SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

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

2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Each 5 ml. contains:

Albendazole	BP	100 mg.
Flavoured base		q.s.

Colour: Sunset Yellow FCF

01.	Albendazole
02.	Liquid Sorbitol (Sorbitol Solution 70%)
03.	Sod. Methyl Hydroxybenzoate (Sodium Methylparaben)
04.	Sod. Propyl Hydroxybenzoate (Sodium Propylparaben)
05.	Xanthan Gum
06.	Saccharin Sodium
07.	Polysorbate-80
08.	Citric Acid Monohydrate
09.	Col. Sunset Yellow FCF (15985)
10.	Essence Orange Sweet No.1
11.	Purified Water

3. PHARMACEUTICAL FORM

Suspension
Light orange colored flavoured palatable suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Albendazole (Alwo) is indicated in the treatment of single or mixed intestinal parasites. Clinical studies have shown Albendazole effective in the treatment of Ascaris lumbricoides (roundworm), Trichuris trichiura (whipworm), Enterobius vermicularis (pinworm/threadworm), Ancylostoma duodenale and Necator americanus (hookworm), Taenia spp. (tapeworm) and Strongyloides stercoralis. Alwo has been also shown to be

effective in the treatment of Giardia (duodenalis or intestinalis or lamblia) infections in children.

4.2 Posology and method of administration

The usual dose in children between one and two years of age is 10ml (200 mg) of **Alwo oral suspension** as a single dose. In heavly mixed infestation involving Strongyloides or Taeniasis, a single daily dose may be inadequate and the dose may be given for three consecutive days.

Note: 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 400mg daily dose (20ml suspension) for five days.

4.3 Contraindications

Alwo is contra-indicated in patients with a known history of hypersensitivity to Albendazole or constituents.

4.4 Special warnings and special precautions for use

It has been noted that leucopaenia has occurred when used for periods longer than recommended. In order to avoid administering Albendazole during early pregnancy, women of child bearing age should initiate treatment during the first week of menstruation or after a negative pregnancy test. **"DO NOT USE IN PREGNANCY"**

4.5 Interaction with other FPPs and Other forms of Interaction

Praziquantel has been reported to increase the plasma levels of the Albendazole active metabolite.

4.6 Pregnancy and lactation

Albendazole (Alwo) is known to be teratogenic & embryotoxic in animals. The safety of Albendazole during pregnancy has not been established, and Alwo should not be taken by pregnant women at any stage of their pregnancy or by women who are likely to become pregnant, during or shortly after the course of therapy.

4.7 Effects on ability to drive and use machines

Not Known

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: Antihelminthic

ATC Code: P02CA03

Mechanism of action:

Albendazole **(Alwo)** is a benzimidazole carbamate with anthelmintic and antiprotozoal activity against intestinal and tissue parasites. Animal studies have shown that Albendazole exhibits vermicidal, ovacidal and larvacidal activity and exerts its anthelmintic effect by inhibiting tubulin polymerization. This causes the disruption of the helminth metabolism, including energy depletion, which immobilises and then kills the susceptible helminth.

5.2 Pharmacokinetic properties

In man, after oral administration, Albendazole is absorbed and completely metabolized. At a dose of 6.6 mg/kg of Albendazole, the plasma concentration of its main metabolite, the sulfoxide, attains a maximum of 0.25 to 0.30 micrograms/mL after approximately 2½ hours. The half-life of the sulfoxide in the plasma is 8 hours. The metabolite is essentially eliminated via the urine.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Sorbitol (Sorbitol Solution 70%)	BP
Sod. Methyl Hydroxybenzoate (Sodium Methylparaben)	BP
Sod. Propyl Hydroxybenzoate (Sodium Propylparaben)	BP
Xanthan Gum	BP
Saccharin Sodium	BP
Polysorbate-80	BP
Citric Acid Monohydrate	BP
Col. Sunset Yellow FCF (15985)	IH
Essence Orange Sweet No.1	IH
Purified Water	BP

6.2 Incompatibilities

Not sufficient data available

6.3 Shelf life

36 month from the date of manufacturing.

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C. Protect from light. Keep out of reach of Children

6.5 Nature and contents of container

20ml suspension packed in an amber colored PET bottle in an inner carton.

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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Country : INDIA

8. MARKETING AUTHORISATION NUMBER

04492/06837/REN/2018

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of last renewal: May 23, 2019

10. DATE OF REVISION OF THE TEXT

May 23, 2019