1. NAME OF THE MEDICINAL PRODUCT

1.1 Name of Medicinal Product

BLISZOLE 400

(Albendazole Tablets 400 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated chewable tablet contains:

Albendazole USP……..400 mg

Excipients……q.s.

Colour: Sunset Yellow FCF

3. PHARMACEUTICAL FORM

Uncoated Chewable Tablets

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

It is indicated in the treatment of single or mixed intestinal parasites. Clinical studies have shown albeneffective in the treatment of Ascaris lumbricoides (roundworm), Trichuris trichiura (whipworm), Enterobius vermicularis (pinworm/threadworm), Ancylostoma duodenale and Necator americanus (hookworm), Taenia spp. (tapeworm) and Strongyloides stercoralis. It has been shown to be effective in the treatment of Giardia (duodenalis or intestinalis or lamblia) infections in children.

4.2. Posology and method of administration

Route of administration: Oral

BLISZOLE 400 is used in adults and children.

Dosage:

Usual Adult Dose for Hydatid Disease

Less than 60 kg: 15 mg/kg/day orally in divided doses twice a day with meals

Maximum dose: 800 mg/day

60 kg or more: 400 mg orally twice a day with meals

Duration of therapy: 28-day cycle followed by a 14-day drug-free interval, for a total of 3 cycles

Use: For the treatment of cystic hydatid disease of the liver, lung and peritoneum due to the larval form of Echinococcus granulosus

Usual Adult Dose for Neurocysticercosis

Less than 60 kg: 15 mg/kg/day orally in divided doses twice a day with meals

Maximum dose: 800 mg/day

60 kg or more: 400 mg orally twice a day with meals

Duration of therapy: 8 to 30 days

Comments:

- Patients should receive appropriate steroid and anticonvulsant therapy as needed.
- Oral or IV corticosteroids should be considered to prevent cerebral hypertensive episodes during the first week of therapy.

Use: For the treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of Taenia solium

Usual Adult Dose for Cutaneous Larva Migrans

US CDC recommendations: 400 mg orally once a day for 3 to 7 days

Case Report (4)

400 mg orally twice a day for 3 to 5 days

Usual Adult Dose for Ascariasis

US CDC recommendations: 400 mg orally as a single dose

Usual Adult Dose for Pinworm Infection (Enterobius vermicularis)

Some experts recommend: 400 mg orally as a single dose; repeat in 2 weeks

Comments: Some clinicians recommend all household contacts of infected patients receive treatment, especially when multiple or repeated symptomatic infections occur, since such contacts commonly also are infected; retreatment after 14 to 21 days may be needed.

Usual Adult Dose for Filariasis

Some experts recommend: 400 mg orally twice a day for 10 days

Comments: Recommended for infection due to Mansonella perstans

Usual Adult Dose for Hookworm Infection (Necator or Ancylostoma)

US CDC recommendations: 400 mg orally as a single dose

Comments: Recommended for infection due to Ancylostoma duodenal or Necator americanus

Usual Adult Dose for Enterocolitis

Some experts recommend: 400 mg orally as a single dose

Comments: Recommended for eosinophilic enterocolitis due to A caninum

Usual Adult Dose for Visceral Larva Migrans (Toxicariasis)

US CDC recommendations: 400 mg orally twice a day for 5 days

Comments:

-Recommended for visceral toxocariasis

-Optimum duration of therapy is unknown; some clinicians recommend 20 days of therapy.

Usual Adult Dose for Strongyloidiasis

Some experts recommend: 400 mg orally twice a day for 7 days

Comments:

-Recommended as alternative therapy

-May be necessary to repeat or prolong therapy or use other agents in immunocompromised patients or patients with disseminated disease

Usual Adult Dose for Trichinosis

US CDC recommendations: 400 mg orally twice a day for 8 to 14 days

Usual Adult Dose for Trichostrongylosis

Some experts recommend: 400 mg orally as a single dose

Comments: Recommended as an alternative therapy

Usual Adult Dose for Whipworm Infection (Trichuris trichiura)

