Summary of Product Characteristics (SmPC)
PRODUCT NAME: Wormidan Tablets

1. {(Invented) name strength pharmaceutical form}

A) Product Name :Wormidan Tablets (Albendazole B.P. 400 mg)
B) Strength : 400 mg
C) Pharmaceutical dosage form: Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains: Albendazole B.P. 400 mg
Quantitative Declaration, the quantity of the active substance must be expressed per dosage unit

SNo.	Name of Material	Specification	Label claim	Quantity(mg/Tablet)	Active/Inactive
1.	Albendazole B.P	BP	400mg	400mg	Active

3. PHARMACEUTICAL FORM:

Orange coloured caplet shaped tablets having one face central break line and other face plain.

4. CLINICAL PARTICULARS:

Wormidan Tablet is indicated in the treatment of single or mixed invasion caused by threadworm human whipworms human, human worm, hookworm duodenal, American hookworm, tapeworm and nematode intestinal tapeworm unarmed and armed.

4.2 Posology and method of administration:

Hydatid Disease:

For 60 kg or above body weight- 400 mg twice daily with meals For less than 60 kg body weight-15 mg/kg/day given in divided doses twice daily with meals (maximum total daily dose 800 mg)

Duration: 28-day cycle followed by a 14-day albendazole-free interval, for a total of 3 cycles NOTE: When administering Wormidan Tablet in the pre- or post-surgical setting, optimal killing of cyst contents is achieved when 3 courses of therapy have been given.

Neurocysticercosis: For 60 kg or above body weight- 400 mg twice daily with meals For less than 60 kg body weight-15 mg/kg/day given in divided doses twice daily with meals (maximum total daily dose 800 mg) Duration: 8-30 days

Method of administration: Wormidan Tablets can be taken by oral route only.

4.3 Contraindications:

Hypersensitivity to any component of the formulation or suspected pregnancy. In women of childbearing potential use of the drug is limited to the first 7 days after the onset of menstruation or after obtaining a negative pregnancy test. Do not use in children under 2 years of age. Treatment with albendazole may disclose CNS cysticercosis, before extending symptoms, neurological symptoms (convulsions, increased intracranial pressure, focal symptoms) may occur soon after treatment, immediately start administering anticonvulsants and steroids.

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4.4 Special warnings and precautions for use:
Gastrointestinal discomfort, diarrhoea, headache and dizziness have been reported. Hypersensitivity reactions including rash, pruritus and urticaria have been reported less frequently

4.5 Interaction with other medicinal products and other forms of interaction
Concurrent use of dexamethasone, praziquantel or cimetidine increases the plasma concentrations of albendazole. The drugs carbamazepine, phenytoin, and phenobarbital lower the plasmatic concentration and the half-life of albendazole. Ritonavir, phenytoin, carbamazepine and phenobarbital may decrease concentrations of the active metabolite of albendazole in serum; significance of this interaction is unknown, however, because of the risk of reducing the effectiveness of the drug should monitor the effectiveness of treatment, particularly when treating systemic infections and, if necessary, modify the dosage.

4.6 Pregnancy and Lactation:
Pregnancy: Category C: Do not use during pregnancy. Albendazole has harmful effects on the fetus and causes developmental defects in animals. In the course of treatment and one month after its completion should use effective methods of contraception. In women of childbearing age, treatment should be carried out during the first 7 days of menstruation or after a negative pregnancy test. Lactation: Should not be used during breastfeeding unless the potential benefits outweigh the risks of treatment.

4.7 Undesirable effects:
Gastrointestinal discomfort, diarrhoea, headache and dizziness have been reported. Hypersensitivity reactions including rash. Pruritus and urticaria have been reported less frequently.

4.8 Overdose:

If poisoning or excessive over dosage 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.

5.1 Pharmacokinetics properties:

5.2 Pharmacodynamics properties

Pharmaco-therapeutic group: Anthelmintics, benzimidazoles derivatives ATC code: P02CA03 Albendazole is a broad-spectrum anthelmintic. The principal mode of action for
albendazole is by its inhibitory effect on tubulin polymerization which results in the loss of cytoplasmic microtubules. Albendazole 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. Degenerative changes in the endoplasmic reticulum, the mitochondria of the germinal layer, and the subsequent release of lysosomes result in decreased production of adenosine triphosphate (ATP), which is the energy required for the survival of the helminth. Due to diminished energy production, the parasite is immobilized and eventually dies.

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5.2 Pharmacokinetics properties:

Absorption: In man, the full extent of albendazole absorption following oral administration has not been established. However, it is known that albendazole is poorly absorbed (Distribution Albendazole is widely distributed throughout the body including into urine, bile, liver, cyst wall, cyst fluid, and cerebrospinal fluid (CSF). It is about 70% bound to plasma protein.

Distribution: Albendazole is widely distributed throughout the body including into urine, bile, liver, cyst wall, cyst fluid, and cerebrospinal fluid (CSF). It is about 70% bound to plasma protein.

Metabolism: Albendazole rapidly undergoes extensive first-pass metabolism in the liver, and is generally not detected in plasma or in urine. Albendazole is the primary metabolite, which is thought to be the active moiety in effectiveness against systemic tissue infections (anthelmintic activity). Peak plasma concentrations of albendazole attained 2–5 hours after a dose. Albendazole is further metabolized to albendazole and other primary oxidative metabolites.

Elimination:

Albendazole and its metabolites appear to be principally eliminated in bile, with only a small proportion (<1% of Albendazole) appearing in the urine. The plasma half-life of albendazole sulphoxide is 8-12 hours.

Special population: Patients with extrahepatic obstruction: Increased albendazole serum concentration and prolonged half-life. Elimination half-life may be 31.7 hours.

5.3 Preclinical safety data:

No relevant data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

Sr. No	Name of the Raw Material(s)
	PART 1- DRY MIXING
1	Microcrystalline cellulose
2	Sucrose
3	Maize Starch
	PART I1- BINDER PREPARATION:
4	Sodium Methyl Hydroxy Benzoate BP
5	Sodium Propyl Hydroxy Benzoate BP
6	Sucrose
7	Colour Sunset Yellow
	PART II1- LUBRICATION:
8	Orange Dry Flavour IH
9	Purified Talc BP

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10	Aspartame BP
11	Magnesium Stearate BP
12	Colloidal Anhydrous Silica BP
13	Purified Water BP

6.2 Incompatibilities:
None known.

6.3 Shelf life:
3 years from the manufacturing date.

6.4 Special precautions for storage:

Store below 30^0C, store in a cool, dry place away from sunlight Keep from the reach of children.

6.5 Nature and contents of container <and special equipment for use, administration or implantation:

1 × 1 Tablet Alu-PVC Blister packs.

6.6 Special precautions for disposal:

Not applicable.

Marketing authorization holder

Dana Pharmaceuticals Ltd.
Shiroro Dam Road, Maitumbi, Minna.
Niger State. Nigeria.

Marketing authorization number(s)
B4-4303