarily during its first pass in the liver), and has a half-life of 2–6 hours. It is excreted mostly in the urine, principally as decarboxylated derivatives. In addition, a portion of absorbed drug and its derivatives are excreted in bile. Absorption is increased if drug is ingested with a fatty meal.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

SN	Ingredients	Spec.
01.	Liquid Sorbitol (Noncrystallizing)	BP
02.	Sodium Methyl Hydroxybenzoate (Sod. Methylparaben)	BP
03.	Sodium Propyl Hydroxybenzoate (Sod. Propylparaben)	BP
04.	Xanthan Gum (Transparent)	BP
05.	Acesulfame Potassium	BP
06.	Polysorbate-80	BP
07.	Citric Acid Monohydrate	BP
08.	Col. Sunset Yellow FCF	IH
09.	Essence Mango	IH
10.	Purified Water	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C. Protect from light. Keep out of reach of children. Keep container tightly closed.

6.5 Nature and contents of container

30 ml. in an amber coloured PET bottle in an inner carton.

6.6 Instructions for use and handling

SHAKE WELL BEFORE USE.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKETING AUTHORISATION NUMBER

06904/08247/REN/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Nov 28, 2021

10. DATE OF REVISION OF THE TEXT

01/01/2023