SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

WORMZAP® SUSPENSION

Strength

Each 5 ml contain:
Albendazole BP 100mg

Pharmaceutical/Dosage form

Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contain:
Albendazole BP 100mg

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension

White coloured viscous aqueous suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Wormzap® Suspension is a broad spectrum anthelminthic used for the treatment of single or mixed infestations of:Enterobious vermiclaris (pinworm or threadworm), Trichuris trichuria (whipworm), Ascaris lumbricoides (large roundworm),Ancylostoma duodenale and Necator americanus (hookworm), Strongyloides stercoralis and Taenia spp. (tapeworm).

4.2 Posology and method of administration

Posology

Indications	Daily dose	Treatment duration
Intestinal and skin infections (short-term treatment with lower dose)		
Oxyurosis	Children from 1 to 2 years: 10 ml suspension (200 mg) in one single dose Adults and children older than 2 years: 20 ml of suspension (400mg) in single dose Strict hygiene measures should be taken, and the family environment should also be treated.	Single does to be repeated 7 days after.
Roundworms Hookworms Whipworms	Children from 1 to 2 years: 10 ml of suspension (200 mg) Adults and children older than 2 years: 20 ml of suspension (400mg) in single dose.	Single dose. *
Anguillulosis Taeniasis (associated with others parasitosis)	Adults and children older than 2 years: 20 ml of suspension (400mg) daily	1 daily dose for 3 days. *
Giardiasis	Children older than 2 years: 20 ml of suspension daily.	1 daily dose for 5 days.
Systemic infections (long-term treatment with higher doses)		
Trichinosis	Children: 15 mg/kg/day divided into two daily doses Adults: 20 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.

*If the worm control performed 3 weeks after the treatment is positive, a second treatment should be administered.

Special populations
Elderly people:
Data concerning patients from 65 years old are limited. Reports suggest that no adaptation of the posology is required in elderly people. However, Wormzap Suspension should be used with care in patients with liver dysfunction.

Liver failure:
Albendazole is rapidly metabolized by the liver, the main metabolite, albendazole sulfoxide, is pharmacologically active. Hence, liver failure might result in significant effect on the pharmacokinetics of albendazole sulfoxide.
Patients with abnormal liver function tests (transaminases) prior to treatment with albendazole should be closely monitored. The treatment should be stopped in case of significant increase in liver enzymes or in case of clinically significant decrease in blood formula numeration (see section 4.4).

Renal failure:
As the elimination of albendazole and its main metabolite, albendazole sulfoxide are negligible, it is unlikely that the clearance of these compounds are modified in patients with renal failure. No dose adaptation of posology is required, however, patients with renal failure should be closely monitored.

Method of administration
Oral route.

Neither purge, nor fast prior treatment is necessary

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 (see section 4.6)
- Breastfeeding

4.4 Special warnings and precautions for use

Neurologic symptoms
A treatment with Wormzap Suspension might reveal a pre-existing neurocysticercosis, 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.

Precautions for use when using Wormzap Suspension for systemic infections (long-term treatment with higher doses):

- Liver disorders

Wormzap Suspension 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) (see section 4.8). Tests of the liver function should be carried out prior to starting the treatment and at least every second week during the treatment. Wormzap Suspension 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, 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) (see section 4.8). Numerations of blood formula should be performed when starting the treatment and then after two weeks of treatment with Wormzap Suspension.
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.
Wormzap Suspension shall be stopped in case of significant decrease in the number of blood cells (see section 4.2 and 4.8).
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, on the intestinal forms and of the larvae in the early phase of the tissue migration, it is recommended to administer Wormzap Suspension as early as possible at the start of the infestation 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 Wormzap Suspension, 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 potential consequences on pregnancy if it occurs during the treatment with albendazole (see section 4.6).

