Summary of Product Characteristics
ALBENCEL
(Albendazole Tablets USP 400mg)

1. Name of the medicinal product
ALBENCEL (Albendazole Tablets USP 400mg)

2. Qualitative and Quantitative composition
Each uncoated tablet contains 400mg Albendazole USP

3. Pharmaceutical form
Tablet
Light orange coloured caplet plain on one side and scored on the other.

4. Clinical Particulars
4.1 Therapeutic indications
Intestinal and skin infections ▪ Threadworms (Enterobius vermicularis), ▪ Roundworms (Ascaris lumbricoïdes), ▪ Hookworms (Ankylostoma duodenale, Necator americanus), ▪ Whipworms (Trichuris trichuria), ▪ Anguillulosis (Strongyloides stercoralis), ▪ Taeniasis (Taenia saginata, Taenia solium), ▪ Giardiasis (Gardia intestinalis or duodenalis) in children, Systemic infections ▪ Trichinosis (Trichinella spiralis)

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: 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 tablet or 10 ml of suspension in single dose. 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 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. * For children under 6 years, tablet form of 400 mg is inappropriate due to wrong route risk, and only suspension form should be used. **If the worm control performed 3 weeks after the treatment is positive, a second treatment should be administered

Method of administration
Oral

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.

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 Pregnancy and Fertility
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. albendazole has an aneugic activity, which is a risk factor for alteration of fertility in man.

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
Erythema multiforme and Stevens-Johnson syndrome have been reported very rarely. Diarrhoea, nausea, vomiting, dizziness, headache and gastrointestinal disturbance have been reported.
Itchiness and/or skin rashes were reported rarely.
Reversible alopecia has been reported.

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 to National Regulatory Agents.

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. 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 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

Croscarmellose Sodium
Sugar
Sodium Saccharine
Maize Starch
Colour: Sunset Yellow FCF/Supra
Sodium Benzoate
Purified Water
Sodium Methyl Paraben
Magnesium Stearate
Purified Talc
Colloidal Anhydrous Silica
Dry Orange Flavour
Sodium Saccharine
Croscarmellose Sodium

6.2 Incompatibilities

None known

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store in a dry place at a temperature below 30°C.

6.5 Nature and contents of container

1 tablet packed in one blister pack coded with batch number, manufacturing date and expiry dates packed in an inner carton with insert.

6.6 Special precautions for disposal and other handling

No special requirements

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURER

Marketing Authorisation Holder:
ZAIN PHARMA LIMITED

Plot No: 209/13741, Colchester Park,
Go-Down No.1, 2, 3, Off Mombasa Road,
Behind Nice and Lovely House,
P.O. Box: 100167-00101, Nairobi, Kenya

8. Marketing Authorization Number:
H2025/CTD11402/21420

9. Date of First <Registration> / Renewal of The <Registration>
November 2025

10. Date of Revision of the Text:
November 2025