Summary of Product Characteristics

1. Name of the product:
Womnil suspension

2. Qualitative and quantitative composition: Each 5ml contains: Albendazole BP 200mg
Full list of excipients see section
6.1

3.0 Pharmaceutical form:
Suspension for oral administration.
Physical Characteristics: A Green, viscous suspension, free from visible evidence of contamination.

4.0 Clinical particulars:
4.1Therapeutic indications:
Womnil suspension (Albendazole suspension) is a Benzimidazole carbamate with anthelmintic and antiprotozoal activity against the following intestinal and tissue parasites: Round-worm (Ascaris lumbricoides), pinworm (Enterobius vermicularis), hook-worm (Necator americanus, Ancylostoma duodenale), whipworm (Trichuris trichiura), thread-worm (Strongyloides stercoralis), tapeworm (Taenia spp and Hymenolepis nana only in the case of associated parasitism), Chlonorchiasis (Chlonorchis sinensis), Opisthorchiasis (Opisthorchis viverrini) and cutaneous larva migrans; Giardiasis (G.lamblia, G.duodenalis, G.intestinalis, Lamblia intestinalis) and in relatively high doses for treatment of cestode infections cysticercosis and echinococcosis (hydatid disease)

4.2 Posology and Method of Administration:
Route of administration: Oral route
(i) For Roundworm, Pinworm, Threadworm, Hook Worm, Whipworm
Children 1-2 years: 5ml taken as a single dose
Adults and Children over 2 years: 10ml taken as a single dose
(ii) For Strongyloidiasis, Taeniasis and Hymenolepiasist
*Children 1-2 years :*5ml taken as a single dose for 3 consecutive days.
*Adults and Children over 2 years:*10ml taken as a single dose for 3 consecutive days.

(iii) Chlonorchiasis, Opisthorchiasis
Children 1-2 years: 5ml taken as a single dose for 3 consecutive days.
Adults and Children over 2 years:10ml taken twice a day for 3 consecutive days.

(iv) Giardiasis
Children 2-12 years of age only:10ml taken as a single dose for 5 consecutive days. In cases of proven Hymenolepiasis, retreatment in 10-21 days is recommended.

4.3 Contraindications:
Albendazole should not be administered during pregnancy or in women thought to be pregnant.
Contra-indicated in patients with a known history of hypersensitivity to the active substance or excipients

4.4 Special warnings and precautions for use:
In order to avoid administering Albendazole during early pregnancy, women of Child bearing age should: - initiate treatment only after a negative pregnancy test
Treatment with Albendazole may uncover pre-existing neurocysticercosis, particularly in areas with high taenosis infection. Patients may experience neurological symptoms e.g. seizures, increased intracranial pressure and focal signs as a result of an inflammatory reaction caused by death of the parasite within the brain. Symptoms may occur soon after treatment, appropriate steroid and anticonvulsant therapy should be started immediately.
Albendazole contains benzoic acid which is a mild irritant to the skin, eyes and mucous membrane.
Albendazole may increase the risk of jaundice in newborn babies.

Patients with liver disease, including hepatic echinococcosis, appear to be more susceptible to bone marrow suppression leading to pancytopenia, aplastic anaemia, agranulocytosis and leucopenia and therefore warrant closer monitoring of blood counts.
Care should be taken for patients with severe renal and severe hepatic impairment

4.5 Interaction with other medicinal products and other forms of interactions:
Albendazole has been shown to induce liver enzymes of the cytochrome P450 system responsible for its own metabolism.
Drugs that can reduce the effectiveness of Albendazole–monitor effect-other dose regimens or therapies may be required. Anticonvulsants, Levamisole and Ritonavir
Drugs that may increase levels of the active metabolite of albendazole–monitor to possible increased albendazole adverse effects.: Cimetidine, Dexamethasone (continuous use raises Albendazole levels by 50%), Praziquantel
Grapefruit juice also increases the plasma levels of Albendazole sulfoxide.
Other possible interactions
Alterations in cytochrome P450 activity may increase risk of an interaction with: Oral contraceptives, Anticoagulants, Oral hypoglycaemics and Theophylline
Care should be exercised when Albendazole is given to patients taking above medicines.

