MECURE INDUSTRIES PLC

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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1. Name of the medicinal product

FlushOf Tablets (Albendazole 400mg caplets)

2. Qualitative and quantitative composition

Albendazole tablets:

Each caplet contains 400mg of Albendazole.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Uncoated caplet

Albendazole 400 mg uncoated caplet*:*

Orange colored caplet with a break on one side and plain on the other side.

4. Clinical particulars

4.1 Therapeutic indications

FLUSHOF (albendazole) is indicated for the treatment of the following infections:

Neurocysticercosis. ***FLUSHOF*** *is* indicated for the treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, *Taenia solium* .

Lesions considered responsive to albendazole therapy appear as nonenhancing cysts with no surrounding edema on contrast-enhanced computerized tomography. Clinical studies in patients with lesions of this type demonstrate a 74% to 88% reduction in number of cysts; 40% to 70% of albendazole-treated patients showed resolution of all active cysts.

Hydatid disease. ***FLUSHOF*** is indicated for the treatment of cystic hydatid disease of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm, *Echinococcus granulosus* .

This indication is based on combined clinical studies which demonstrated non-infectious cyst contents in approximately 80-90% of patients given *FLUSHOF* for 3 cycles of therapy of 28 days each.

Clinical cure (disappearance of cysts) was seen in approximately 30% of these patients, and improvement (reduction in cyst diameter of ≥25%) was seen in an additional 40%.

NOTE: When medically feasible, surgery is considered the treatment of choice for hydatid disease. When administering ***FLUSHOF*** in the pre- or post-surgical setting, optimal killing of cyst contents is achieved when three courses of therapy have been given.

NOTE: The efficacy of albendazole in the therapy of alveolar hydatid disease caused by *Echinococcus multilocularis* has not been clearly demonstrated in clinical studies.

4.2 Posology and method of administration

Usual Dose:
400 mg (one FLUSHOF tablet) as a single dose in both adults and children over two years of age.

In heavy mixed infestation involving *Strongyloides* or *Taeniasis*, a single daily dose may be inadequate and the dose may be given for three consecutive days.

Note:
If the patient is not cured after three weeks, a second course of treatment may be given. No special procedures, such as fasting or purging, are required.
Albendazole has not been adequately studied in children under one year of age.

Giardiasis (dose in children over 2 years of age):
A single 400 mg (one FLUSHOF tablet) daily dose for five days.
Some people, particularly young children, may experience difficulties swallowing the tablets whole and should be encouraged to chew the tablets with a little water; alternatively tablets may be crushed and mixed with food.

Elderly:
Experience in patients 65 years of age or older is limited. Reports indicate that no dosage adjustment is required; however albendazole should be used with caution in elderly patients with evidence of hepatic dysfunction (see Hepatic Impairment below).

Renal impairment:
Since renal elimination of albendazole and its primary metabolite, albendazole sulfoxide, is negligible, it is unlikely that clearance of these compounds would be altered in these patients. No dosage adjustment is required; however patients with evidence of renal impairment should be carefully monitored.

Hepatic impairment:
Since albendazole is rapidly metabolised by the liver to the primary pharmacologically active metabolite, albendazole sulfoxide, hepatic impairment would be expected to have significant effects on the pharmacokinetics of albendazole sulfoxide. Patients with abnormal liver function test results (transaminases) prior to commencing albendazole therapy should be carefully monitored.

4.3 Contraindications

FLUSHOF is contra-indicated in patients with a known history of hypersensitivity to

albendazole or constituents of FLUSHOF.

4.4 Special warnings and precautions for use

Leucopenia may occur when FLUSHOF is used for periods longer than recommended. In order to avoid administering FLUSHOF during early pregnancy, women of childbearing age should initiate treatment during the first week of menstruation or after a negative pregnancy test.

Sub-clinical neurocystercosis may manifest after a single dose of FLUSHOF.

Treatment with albendazole may uncover pre-existing neurocysticercosis, particularly in areas with high taenosis infection. Patients may experience neurological symptoms e.g. seizures, increased intracranial pressure and focal signs as a result of an inflammatory reaction caused by death of the parasite within the brain. Symptoms may occur soon after treatment, appropriate steroid and anticonvulsant therapy should be started immediately.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Praziquantel increase the plasma levels of the active metabolite of FLUSHOF.
Ritonavir, phenytoin, carbamazepine and phenobarbital may reduce plasma concentrations of the active metabolite of FLUSHOF; albendazole sulfoxide. The clinical relevance of this is unknown, but may result in decreased efficacy, especially in the treatment of systemic helminth infections. Patients should be monitored for efficacy and may require alternative dose regimens or therapies.

4.6 Fertility, pregnancy and lactation

FLUSHOF should not be administered during pregnancy.
(refer to CONTRA-INDICATIONS).

Albendazole is known to be teratogenic and embryotoxic in animals.

Adequate human data during lactation are not available.

4.7 Effects on ability to drive and use machines

Since dizziness has been reported following treatment with FLUSHOF, caution is recommended in patients performing skilled tasks.

4.8 Undesirable effects

Data from clinical studies were used to determine the frequency of very common to rare undesirable reactions.
The following convention has been used for the classification of frequency: Very common ≥ 1/10, common ≥ 1/100 to < 1/10, uncommon ≥ 1/1 000 to < 1/100, rare

≥ 1/10 000 and < 1/1 000, very rare < 1/10 000.
Immune system disorders:
Rare: Hypersensitivity reactions
Nervous system disorders:
Uncommon: Headache and dizziness
Gastrointestinal disorders:
Uncommon: Upper gastrointestinal symptoms (e.g. epigastric or abdominal pain, nausea, vomiting) and diarrhoea
Hepatobiliary disorders:
Rare: Elevations of hepatic enzymes
Skin and subcutaneous tissue disorders:
Rare: Rash, pruritus and urticaria.
Post-marketing Side Effects:
Skin and subcutaneous tissue disorders:

Unknown: Erythema multiforme, Stevens-Johnson syndrome.

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.

4.9 Overdose

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Albendazole is a benzimidazole carbamate with anthelmintic and antiprotozoal activity against intestinal and tissue parasites. Animal studies have shown that albendazole exhibits vermicidal, ovacidal and larvacidal activity and exerts its anthelmintic effect by inhibiting tubulin polymerization. This causes the disruption of the helminth metabolism, including energy depletion, which immobilises and then kills the susceptible helminth.

5.2 Pharmacokinetic properties

In man, after oral administration, albendazole is absorbed and completely metabolised. At a 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 µg/ml after approximately 2½ hours.

The half-life of the sulfoxide in the plasma is 8½ hours. The metabolite is essentially eliminated via the urine.

5.3 Preclinical safety data

As a well-established and widely used product, the pre-clinical safety of ibuprofen is well documented.

6. Pharmaceutical particulars

6.1 List of excipients

Starch

Lactose

Mannitol

Aspartame

Colour Sunset Yellow

Flavour Orange

Flavour Raspberry

Aerosil

Magnesium Stearate

Talcum

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Albendazole Caplets are packaged in clear PVC– Aluminum foil blister pack.

Pack size: Blisters pack of 1 uncoated caplet.

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 authorization holder

Me Cure Industries Limited
Plot 6 Block H Debo Industries Compound,
Oshodi Industrial Scheme,
Oshodi,
Lagos,
Nigeria.

8.0 NAFDAC Registration Number: A4-0484