SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

BEKRAZOL Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Albendazole ..... 400 mg

3. PHARMACEUTICAL FORM

Tablet

4. CLINICAL DATA

4.1. Therapeutic indications

Intestinal and cutaneous infections

• oxyurosis (Enterobius vermicularis),

• ascariasis (Ascaris lumbricoides),

• hookworm (Ankylostoma duodenale, Necator americanus),

• trichuriasis (Trichuris trichiura),

• Anguillulose (Strongyloides stercoralis),

• taeniasis (Taenia saginata, Taenia solium), treatment with albendazole should be considered only in the case of associated parasitoses susceptible to albendazole,

• giardiosis (Giardia intestinalis or duodenalis) of the child.

- Systemic infection

• trichinellosis (Trichinella spiralis).

4.2 Posology

Indications	**Daily dose**	**Duration of treatment**
Pinworms	Child from 1 to 2 years *: 200 mg, Adult and child over 2years **: 400 mg or one tablet of 400 mg. Hygiene measures rigorous must be imposed and the entourage should also be treated.	A single take to repeat 7 days later
Ascariasis Hookworms Trichuriasis	Child from 1 to 2 years *: 200 mg Adult and child over 2 years **: 400 mg or 400 mg tablet	One daily dose
Strongyloides Taeniasis (associated with others parasitosis)	Adult and child over 2 years **: 400 mg or 400 mg tablet	Daily intake repeat 3 days in a row
Giardiosis	Child **: 400 mg or 400 mg tablet	Daily intake repeat 5 days in a row
Trichinellosis	Child **: 15 mg / kg / day divided into 2 shots per day Adult: 800 mg or 400 mg tablet 2 times per day	A morning and evening catch for 10 to 15 days in according to the severity of the symptomatology and early management therapeutic.

Data for patients aged 65 and over are limited. Reports indicate that no dose adjustment is necessary in the elderly. However, albendazole should be used with caution in elderly patients with hepatic dysfunction.

Hepatic insufficiency:

Albendazole is rapidly metabolized by the liver, with the main metabolite albendazole sulfoxide being pharmacologically active. Therefore, hepatic impairment may have significant effects on the pharmacokinetics of albendazole sulfoxide.

Patients with abnormal liver function tests (transaminases) prior to initiation of treatment with albendazole should be closely monitored. Treatment should be stopped if there is a significant increase in liver enzymes or if there is a clinically significant reduction in the blood count (see section 4.4).

Renal insufficiency:

As the renal elimination of albendazole and its main active metabolite, albendazole sulfoxide is negligible, it is unlikely that the clearance of these compounds will be altered in patients with renal impairment. No dosage adjustment is necessary, however, patients with renal impairment should be closely monitored.

Administration mode

Oral way.

Neither purging nor fasting prior to treatment is necessary.

In the treatment of trichinellosis, albendazole should be administered at mealtimes.

4.3. Contra-indications

Known hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4. Special warnings and precautions for use

Neurological symptoms

Treatment with albendazole may reveal pre-existing neurocysticercosis, particularly in areas of high taenia infestation. Patients may experience neurological symptoms such as seizures, increased intracranial pressure and focal signs resulting from the inflammatory response caused by the death of the parasite in the brain. Symptoms may occur shortly after treatment; appropriate treatment with corticosteroids and anticonvulsants should be instituted immediately.

Precaution for use when using albendazole in systemic infections (long-term, higher-dose treatment):

• Liver disorders

Albendazole may cause a mild to moderate increase in liver enzymes, which usually normalize when treatment is discontinued. Serious cases of hepatitis have also been reported during treatment of systemic helminthic infections (long-term, higher-dose treatment) (see section 4.8). Hepatic function tests should be performed before initiation of treatment and at least every two weeks during treatment. Albendazole should be discontinued if hepatic enzymes increase (more than twice normal). If the reintroduction of this treatment is essential, this should be done after normalization of liver enzymes. In addition, close monitoring should be done because of possible recurrence because an allergic mechanism can not be ruled out.

• Medullary depression

Cases of bone marrow depression have been reported during treatment of systemic helminth infections (long-term, higher-dose treatment) (see section 4.8). Blood cell counts should be performed at initiation of treatment and after two weeks of albendazole therapy.

Patients with hepatic pathology, including hepatic echinococcosis, appear more susceptible to developing bone marrow depression leading to pancytopenia, bone marrow suppression, agranulocytosis and leukopenia. Therefore, enhanced blood count monitoring is therefore recommended in patients with liver disease.

Albendazole should be discontinued if there is a significant decrease in the number of blood cells (see sections 4.2 and 4.8).

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

In trichinellosis treatment, due to an activity especially on the intestinal forms and larvae at the beginning of tissue migration, it is recommended to administer albendazole as early as possible at the beginning of the infestation to reduce the symptoms. and complications. This treatment remains inactive on encysted larvae in chronic forms and when it is started late.