4.6 Pregnancy and Lactation:
Pregnancy: Albendazole should not be administered during pregnancy or in women thought to be pregnant Lactation: Albendazole should not be used during lactation unless the potential benefits are considered to outweigh the potential risks associated with treatment.

4.7 Effects on the ability to drive and use machines:
Adverse effects on the ability to drive or operate machinery have not been observed.

4.8 Undesirable effects:
Rare: Hypersensitivity reactions including rash, pruritus and urticaria, elevations of hepatic enzymes
Reversible alopecia and bone marrow depression.
*Uncommon***:** Headache and dizziness, Upper gastrointestinal symptoms (e.g. epigastric or abdominal pain nausea vomiting) and diarrhoea.
Very rare: Erythema multiforme, Stevens-Johnson syndrome

4.9 Overdose:
In case of overdosage, symptomatic therapy (gastric lavage) and general supportive measures should be undertaken.

5.0 Pharmacological Properties:
5.1Pharmacodynamic properties:
Pharmacotherapeutic group: Benzimidazole derivatives, ATC code: P02CA03
Albendazole is a benzimidazole carbamate with anthelmintic effects against tissue parasites.
Albendazole exhibits larvicidal, ovicidal and vermicidal activity, and it is thought to exert its anthelmintic effect by inhibiting tubulin polymerisation.
This causes the disruption of the helminth metabolism, including energy depletion, which immobilises and then kills the susceptible helminth.

5.2Pharmacokinetic Properties:
Absorption and metabolism
In man, after oral administration, albendazole is absorbed and completely metabolized. Albendazole rapidly undergoes extensive first-pass metabolism in the liver, and is generally not detected in plasma. Albendazole sulfoxide is the primary metabolite, which is thought to be the active moiety in effectiveness against systemic tissue infections. The plasma half-life of Albendazole sulfoxide is 8½ hours.Following oral administration of a single dose of 400 mg Albendazole, the pharmacologically active metabolite, Albendazole sulfoxide, has been reported to achieve plasma concentrations from 1.6 to 6.0 micromol/litre when taken with breakfast. The systemic pharmacological effect of Albendazole is augmented if the dose is administered with a fatty meal, which enhances the absorption by approximately 5-fold.

Excretion
Albendazole sulfoxide and its metabolites appear to be principally eliminated in bile, with only a small proportion appearing in the urine. Elimination from cysts has been shown to occur over several weeks following high and prolonged dosing.

Special Patient Populations

Elderly

Although no studies have investigated the effect of age on Albendazole sulfoxide pharmacokinetics, data in 26 hydatid cyst patients (up to 79 years) suggest pharmacokinetics similar to those in young healthy subjects. The number of elderly patients treated for either hydatid disease or neurocysticercosis is limited, but no problems associated with an older population have been observed.

Renal Impairment

The pharmacokinetics of Albendazole in patients with impaired renal function have not been studied.

Hepatic Impairment

The pharmacokinetics of Albendazole in patients with impaired hepatic function have not been studied.

5.3 Preclinical safety data: Not applicable

6.0 Pharmaceutical Particulars:

6.1 List of excipients:

Simethicone, Tween 80, Xanthan gum, Sugar, Sorbitol, Sodium benzoate, Sodium methyl paraben, Sodium propyl paraben, Potassium Sorbate, Citric Acid, Bronopol, Orange flavor, Green colour and Purified Water

6.2 Incompatibilities:

Not known

6.3 Shelf life :

36 months from the date of manufacture.

6.4 Special precautions for storage:

Store in a dry place, below 30^0C, protect from direct sunlight.
Keep out of reach of children.

6.5 Nature and content f container:

10ml amber coloured glass bottle contained in a unit box

6.6 Special precaution for disposal:

No special requirements

7.0 Marketing authorization holder/Registrant.

Dawa Limited,
Plot No. 7879/8, Baba Dogo Road, Ruaraka,
P.O Box 16633-00620,
Nairobi, Kenya.
Email:admin@dawalimited.com.

8.0 Manufacturer:

Dawa Limited,
Plot No. 7879/8, Baba Dogo Road, Ruaraka.
P.O Box 16633-00620,
Nairobi, Kenya.
Email:admin@dawalimited.com.

9.0 Date of first authorisation/renewal of the authorization:

Kenya, License No.: H2009/19999/288

10 . Legal category : Pharmacy Only

11. Date of revision of the text:

December 2019