SCHEDULING STATUS: S4

PROPRIETARY NAME (AND DOSAGE FORM):

**Bendex-400**  
(Tables)

COMPOSITION:
Each tablet contains 400 mg Albendazole.
Preservatives:
Methylparaben 0.043 % m/m  
Propylparaben 0.003 % m/m

PHARMACOLOGICAL CLASSIFICATION:
A 12 Anthelmintics.

PHARMACOLOGICAL ACTION:
Animal studies have shown that albendazole exhibits vermicidal, ovicidal and larvicidal activity. The medicine is thought to exert its anthelmintic effect by blocking glucose uptake by the susceptible helminths, thereby depleting the energy level until it becomes inadequate for survival. BENDEX-400 initially immobilises, then kills the susceptible helminth.

In human subjects after oral administration, albendazole is absorbed and completely metabolised. The principle metabolite albendazole sulfoxide has anthelmintic activity and a plasma half life of about 8.5 hours. Following an oral dose of 6.6 mg/kg of albendazole the plasma concentration of its main metabolite, the sulfoxide, attains a maximum of 0.25 to 0.30 mcg/ml after approximately 2 hours. The metabolite is essentially eliminated via the urine.

INDICATIONS:
BENDEX-400 is indicated in the treatment of single or mixed intestinal parasites. Clinical studies have shown albendazole to be effective in the treatment of Ascaris lumbricoides (roundworm), Trichuris Trichiura (whipworm), Enterobius vermicularis (pinworm), Ancylostoma duodenale and Necator americanus (hookworm), Taenia spp. (tapeworm) and Strongyloides stercoralis (threadworm).

BENDEX-400 has been shown to be effective in the treatment of Giardia (duodenalis or intestinalis or lamblia) infections in children.

CONTRA-INDICATIONS:
Albendazole is known to be teratogenic and embryotoxic in animals. Hypersensitivity to any of the ingredients. BENDEX-400 should not be taken by pregnant women at any stage of their pregnancy or by women who are likely to become pregnant, during or shortly after the course of therapy.

WARNINGS:
It has been noted that leucopenia has occurred when used for periods longer than recommended.

DOSEAGE AND DIRECTIONS FOR USE:
Adults and children over two years.
Usual dose: One BENDEX-400 tablet. Tablets may be chewed and swallowed, or crushed and mixed with food. Albendazole is given orally, usually as a single dose, in the treatment of single or mixed intestinal nematode infections. The usual dose for adults and children ages 2 years or over with ascariasis, hookworm infections, or trichuriasis is 400 mg as a single dose. In strongyloidiasis, 400 mg is given daily for 3 consecutive days: this may be repeated after 3 weeks if necessary: a similar schedule is used for taeniasis when mixed with other worm infections. Giardiasis (dose in children over 2 years of age): A single 400 mg daily dose for five days.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Gastrointestinal disturbances and headaches have been reported. Since albendazole is poorly absorbed from the gastrointestinal tract at the usual therapeutic doses, side-effects have generally been restricted to gastrointestinal disturbances, such as transient abdominal pain and diarrhoea, and have tended to occur in patients being treated for heavy intestinal infection. However, adverse effects have been reported more frequently with the high doses and have included allergic reactions, raised liver enzyme values, alopecia and bone marrow depression which can be severe.

Precautions:
Albendazole is teratogenic in rats (see “CONTRA-INDICATIONS”).

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Since no specific antidote is known, recommended treatment of albendazole overdose consists of the following:
Gastric lavage, which may be undertaken within the first 2 to 3 hours after ingestion.  
Supportive and symptomatic treatment.

IDENTIFICATION:
Flat, round, pink tablets with “BDX” embossed on one side and a breakline on the other side.

PRESENTATION:
Aluminium strips containing 1 tablet in packs containing 20 x 1 tablet.

STORAGE INSTRUCTIONS:
Store below 25°C.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER: 31/12/0472

NAME AND BUSINESS ADDRESS OF APPLICANT:
CIPLA MEDPRO (PTY) LTD  
Rosen Heights, Pasita Street  
Rosen Park, Bellville 7530 RSA

DATE OF PUBLICATION OF THIS PACKAGE INSERT: MARCH 2005

© CIPLA MEDPRO 2005