**Summary of Product Characteristics for Pharmaceutical Products**

## 1. Name of the medicinal product

Dinlazole Suspension

## 2. Qualitative and quantitative composition

Each 5 ml suspension contains Albendazole USP 200 mg

Excipients with known effect

Sorbitol and propylene glycol

For the full list of excipients, see section 6.1.

## 3. Pharmaceutical form

Oral oral suspension.

Orange red colored, suspension filled in 10 ml amber plastic bottle, sealed and packed in unit carton.

## 4. Clinical particulars

### 4.1 Therapeutic indications

Dinlazole is indicated in the treatment of single or mixed infestations of intestinal and tissue parasites, in adults and children over 2 years of age. Clinical studies have shown to be effective in the treatment of infections caused by: Enterobius vermicularis (pinworm/threadworm), Ascaris lumbricoides (roundworm), Ancylostoma duodenale and Necator americanus (hookworms), Trichuris trichiura (whipworm), Strongyloides stercoralis, animal hookworm larvae causing cutaneous larva migrans, and the liver flukes Opisthorchis viverrini and Clonorchis sinensis. Dinlazole is also indicated for the treatment of Hymenolepis nana and Taenia spp. (tapeworm) infections, when other susceptible helminths species are present. Treatment courses should be extended to 3 days.

### 4.2 Posology and method of administration

**Posology**

| Indication | Daily dose | Treatment duration |
|---|---|---|
| Intestinal and skin infections (short-term treatment with lower dose) | | |
| Oxyurosis | Children from 1 to 2 years: 5 ml suspension (200 mg) in one single dose Adults and children older than 2 years*: 400 mg, 1 single tablet or 10 ml of suspension in single dose Strict hygiene measures should be taken and family environment should also be treated | Single dose to be repeated 7 days after |
| Roundworms Hookworms Whipworms | Children from 1 to 2 years: 5 ml of suspension (200 mg) Adults and children older than 2 years*: 400 mg, 1 | Single dose. ** |

| | | |
|---|---|---|
| | single tablet or 10 ml of suspension in single dose | |
| Anguillulosis Taeniasis (associated with others parasitosis) | Adults and children older than 2 years *: 400 mg, 1 tablet or 10 ml of suspension daily | 1 daily dose during 3 days. ** |
| Giardiasis | Children older than 2 years*: 1 tablet or 10 ml of suspension daily | 1 daily dose during 5 days. |
| Systemic infections (long-term treatment with higher doses) | | |
| Trichinosis | Children*: 15 mg/kg/day divided into two daily doses<br>Adults: 1 tablet or 10 ml of suspension twice daily | 2 daily doses (morning & evening) during 10 to 15 days depending on the severity of the symptoms and on the onset of treatment. |
| | | |

**Method of Administration**

If the patient is not cured after three weeks, a second course of treatment is indicated. No special procedures, such as fasting or purging, are required. The tablets can be chewed or taken with water. Some people, particularly young children, may experience difficulties swallowing the tablets whole and should be encouraged to chew the tablets with a little water, alternatively the tablets may be crushed.

## 4.3 Contraindications

Hypersensitivity to albendazole or to any of the components

Pregnancy and women of childbearing age who do not use an efficient contraceptive method

Breastfeeding

## 4.4 Special warnings and precautions for use

Neurologic symptoms

A treatment with albendazole might reveal a pre-existing neurocysticercosis, in particular in regions of strong infestation with taeniasis. Patients might feel neurological symptoms such as convulsions, increase in intracranial pressure and focal signs resulting from the inflammatory reactions following the death of the parasite in the brain. Symptoms might appear shortly after the treatment; an adapted treatment with corticoids and anticonvulsants should be immediately started.

Precaution for use when using albendazole for systemic infections (long-term treatment with higher doses):

Liver disorders

Albendazole might result in a slight to moderate increase in liver transaminases, normalising generally when stopping the treatment. Serious cases of hepatitis have also been reported when treating systemic helminth infections (long-term treatment with higher doses). Tests of the liver function should be carried out prior to starting the treatment and at least every second week during the treatment. Albendazole shall be stopped in case of increase in hepatic enzymes (more than twice normal). If reintroducing the treatment is indispensable, this should be done after normalisation of liver enzymes. Moreover, a close monitoring should be carried out, keeping in mind that potential relapses might appear because an allergic mechanism cannot be discarded.

