SUMMARY OF PRODUCT & CHARACTERISATION

1 NAME OF THE MEDICINAL PRODUCT

ZESFIL-SUSPENSION - Albendazole Oral Suspension 200mg/ 5 ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml Contains:

Albendazole USP	200 mg

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

Adults and children over 2 years:

Enterobiasis:

1 x 5 ml (1 dosing cup).

It is highly recommended that a second dose is taken after 2 weeks, if reinfection is suspected.

Ascariasis, trichuriasis, ancylostomiasis, necatoriasis and mixed infections:

1 x 5 ml (1 dosing cup) bd for three days.

Children under 2 years:

Albendazole has not been extensively studied in children below the age of 2 years.

Currently available data are described in section 4.4, 4.8 and 5.2, but no recommendations on a posology can be made.

Because of the lack of sufficient safety data, Albendazole should not be used in children below the age of 1 year

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

there have been rare reports of reversible liver function disturbances, hepatitis and neutropenia described in patients who were treated with mebendazole at recommended dosages for indicated conditions (see section 4.8 'Undesirable effects'). Agranulocytosis and glomerulonephritis have also been reported in patients treated for Echinococcosis.

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

Convulsions in children, including in infants below 1 year of age, have been reported very rarely during post-marketing experience (see section 4.8 'Undesirable effects'). Albendazole has not been extensively studied in children below the age of 2 years. Therefore, Albendazole should be used in children aged 1-2 years only if the potential benefit justifies the potential risk.

Because of the lack of sufficient safety data, Albendazole should not be used in children below the age of 1 year.

Albendazole should only be given to very young children if their worm infestation interferes significantly with their nutritional status and physical development.

Albendazole oral suspension contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This medicinal product contains less than 1 mmol sodium (23 mg) per mL, that is to say essentially 'sodium-free'.

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

Pregnancy

Since Albendazole is contraindicated in pregnancy, patients who think they are or may be pregnant should not take this preparation.

Breast-feeding

Limited data from case reports demonstrate that a small amount of mebendazole is present in human milk following oral administration. Therefore, caution should be exercised when Albendazole is administered to breast-feeding women.

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 Vermox based on the comprehensive assessment of the available adverse event information. A causal relationship with Vermox 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.

The safety of Vermox was evaluated in 6276 subjects who participated in 39 clinical trials for the treatment of single or mixed parasitic infestations of the gastrointestinal tract. In these 39 clinical trials, no adverse drug reactions (ADRs) occurred in ≥ 1% of Vermox-treated subjects.

ADRs identified from clinical trials and post-marketing experience with Vermox are included in Table 1. The displayed frequency categories use the following convention:

Very common (≥ 1/10); Common (≥ 1/100 to <1/10); Uncommon (≥ 1/1000 to <1/100); Rare (≥ 1/10,000 to <1/1000); Very rare (<1/10,000), Not known (cannot be estimated from the available data).

SUMMARY OF PRODUCT & CHARACTERISATION

Table 1: Adverse Drug Reactions Reported in Clinical Trials and Post-marketing Experience for Vermox

ystem Organ lass	**dverse Drug Reactions**		
	equency Category		
	ommon 1/100 to < 1/10)	**ncommon** 1/1000 to < 1/100)	**are** 1/10,000 to <1/1000)
ood and mphatic ystem Disorders			eutropenia[b] granulocytosis[b] *
mune System sorders			ypersensitivity cluding anaphylactic action and aphylactoid reaction[b]
ervous System sorders			onvulsions[b] zziness[a]
astrointestinal sorders	odominal pain[a]	odominal discomfort[a]; arrhoea[a]; atulence[a] ausea[a], Vomiting[a]	
epatobiliary sorders			epatitis; [b] normal liver function sts[b]
kin and ubcutaneous ssue Disorders			ash[a] oxic epidermal ecrolysis [b]; evens-Johnson ndrome [b]; xanthema [b]; ngioedema [b]; rticaria [b]; opecia [b]
enal and Urinary sorders			omerulonephritis[b] *

[a] ADR frequency data derived from Clinical Trials or Epidemiological Studies

[b] ADRs not observed in clinical trials and frequency calculated based on 6276 patients exposed in clinical trials and epidemiological studies, divided by 3 (Frequency = 1/2092).

* Observed in patients treated for Echinococcosis

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via: https://pv.pharmacyboardkenya.org

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.

6. PHARMACEUTICAL PARTICULARS

SUMMARY OF PRODUCT & CHARACTERISATION

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

Medina Chemicals Limited

8. MARKETING AUTHORISATION NUMBER

CTD11824

9.DATE OF INITIAL AUTHORIZATION

17TH MAY,2026