SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

OVIS (Albendazole) 400mg tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

OVIS (Albendazole) 400mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DAE HWA ALBENDAZOLE Tab. is indicated for the treatment of Enterobius vermicularis(pinworm), Trichuris trichiura(whip worm), Ascaris lumbricoides(common roundworm), Strongyloides stercoralls, Ancylostoma duodenale(common roundworm), Necator americanus (American hookworm).

4.2 Posology and method of administration

In adults and children aged 2 years or over:

- Ascariasis, Enterobiasis, Hookworm infections, Trichuriasis, American trypanosomiasis : 1 tablet(400mg) as a single dose.
- Strongyloidiasis : 1 tablet daily for 3 days.
- Enterobiasis in children aged 2 years or over : 1/2 tablet as a single dose, administer it after 7days again.
- Chew it or take it with a little water and the particular processes are not necessary like interruption of meal or use of purgative, etc.
- If the helminth is not exterminated after 3 weeks of the treatment, execute 2nd administration.

4.3 Contraindications

- Patients who have shown hypersensitivity to albendazole or any component of this drug.
- Pregnancy woman or woman with pregnant potentiality.
- Infants aged under 2 years.

4.4 Special warnings and precautions for use

Special care should be taken with the following patients.

1) Clinical laboratory Tests: Albendazole has been shown to cause occasional reversible reductions in total white blood cell count. Rarely, more significant reductions may be encountered including pancytopenia. In clinical trials, treatment with albendazole has been associated with mild to moderate elevations of hepatic enzymes.

2) Praziquantel has been reported to increase the plasma levels of the albendazole active metabolite.

4.5 Interaction with other medicinal products and other forms of interaction

DAE HWA ALBENDAZOLE Tab. may inhibit theophylline metabolism.

4.6 Fertility, pregnancy and lactation

During pregnancy, this medication should be used only when clearly needed. It may harm an unborn baby. Discuss the risks and benefits with your doctor. Women of child-bearing age should have a negative pregnancy test before starting this medication. It is important that women taking this medication use reliable forms of birth control (such as condoms, birth control pills) while taking this medication and for 1 month after treatment stops. It is not known if this medication passes into breast milk. Consult your doctor before breastfeeding.

4.7 Effects on ability to drive and use machines

None reported.

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.

4.9 Overdose

Recommendations for treatment of overdose are the usual measures to remove the unabsorbed materials from the gastro-intestinal tract and supportive therapy for the evolving clinical syndrome.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Albendazole is a broad-spectrum anthelmintic, which is highly effective against a wide range of intestinal helminths. Albendazole is also effective against tissue helminth infections, such as cutaneous larva migrans.

Albendazole therapy has also been used in the high dose, long term treatment of tissue helminth infections including hydatid cysts and cysticercosis.

The antihelminthic action of albendazole is thought to be mainly intra-intestinal. However, at higher albendazole doses, sufficient is absorbed and metabolised to the active sulphoxide metabolite, to have a therapeutic effect against tissue parasites.

Albendazole exhibits larvicidal, ovicidal and vermicidal activity, and is thought to act via inhibition of tubulin polymerization. This causes a cascade of metabolic disruption, including energy depletion, which immobilizes and then kills the susceptible helminth.

5.2 Pharmacokinetic properties

In man, the full extent of albendazole absorption following oral administration has not been established. However, it is known that albendazole is poorly absorbed with most of an oral dose remaining in the gastrointestinal tract. The poor absorption is believed to be due to the low aqueous solubility of albendazole. Absorption is significantly enhanced (approximately 5 fold) if albendazole is administered with a fatty meal.

Albendazole rapidly undergoes extensive first-pass metabolism in the liver, and is generally not detected in plasma. Albendazole sulphoxide is the primary metabolite, which is thought to be the active moiety in effectiveness against systemic tissue infections. The plasma half life of albendazole sulphoxide is 8½ hours. Albendazole sulphoxide and its metabolites appear to be principally eliminated in bile, with only a small proportion appearing in the urine.

5.3 Preclinical safety data

A clinical trial of albendazole (Zentel R) was carried out at the Hospital for Tropical Diseases in 1981. Thirty-five patients with hookworm infection were divided into 2 groups A, B and treated with a single dose of albendazole 400 mg and 600 mg respectively. The age of the

patients ranged from 12 to 66 years and their weights ranged from 25 to 62 kilograms. Concentration and Stoll egg count methods were done at pretreatment, day 14 and day 21. At each interval two aliquots from each of the two faecal specimens were collected. The geometrical mean of EPG in Group A and B were 5406 and 5617 respectively. The cure rate in patients with less than 5000 EPG was 75% on day 21 in Group A and 67% in Group B. The mean percentage egg reduction was 95% in Group A and 99% in Group B. In patients with a higher egg out-put, the cure rate on day 21 was 50% in Group A and 29% in Group B. The mean percentage egg reduction was 91% in Group A and 93% in B. The side effects were mild and transient.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

lactose hydrate
Hypromellose 2910
Corn Starch
Methylene Chloride
Ethanol
Titanium Oxide
Povidone
polyethylene glycol 6000
Magnesium Stearate
Strawberry flavored cotton
Polysorbate 80
Croscarmellose Sodium
Crospovidone
Sodium Starch Glycolate
Stevioside

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in a dry place below 30°C.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

1 tablets/ blister; 1 blister/box

6.6 Special precautions for disposal <and other handling>

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

7. MARKETING AUTHORISATION HOLDER

Name and address: DAE HWA PHARMA CO. LTD

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8. MARKETING AUTHORISATION NUMBER(S)

06608/08028/REN/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of latest renewal: Oct 19, 2021

10. DATE OF REVISION OF THE TEXT

July, 2023