Caution of use

- ritonavir
- enzyme-inducing anticonvulsants
- rifampicin

Significant decrease in plasma concentrations of albendazole and its active metabolite by the inducer, with the risk of a decrease in its efficacy.

Clinical monitoring of the therapeutic response and possible adjustment of the dosage of albendazole during treatment with the enzyme inducer and after discontinuation.

4.6. Pregnancy and breast feeding

Pregnancy

Studies in animals have shown a teratogenic effect.

In clinical practice, there are currently no data of sufficient relevance to evaluate the possible malformative or fetotoxic effect of albendazole when administered during pregnancy.

Consequently, the use of this treatment is not recommended during pregnancy and in women of child-bearing age who do not use contraception, especially since there are therapeutic alternatives that are better evaluated, in terms of safety, at home. the pregnant woman.

Feeding

The passage in the milk is not known. Use is not recommended during breastfeeding.

4.7. Effects on ability to drive and use machines

When driving vehicles or using machines, it should be taken into account that dizziness has been reported after use of albendazole (see section 4.8).

4.8. Side effects

The frequency of very common to rare adverse reactions was determined based on clinical trial data. The frequencies of the other adverse events were mainly determined from the post-marketing data and refer to reported observation frequencies rather than actual frequencies.

The undesirable effects listed below are classified by organ system and frequency, according to the following convention:

Very common ≥1 / 10 Common ≥1 / 100 to <1/10

Peu fréquents ≥ 1/1000 à < 1/100 Rares ≥ 1/10 000 à < 1/1000 Très rares < 1/10 000

Fréquence indéterminée (ne peut être estimée sur la base des données disponibles) Infections intestinales et cutanées (traitement de courte durée à dose plus faible).

Reporting of suspected adverse reactions

The reporting of suspected adverse reactions after authorization of the drug is important. It allows continuous monitoring of the benefit / risk ratio of the drug. Health professionals report any suspected adverse reactions through the national reporting system.

4.9. Overdose

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

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: ANTIPARASITIC-ANTIHELMINIC ATC code: P02CA03 (P. Parasitology)
Albendazole is a benzimidazole carbamate. It acts on nematodes, cestodes and some protozoa.

Albendazole acts on the cytoskeleton of helminths by inhibiting the polymerization of tubulins and their incorporation into microtubules, thus blocking glucose uptake by parasites and causing their death.

Albendazole also has activity on Giardia intestinalis (or duodenalis). It exerts an irreversible action targeted on the ventral disk of the trophozoite by effect on the polymerization of tubulin and giardine resulting in disruption of the cytoskeleton and microstrips. Adherence to enterocytes is decreased, resulting in inhibition of parasite growth and multiplication.

5.2. Pharmacokinetic properties

Absorption and Biotransformation

After oral administration, the low proportion of albendazole absorbed (<5%) is metabolized to albendazole sulfoxide and sulfone. The plasma sulfoxide concentration, which is the predominant circulating active metabolite, peaks at about 2.5 hours after dosing.
The systemic pharmacological effect of albendazole is increased if the dose is administered with a high-fat meal, which improves absorption by about five times.

Elimination

The plasma half-life of albendazole sulfoxide is 8 hours 30 minutes.
Albendazole sulfoxide and its metabolites appear to be eliminated mainly by the bile duct and for a small proportion by the urinary tract.
Specific populations:
Renal Insufficiency: The pharmacokinetics of albendazole in patients with renal impairment have not been studied.

Hepatic impairment: The pharmacokinetics of albendazole in patients with hepatic impairment have not been studied.

5.3 Preclinical safety data

No carcinogenic potential was found in carcinogenicity studies in rats (20 mg / kg / day) and mice (400 mg / kg / day). Albendazole did not have a genotoxic effect in in vitro studies performed on bacteria and mammalian cell cultures, as well as in an in vivo rodent micronucleus study.

6. PHARMACEUTICAL DATA

6.1. List of excipients

Aluminum magnesium silicate, sodium carboxymethylcellulose, glycerol, polysorbate 80, sorbitan laurate, potassium sorbate, benzoic acid, sorbic acid, silicone
antifoam 1510, sodium saccharine, vanilla aroma, orange aroma, passion fruit aroma, purified water.

6.2. incompatibility

Not applicable.

6.3. The duration of the conversation

2 years.

6.4. Special precautions for storage

Store at a temperature not exceeding 30 ° C and protected from light.

6.5. Nature and contents of the pack

10 ml in bottle (PVC).

6.6. Special precautions for disposal and handling

Shake before use.

7. HOLDER OF THE MARKETING AUTHORIZATION

BEKRA PHARMA UK LTD. 13 LAVINGTON, LONDON UNITED KINGDOM

8. MARKETING AUTHORIZATION NUMBER (S)

9. DATE OF FIRST AUTHORIZATION / RENEWAL OF AUTHORIZATION

10. DATE OF REVISION OF THE TEXT

01/01/2017

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR THE PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

CONDITIONS OF PRESCRIPTION AND DELIVERANCE
List II.