Medullar depression

Cases of medullar depression have been reported during treatment of systemic helminth infections (longterm treatment with higher doses). Numerations of blood formula should be performed when starting the treatment and then after two weeks of treatment with albendazole.

Patients with a liver disease, including liver echinococcosis, seem more likely to develop a medullar depression, leading to pancytopenia, medullar aplasia, agranulocytosis and leucopoenia. Then, an increase monitoring of the blood formula is recommended in patients showing a liver disease.

Albendazole shall be stopped in case of significant decrease in the number of blood cells.

In the treatment of trichinosis, few data are available with albendazole in children under 6 years of age.

In the treatment of trichinosis, because of the activity, in particular on the intestinal forms and of the larvae in the early phase of the tissue migration, it is recommended to administer albendazole as early as possible at the start of the infestation in order to decrease the symptoms and the complications. This treatment remains inactive on the encysted larvae in chronic forms and when it is initiated belatedly.

Contraception

Before initiating the treatment with albendazole, the doctor should inform the patient of the embryotoxic, teratogenic and aneugenic risks of albendazole, of the necessity of an efficient contraception and of the 5 potential consequences on pregnancy if it occurs during the course of the treatment with albendazole.

## 4.5 Interaction with other medicinal products and other forms of interaction

Enzymes inducers anticonvulsivants, ritonavir and rifampicine may have the potential to reduce plasma concentrations of albendazole and of its active metabolite, albendazole sulfoxide with a risk of decrease in its efficacity. Clinical monitoring of the therapeutic efficacy and the potential adaptation of the posology of albendazole during the course of the treatment with an enzymatic inducer and after stopping.

## 4.6 Fertility, pregnancy and lactation

Female patients

Given the aneugenic, embryotoxic and teratogenic potential of albendazol, all the precautions should be taken in order to avoid pregnancy in these female patients. Treatment with albendazole should not be initiated before a negative result to a pregnancy test performed risht before the treatment initiation. Women of childbearing age should use an efficient contraceptive method during the treatment and 6 months after stopping the treatment.

Male patients and their female partners

All precaution should be taken in order to avoid pregnancy in the partners of male patients treated with albendazole. It is not known if the presence of albendazole in sperm can cause teratogenic or genotoxic effects on human embryo/foetus.

Men or their female partners of childbearing age must be informed of the obligation to use an efficient contraceptive method during all the course of the treatment with albendazole and during 3 months after stopping the treatment. Men whose partners are pregnant should be informed of the obligation to use a condom in order to reduce the exposition of their partner to albendazole.

Pregnancy

Studies in animal showed teratogenic embryotoxic effects in rat and rabbit at doses close to those used in men. in clinical trials, the data on the use of albendazole during the first term of pregnancy are limited. Albendazole is contraindicated during pregnancy, espacially because

there are therapeutical alternatives that are better assessed in terms of safety in pregnant woman. Female patients should be informed of the necessity to consult their doctor immediately in case of pregnancy. This is based on prenatal monitoring targeted on malformations described in animal (skeletic, cranofacial, limbs).

Fertility

In rat or mouse, studies have showed testicular toxicity of albendazole (see section 5.3). akbendazole has an aneugic activity, which is a risk factor for alteration of fertility in man.

Breasfeeding

Albendazole is present in human breast milk after a single dose of 400 mg. Because of its aneugenic activity, a risk for the new born child cannot be excluded. In case of a single dose, breastfeeding should be stopped at the time of intake and for at least 5.5 half-lives after stopping the treatment. Before initiatiing breastfeeding, pump all the available breask milk and dispose of it; in case of repeated intakes, breastfeeding is contraindicated.

## 4.7 Effects on ability to drive and use machines

when driving or using machines, it should be kept in mind that dizziness have been reported after using albendazole.

