SUMMARY OF PRODUCT CHARACTERISTICS.

1. Name of the medicinal product.

Vermout suspension

2. Qualitative and quantitative composition

Each 5ml contains Mebendazole 100mg.

For more information on excipients see section 6.1

3. Pharmaceutical form

Pink coloured, viscous and homogeneous suspension, free from any visible impurities.

4. Clinical particulars

4.1 Therapeutic indications

Mebendazole is indicated for the treatment of single and mixed helminth infestations caused by:

Nematodes such as: *Trichuris trichiura* (whipworm), *Ancylostoma duodenale* (hookworm), *Necator americanus* (hookworm), *Ascaris lumbricoides* (large roundworm), *Ternidens deminutus*, *Enterobius vermicularis* (pinworm), *Strongyloides stercoralis* (threadworm).

Cestodes such as: *Taenia spp* (tapeworm) and infestations by *Moniliformis moniliformis*.

4.2 Posology and method of administration

For oral administration.

The suspension is preferable for the young children.

A second course of treatment should be given to those patients who are still infected three to four weeks after the first course.

In worm-eradication campaigns the standard course should be administered every quarter during the first year.

If a helminth is not susceptible to the standard dosage, a treatment course of longer than three days and/or involving higher doses than 100 mg for tablets is recommended.

The efficacy of Mebendazole is dependent upon the duration of physical contact between drug and parasite. When gastro-intestinal transit time is accelerated, e.g. in diarrhoea, it is necessary to repeat the dose at more frequent intervals daily.

4.3 Contra-indications.

In persons who have shown sensitivity to Mebendazole.

Mebendazole should not be given during pregnancy.

4.4 Special warning and precautions for use.

Not recommended in the treatment of children under 2 years.

A case-control study of a single outbreak of Stevens-Johnson syndrome /toxic epidermal necrolysis (SJS/TEN) suggested a possible association with the concomitant use of metronidazole with Mebendazole. Although there are no additional data on this potential interaction, concomitant use of Mebendazole and metronidazole should be avoided.

Vermout oral suspension contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products 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.

Pregnancy

Since Vermout is contraindicated in pregnancy, patients who think they are or may be pregnant should not take this preparation.

Lactation

As it is not known whether Mebendazole is excreted in human milk, it is not advisable to breast feed following administration of Vermout.

Fertility

No data on the effect of Mebendazole on fertility are available.

4.7 Effects on ability to drive and use machines.

Vermout has no influence on the ability to drive and use of machines.

4.8 Undesirable effects.

Throughout this section adverse reactions are reported. Adverse reactions are adverse events that were considered to be reasonably associated with the use of mebendazole based on the comprehensive assessment of the available adverse event information. A causal relationship with mebendazole cannot be reliably established in individual cases. Further, because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The safety of Vermox was evaluated in 6276 subjects who participated in 39 clinical trials for the treatment of single or mixed parasitic infestations of the gastrointestinal tract. In these 39 clinical trials, no adverse drug reactions (ADRs) occurred in ≥1% of Vermox-treated subjects.

ADRs identified from clinical trials and post-marketing experience included in Table 1. The displayed frequency categories use the following convention:

Very common (≥1/10); Common (≥1/100 to <1/10); Uncommon (≥1/1000 to <1/100); Rare (≥1/10,000 to <1/1000); Very rare (<1/10,000), Not known (cannot be estimated from the available data).

System Organ Class	Adverse Drug Reactions		
	Frequency Category		
	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1000 to < 1/100)	Rare (≥1/10,000 to <1/1000)
Blood and lymphatic system disorders			Neutropenia[b]
Immune system disorders			Hypersensitivity including anaphylactic reaction and anaphylactoid reaction[b]
Nervous system disorders			Convulsions[b] Dizziness[a]
Gastrointestinal disorders	Abdominal pain[a]	Abdominal discomfort[a]; Diarrhoea[a]; Flatulence[a]	
Hepatobiliary disorders			Hepatitis; [b] Abnormal liver function tests[b]
Skin and subcutaneous tissue disorders			Rash[a] Toxic epidermal necrolysis [b]; Stevens-Johnson syndrome [b]; Exanthema [b]; Angioedema [b]; Urticaria [b]; Alopecia [b]

[a] ADR frequency data derived from Clinical Trials or Epidemiological Studies

[b] ADRs not observed in clinical trials and frequency calculated using "Rule of 3", as detailed in SmPC guideline 2009. 6276 patients exposed in clinical trials and epidemiological studies, divided by 3 (Frequency = 1/2092). Note: frequencies differ from those reported in the August 2009 CCDS, as these were not calculated using the formula detailed in the SmPC guideline 2009.

4.9 Overdose.

In the event of accidental overdosage, abdominal cramps, nausea, vomiting and diarrhoea may occur. If poisoning or excessive overdosage is suspected it is recommended, on general principles, that vomiting be induced or gastric lavage be performed, and such symptomatic supportive therapy be administered as appears indicated. Activated charcoal may be given.

5. Pharmacological properties.

5.1 Pharmacodynamic properties.

Pharmacotherapeutic group: ***Anthelmintic for oral administration, benzimidazole derivatives;***
ATC code: P02CA01.

Mebendazole is a broad-spectrum anthelmintic. It appears to affect the cytoplasmic microtubules of the tegumental or intestinal cells of parasitic worms resulting in a transport blocking of secretory vesicles. This may lead to impaired coating of the membranes followed by a decreased digestion and absorption of nutrients, e.g. glucose, thereby depleting the energy level until it is inadequate for survival.

5.2 Pharmacokinetic properties:

Mebendazole is poorly absorbed from the gastrointestinal tract and undergoes extensive first-pass elimination, being metabolised in the liver, eliminated in the bile as unchanged drug and metabolites, and excreted in the faeces. Only about 2% of a dose is excreted unchanged or as metabolites in the urine. Mebendazole is highly protein bound.

5.3 Preclinical safety data.

Non-clinical data have not revealed significant hazards for humans, based on standard studies of safety pharmacology, repeated-dose toxicity, genotoxicity, carcinogenic potential, and reproductive toxicity.

6. Pharmaceutical particulars.

6.1 List of excipients

Sodium methyl paraben
Sodium propyl paraben
Sugar
Glycerin
Xanthan gum
Sodium CMC
Vanilla flavour
Tween 80
Sodium Saccharin
Erythrosine colour
Sodium benzoate
Bronopol
Propylene Glycol
Citric acid
Purified Water

6.2 Incompatibilities

None

6.3 Shelf life.

3 years from the date of manufacture.

6.4 Special precautions for storage:

Store in a dry place, below 30ºC, protected from light.
Keep all medicines out of reach of children.

6.5 Nature and contents of container.

30ml glass bottle in a unit carton along with a literature insert.

6.6 Special precautions for disposal and other handling

No special instructions

7. Marketing authorization holder.

Dawa limited,
Plot No: 7879/8, Baba Dogo road, Ruaraka,
P.o Box 16633-00620, Nairobi –Kenya.

8. Registration number(s)

Kenya registration number: H2009/20107/582.

Uganda registration number: 6/10/6856

9. Date of initial or renewed registration.

Initial date of registration (Kenya): 22nd October 2009.

Initial date of registration (Uganda): 12th October 2010.

10. Date of revision of the text.

March 2019.

1.5.2 Container labeling: Unit box, Leaflet and printed Label