UGOLAB PRODUCTIONS (NIG.) LTD.

MANUFACTURERS OF PHARMACEUTICAL PRODUCTS AND GENERAL MERCHANTS

Head office: 31A Burma Road, Sabon Gari, Kano. **Factory:**157/159, Club Road, Bompai Ind. Layout, Kano.
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SUMMARY OF PRODUCT CHARACTERISTICS ALBENDAZOLE SUSPENSION

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SUMMARY OF PRODUCT CHARACTERISTICS
ALBENDAZOLE SUSPENSION

1. Name of the Medicinal Product

(a) Product Name : Albendazole Suspension (Albendazole Oral Suspension)
(b) Strength : 100 mg/5ml
(c) Pharmaceutical Dosage Form : Suspension

2. Quality and Quantitative Composition

Composition:
Each 5 ml contains:
Albendazole B.P. 100 mg

Sr. No.	Name of the Materials	Specification	Label Claim	Quantity (mg/5ml)	Active/ Inactive
1	Albendazole	B.P.	100 mg	100.0 mg	Active

3. Pharmaceutical Form

A thick suspension filled in amber colour pet bottle.

4. Clinical Particulars

4.1.Therapeutic Indications:

Albendazole Suspension 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:

The usual dose of Albendazole Suspension in children between one and two years of age is 10 mL of suspension as a single dose.

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In heavy mixed infestation involving Strongyloides or Taeniasis, a single daily dose may be inadequate and the dose may be given for three consecutive days.

20 mL of Albendazole suspension dose in both adults and children over two years of age.

If the patient is not cured after three weeks, a second course of treatment may be given. No special procedures, such as fasting or purging, are required. Albendazole has not been adequately studied in children under one year of age.

Giardiasis (dose in children over 2 years of age):
A single 20 mL suspension for five days.

Method of administration:
Albendazole l suspension 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.

4.4 Special warning 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.

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4.5 Interaction with other medicinal products and other forms of interactions:
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 Effects on ability to drive and use machine:
Albendazole has no influence on the ability to drive and use machines.

4.8 Undesirable effects:
Gastrointestinal discomfort, diarrhoea, headache and dizziness have been reported.

Hypersensitivity reactions including rash. pruritus and urticaria have been reported less frequently.

4.9 Overdose:
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.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties:
Pharmacotherapeutic group: Anthelmintics, benzimidazoles derivatives

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.

5.2 Pharmacokinetic 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 (<5%) with most of an oral dose remaining in the gastrointestinal tract. The poor absorption is believed to be due to the low aqueous solubility of

albendazole. Absorption is significantly enhanced (up to 5 fold) if albendazole is administered with a fatty meal compared with fasted state.

Distribution
Albendazole sulfoxide 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 sulphoxide 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 sulfoxide attained 2–5 hours after a dose. Albendazole sulphoxide is further metabolized to albendazole sulfone and other primary oxidative metabolites.

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

Special population
Patients with extrahepatic obstruction: Increased albendazole sulfoxide 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 Materials

1	Sorbitol
2	Xanthan Gum
3	Sodium citrate
4	Methylparaben
5	Propylparaben
6	Tetrazine yellow
7	Anise oil
8	Tween-80
9	Purified Water

6.2 Incompatibilities
None known

6.3 Shelf life
36 months

6.4 Special precautions for storage
Do not store above 25°C

6.5 Nature and contents of container

Bottle:	Amber PET
Closures:	28mm ROPP, tamper evident, child resistant.
Pack Sizes:	20ml

6.6 Special precautions for disposal and other handling
No special requirements.

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Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required (these should be disposed of in line with local requirements). These measures will help to protect the environment.

7. Marketing authorisation holder
UGOLAB PRODUCTIONS NIG. LTD
157/159 CLUB ROAD, BOMPAI INDUS LAYOUT, KANO,
KANO STATE.
NIGERIA.

8. Marketing authorisation number(s)
A4-3534

9. Date of first authorisation/renewal of the authorisation
26th MAY, 2015

10. Date of revision of the text
Not Applicable

Company Contact Details
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