SUMMARY OF PRODUCT & CHARACTERISATION

1 NAME OF THE MEDICINAL PRODUCT

AZ-SUSPENSION

Albendazole Oral Suspension 200mg/ 5 ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml Contains:

Albendazole USP	200 mg
Flavoured Syrupy base	q.s.
Colour : Tartrazine	

3 PHARMACEUTICAL FORM

Oral Suspension

4.1 THERAPEUTIC INDICATIONS

For the treatment of Trichuris trichuria (whipworm), Enterobius vermicularis (pinworm or threadworm), Ascaris lumbricoides (roundworm), Ancylostoma duodenale (common hookworm), Necator americanus (American hookworm) in single or mixed gastrointestinal infestations.

There is no evidence that albendazole are effective in the treatment of cysticercosis.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Posology and method of administration:
Adults and children over 12 years:

Adults and children over 2 years:

For the control of trichuriasis, ascariasis and hookworm infections, one tablet twice a day for three consecutive days.

For the control of enterobiasis a single tablet is administered. It is highly recommended that a second tablet is taken after two weeks, if re-infection is suspected.

Tablets may be chewed or swallowed whole. Crush the tablet before giving it to a young child. Always supervise a child while they are taking this medicine.

Method of Administration

Oral use.

4.3 CONTRAINDICATIONS

Albendazole is contraindicated in pregnancy and in patients who have shown hypersensitivity to the product or any components.

4.4 SPECIAL WARNINGS 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 Albendazole. Although there are no additional data on this potential interaction, concomitant use of Albendazole and metronidazole should be avoided.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Concomitant treatment with cimetidine may inhibit the metabolism of Albendazole in the liver, resulting in increased plasma concentrations of the drug.

Concomitant use of Albendazole and metronidazole should be avoid

4.6 FERTILITY, PREGNANCY AND LACTATION

Since albendazole is contra-indicated in pregnancy, patients who think they are, or may be, pregnant should not take this preparation.

Lactation

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

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

It has no or negligible influence on the ability to drive and use 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 albendazole based on the comprehensive assessment of the available adverse event information. A

causal relationship with albendazole 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.

4.9 OVERDOSE

In patients treated at dosages substantially higher than recommended or for prolonged periods of time, the following adverse reactions have been reported rarely: alopecia, reversible liver function disturbances, hepatitis, agranulocytosis, neutropenia and glomerulonephritis. With the exception of agranulocytosis and glomerulonephritis, these also have been reported in patients who were treated with Albendazole at standard dosages.

Signs and symptoms

In the event of accidental overdosage, abdominal cramps, nausea, vomiting and diarrhoea may occur.

Treatment

There is no specific antidote. Activated charcoal may be given if considered appropriate.

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: anthelmintic for oral administration, benzimidazole derivatives;

ATC code: P02CA01.

In vitro and in vivo work suggests that Albendazole blocks the uptake of glucose by adult and larval forms of helminths, in a selective and irreversible manner. Inhibition of glucose uptake appears to lead to endogenous depletion of glycogen stores within the helminth. Lack of glycogen leads to decreased formation of ATP and ultrastructural changes in the cells.

There is no evidence that Albendazole is effective in the treatment of cysticercosis.

5.2 PHARMACOKINETIC PROPERTIES

Absorption :

Following oral administration, < 10% of the dose reaches the systemic circulation, due to incomplete absorption and to extensive pre-systemic metabolism (first-pass effect). Maximum plasma concentrations are generally seen 2 to 4 hours after administration. Dosing with a high fat meal leads to a modest increase in the bioavailability of Albendazole.

Distribution :

The plasma protein binding of Albendazole is 90 to 95%. The volume of distribution is 1 to 2 L/kg, indicating that Albendazole penetrates areas outside the vascular space. This is supported by data in patients on chronic Albendazole therapy (e.g., 40 mg/kg/day for 3-21 months) that show drug levels in tissue.

Metabolism :

Orally administered Albendazole is extensively metabolised primarily by the liver. Plasma concentrations of its major metabolites (amino and hydroxylated amino forms of Albendazole) are substantially higher than those of Albendazole. Impaired hepatic function, impaired metabolism, or impaired biliary elimination may lead to higher plasma levels of Albendazole.

Elimination :

Albendazole, the conjugated forms of Albendazole, and its metabolites likely undergo some degree of enterohepatic recirculation and are excreted in the urine and bile. The apparent elimination half-life after an oral dose ranges from 3 to 6 hours in most patients.

SUMMARY OF PRODUCT & CHARACTERISATION

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

No.	Name of the Excipients
1	Albendazole
2	Sodium CMC
3	Xanthan gum
4	Sodium methyl Paraben
5	Sodium propyl Paraben
6	Potassium sorbate
7	Simethicone
8	Sodium Saccharin
9	Pineapple Flavour
10	Citric acid
11	Tartrazine colour
12	Aspartame
13	Tween 80
14	Purified Water

6.2 INCOMPATIBILITIES : Not applicable.

6.3 SHELF LIFE : 36 Months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C.,Protect from light & moisture.

6.5 NATURE AND CONTENTS OF CONTAINER

10ml, plastic , pet bottle with measuring cup.

7 MARKETING AUTHORISATION HOLDER