## 4.8 Undesirable effects

The frequency of side effects very common to rare have been determined based on the data from the clinical trials. The frequencies of the other side effects are mainly based on the post-marketing data and are referred to the reported observations rather than the real frequencies.

Headaches, Dizziness, Gastro-intestinal symptoms (epigastric or abdominal pains, nausea, vomiting) and diarrhoea,

## 4.9 Overdose

In case of overdose, symptomatic treatment and medical monitoring are recommended.

# 5. Pharmacological properties

## 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiparasitics - antihelmintics, ATC code: P02CA03.

Albendazole is a benzimidazole carbamate. Albendazole is broad-spectrum antihelmintics, which is effective against a wide range of intestinal helminths.

Albendazole acts on helminths'cytoskeleton by the inhibition of tubulin polymerisation and thus, their introduction in the microtubules, blocking glucose absorption of parasites and resulting in their death.

Albendazole is also active on Giardia intestinalis (or duodenalis). It has an irreversible action that is targeted on the ventral disc of the trophozoites by acting on the polymerisation of tubulin and giardine, leading to a disorganisation of the cytoskeleton and micro strips. The ability of adhesion to the enterocytes is decreased, resulting in an inhibition of the growth and multiplication of the parasite.

## 5.2 Pharmacokinetic properties

Absorption and biotransformation
Following the administration, the low proportion of albendazole is absorbed (< 5 %) is metabolised into albendazole sulfoxide and sulfone. The plasma concentration in sulfoxide, the main active circulating metabolite reaches its maximum about two and a half hours after its administration.
The systemic pharmacological effect of albendazole is increased if the dose is administered concomitantly with a fat-rich meal, improving absorption by about 5.

Elimination
The plasma half-life of albendazole sulfoxide is 8 and a half hours.
Albendazole sulfoxide and its metabolites seem to be mainly eliminated by biliary route and for a lower proportion by urinary route.

Specific population
Renal failure: albendazole pharmacokinetics has not been studied in patients with renal failure.

Hepatic failure: albendazole pharmacokinetics has not been studied in patients with hepatic failure.

## 5.3 Preclinical safety data

Degeneration of the seminiferous tubules has been reported in cancerogenesis studies at dose of 100 mg/kg/day in mouse and 20 mg/kg/day in rat. A decrease in the testicle weight has been observed in dog treated with 60 mg/kg/day during 6 months. These doses correspond respectively to 2.4; 0.24 and 2.5 times the maximum therapeutic dose (based on the human equivalence). Albendazole has not altered fertility in males or female rat up to the maximum dose of 30 mg/kg/day, or 0.36 times the maximum therapeutic dose (based on the human equivalence).

Albendazole appeared to be teratogenic and embryotoxic in rat and rabbit.

No cancerogenic potential has been was shown during the cancerogenesis studies in rats (20 mg/kg/day) and in mice (400 mg/kg/day). Albendazole

did show any genotoxic effects in in vitro trials carried out on bacteria and mammal cells cultures, as well as in an in vivo micronucleus trial in rodents. A positive result has been reported in another micronucleus study in omuse, and is regarded as resulting from an aneugenic effect of albendazole.

## 6. Pharmaceutical particulars

### 6.1 List of excipients

Sugar
Citric acid Monohydrate
Methyl Paraben Sodium
Propyl Paraben Sodium
Sorbitol solution (non crystallized)
Orange Dry Mix
Xanthan Gum
Colloidal Anhydrous Silica
Propylene Glycol
Glycerin
Polysorbate 80
Mixed fruit flavor
Purified Water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

24 months

### 6.4 Special precautions for storage

Store below 30°C.

Protect from light.

Keep out of reach of children.

### 6.5 Nature and contents of container

10 ml HDPE bottles contained in unit cartons along with patient information leaflet.

### 6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## 7. Marketing authorisation holder

Dinlas Pharma EPZ Limited
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P.O Box 22661-00505
Nairobi-Kenya

**8. Marketing authorisation number(s)**
CTD 10872
**9. Date of first authorisation/renewal of the authorisation**
15/09/2023
**10. Date of revision of the text**
14/05/2025