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 Wormzap Suspension 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 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 to avoid pregnancy in these female patients. Treatment with Wormzap Suspension 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 to avoid pregnancy in the partners of male patients treated with Wormzap Suspension. 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 Wormzap Suspension and during 3 months after stopping the treatment. Men whose partners are pregnant should be informed of the obligation to use a condom 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 (see section 5.3). in clinical trials, the data on the use of albendazole during the first term of pregnancy are limited. Albendazole is contraindicated during pregnancy (see section 4.3 and 4.4), 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 newborn 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 (about 48 hours) 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 (see section 4.8).

4.8 Undesirable effects

The frequency of side effects that are 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 as the reported observations rather than the real frequencies.
The side effects listed below are classified by organ system and frequency, according to the following convention:

Very common /10

Common ≥ 1/100 to < 1/10

Uncommon ≥ 1/1,000 to < 1/100

Rare ≥ 1/10,000 to < 1/1,000
Very rare < 1/10,000
Unknown frequency (cannot be estimated based on the available data).

Intestinal and skin infections (short-term treatment with low doses)

Systemic class organs	**Uncommon**	**Unknown frequency**
Immune system disorders		Hypersensitivity reaction, including skin rash, itching and hives
Nervous system disorders	Headaches Dizziness (see section 4.7)	
Gastro-intestinal disorders	Gastro-intestinal symptoms (epigastric or abdominal pains, nausea, vomiting) and diarrhoea	
Hepatobiliary disorders		Increase in liver enzymes (see section 4.4)
Skin and subcutaneous tissue disorders		Polymorphic erythema Stevens-Johnson syndrome

Systemic infections (long-term treatment with higher doses)

Systemic class organs	Very common	Common	Uncommon	Unknown frequency
Haematological and lymph system disorders				*Medullar aplasia* *Leucopoenia* *Pancytopenia* *Agranulocytosis* *(see section 4.4)*
Immune system disorders			*Hypersensitivity reactions including skin rash, itching, hives*	
Nervous system disorders	*Headaches*	*Dizziness (see section 4.7)*		
Gastro-intestinal disorders		*Gastro-intestinal disorders (abdominal pains, nausea and vomiting)*		
Hepatobiliary disorders	*Slight to moderate increase in liver enzymes (see section 4.4)*		*Hepatitis (see section 4.4)*	
Skin and subcutaneous tissue disorders		*Reversible alopecia (decrease in thickness of the hair, moderate hair loss)*		*Polymorphic erythema, StevensJohnson syndrome*
General disorders and administration site conditions		*Fever*		

Risk of allergic reactions due to the presence of yellow sunset colouring agent.

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 the national reporting system.

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,

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.
Haptic 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 testicle weight has been observed in dog treated with 60 mg/kg/day for 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 rats and rabbits.
No cancerogenic potential has been 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 vitro* trials carried out on bacteria and mammal cells cultures, as well as *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 anagenic effect of albendazole.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

S.NO	Composition	Reference
1.	Methyl Paraben,	BP
2.	Propyl Paraben	BP
3.	Sucrose	BP
4.	Liquid Sorbitol	BP
5.	Xanthan Gum	BP
6.	Sodium Benzoate	BP
7.	Polysorbate 80	BP
8.	Citric Acid(anhydrous)	BP
9.	Simethicone,	BP
10.	Orange Flavour	IHS
11.	Purified Water.	BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Keep out of sight and reach children.
Protect from light, store below 30 °C.

6.5 Nature and contents of container

Amber glass bottle of 20ml suspension.

Pack size: 20ml

6.6 Special precautions for disposal and other handling

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

7. APPLICANT/HOLDER OF CERTIFICATE PRODUCT REGISTRATION.

Unique Pharmaceuticals Limited
11, Fatai Atere Way, Matori-Mushin Lagos
Tel: +234 8097421000
Email: mail@uniquepharm.com

8. DRUG PRODUCT MANUFACTURER

Unique Pharmaceuticals Limited
Km 38, Abeokuta Road, Sango-Ota,
Ogun State, Nigeria.
Tel: +234 8097421000
Email: mail@uniquepharm.com

9. NAFDAC REGISTRATION NUMBER(S)

A11-0444

10. DATE OF REVISION OF THE TEXT

22/02/2028