SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

BEKRAZOL oral suspension 10 ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Albendazole ..... 200 mg

For a 5 ml oral suspension

One 10 ml vial of oral suspension contains 400 mg of albendazole. For the full list of excipients, see section 6.1.

Excipient with known effect: benzoic acid

3. PHARMACEUTICAL FORM

Oral suspension

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).

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)

Déclaration des effets indésirables suspectés

La déclaration des effets indésirables suspectés après autorisation du médicament est importante. Elle permet une surveillance continue du rapport bénéfice/risque du médicament. Les professionnels de santé déclarent tout effet indésirable suspecté via le système national de déclaration.

4.9. Surdosage

En cas de surdosage, un traitement symptomatique ainsi qu'une surveillance médicale sont recommandés.

5. PROPRIETES PHARMACOLOGIQUES

5.1. Propriétés pharmacodynamiques

Classe pharmacothérapeutique : ANTIPARASITAIRES-ANTIHELMINTIQUE

Code ATC : P02CA03 (P. Parasitologie)

L'albendazole est un carbamate de benzimidazole. Il agit sur les nématodes, les cestodes et certains protozoaires.

L'albendazole agit sur le cytosquelette des helminthes en inhibant la polymérisation des tubulines et leur incorporation dans les microtubules, bloquant ainsi l'absorption du glucose par les parasites et provoquant leur mort.

L'albendazole a également une activité sur Giardia intestinalis (ou duodenalis). Il exerce une action irréversible ciblée sur le disque ventral du trophozoïte par effet sur la polymérisation de la tubuline et de la giardine entraînant une désorganisation du cytosquelette et des microrubans. La capacité d'adhérence aux entérocytes est diminuée, ce qui entraîne une inhibition de la croissance et de la multiplication du parasite.

5.2. Propriétés pharmacocinétiques

Absorption et Biotransformation

Après administration orale, la faible proportion d'albendazole absorbée (< 5 %) est métabolisée en albendazole sulfoxyde et sulfone. La concentration plasmatique en sulfoxyde qui est le métabolite actif circulant prépondérant atteint son maximum environ deux heures et demie après l'administration.

L'effet pharmacologique systémique de l'albendazole est augmenté si la dose est administrée avec un repas riche en graisses, ce qui améliore l'absorption d'environ cinq fois.

Elimination

La demi-vie plasmatique du sulfoxyde d'albendazole est de 8 heures 30.

Le sulfoxyde d'albendazole et ses métabolites semblent être éliminés principalement par voie biliaire et pour une faible proportion par voie urinaire.

Populations spécifiques :

Insuffisants rénaux: La pharmacocinétique de l'albendazole chez les patients présentant une insuffisance rénale n'a pas été étudiée.

Insuffisants hépatiques : La pharmacocinétique de l'albendazole chez les patients présentant une insuffisance hépatique n'a pas été étudiée.

5.3. Données de sécurité préclinique

Aucun potentiel cancérogène n'a été mis en évidence lors des études de cancérogénèse menées chez le rat (20 mg/kg/jour) et chez la souris (400 mg/kg/jour). L'albendazole n'a pas eu d'effet génotoxique dans des études in vitro effectuées sur des bactéries et des cultures de cellules de mammifères, ainsi que dans une étude in vivo du micronoyau chez les rongeurs.

6. DONNEES PHARMACEUTIQUES

6.1. Liste des excipients

Silicate d'aluminium et de magnésium, carboxymethylcellulose sodique, glycérol, polysorbate 80, laurate de sorbitane, sorbate de potassium, acide benzoïque, acide sorbique, silicone

antifoam 1510, saccharine sodique, arôme vanille, arôme orange, arôme fruit de la passion, eau purifiée.

6.2. Incompatibilités

Sans objet.

6.3. Durée de conservation

2 ans.

6.4. Précautions particulières de conservation

A conserver à une température ne dépassant pas 30°C et à l'abri de la lumière.

6.5. Nature et contenu de l'emballage extérieur

10 ml en flacon (PVC).

6.6. Précautions particulières d'élimination et de manipulation

Agiter avant utilisation.

7. TITULAIRE DE L'AUTORISATION DE MISE SUR LE MARCHE

BEKRA PHARMA UK LTD 13 LAVINGTON, LONDON UNITED KINGDOM

8. NUMERO(S) D'AUTORISATION DE MISE SUR LE MARCHE

9. DATE DE PREMIERE AUTORISATION/DE RENOUVELLEMENT DE L'AUTORISATION

10. DATE DE MISE A JOUR DU TEXTE

01/01/2017

11. DOSIMETRIE

Sans objet.

12. INSTRUCTIONS POUR LA PREPARATION DES RADIOPHARMACEUTIQUES

Sans objet.

CONDITIONS DE PRESCRIPTION ET DE DELIVRANCE

Liste II.