US CDC recommendations: 400 mg orally once a day for 3 days

Usual Adult Dose for Capillariasis

US CDC recommendations: 400 mg orally once a day for 10 days

Comments: Recommended as alternative therapy

Usual Adult Dose for Gnathostomiasis

US CDC recommendations: 400 mg orally twice a day for 21 days

Comments: Recommended for cutaneous symptoms

Usual Adult Dose for Clornorchis sinensis (Liver Fluke)

US CDC recommendations: 10 mg/kg/day orally for 7 days

Comments: Recommended as alternative therapy

Usual Adult Dose for Cysticercus cellulosae (Cysticercosis)

Some experts recommend: 400 mg orally twice a day for 8 to 30 days

Comments:

-May repeat as necessary

-Therapy for at least 30 days recommended in patients with subarachnoid cysts or giant cysts in the fissures.

-Surgical intervention (especially neuroendoscopic removal) or CSF diversion followed by treatment with this drug and steroids recommended for obstructive hydrocephalus.

-With prednisone or dexamethasone, recommended for arachnoiditis, vasculitis, or cerebral edema

Usual Adult Dose for Echinococcus Infection

US CDC recommendations: 400 mg orally twice a day for 1 to 6 months

Comments:

-Recommended for cystic echinococcosis in patients with small cysts or multiple cysts in several organs; treatment depends on the WHO classification of the cysts; this drug is not appropriate for all forms of the infection.

-This drug has been administered before surgery to facilitate safe surgical manipulation of cysts by inactivating protoscolices, altering cyst membrane integrity, and reducing cyst turgidity.

Usual Adult Dose for Loiasis

US CDC recommendations: 200 mg orally twice a day for 21 days

Comments:

-Recommended for symptomatic infection with microfilariae of Loa loa/mL less than 8000 and 2 rounds of diethylcarbamazine failed; or recommended for symptomatic loiasis with microfilariae of L loa/mL at least 8000 to reduce level to less than 8000 before diethylcarbamazine therapy

-Treatment of this infection is complex; experts with experience treating this disease and preventing complications of therapy should be consulted.

Usual Adult Dose for Microsporidiosis

Some experts recommend: 400 mg orally twice a day

Comments:

-Recommended for disseminated infection due to Encephalitozoon hellem, E cuniculi, E intestinalis, Pleistophora species, Trachipleistophora species, or Anncaliia vesicularum

-Recommended for intestinal infection due to E intestinalis; duration of therapy is 21 days

-With fumagillin, recommended for ocular infection due to E hellem, E cuniculi, or Vittaforma corneae

US CDC, National Institutes of Health (NIH), and HIV Medicine Association of the Infectious Diseases Society of America (HIVMA/IDSA) recommendations for HIV-infected patients: 400 mg orally twice a day

Comments:

-Recommended as preferred therapy (including treatment and secondary prophylaxis)

-Recommended for intestinal and disseminated (not ocular) infection due to Microsporidia other than Enterocytozoon bieneusi and V corneae

-With fumagillin, recommended for ocular infection for management of systemic infection

Usual Pediatric Dose for Hydatid Disease

Less than 60 kg: 15 mg/kg/day orally in divided doses twice a day with meals

Maximum dose: 800 mg/day

60 kg or more: 400 mg orally twice a day with meals

Duration of therapy: 28-day cycle followed by a 14-day drug-free interval, for a total of 3 cycles

Comments: Hydatid disease is uncommon in infants and young children.

Use: For the treatment of cystic hydatid disease of the liver, lung, and peritoneum due to the larval form of E granulosus

Usual Pediatric Dose for Neurocysticercosis

Less than 60 kg: 15 mg/kg/day orally in divided doses twice a day with meals

Maximum dose: 800 mg/day

60 kg or more: 400 mg orally twice a day with meals

Duration of therapy: 8 to 30 days

Comments:

-Patients should receive appropriate steroid and anticonvulsant therapy as needed.

-Oral or IV corticosteroids should be considered to prevent cerebral hypertensive episodes during the first week of therapy.

Use: For the treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of T solium

Usual Pediatric Dose for Capillariasis

US CDC and American Academy of Pediatrics (AAP) recommendations: 400 mg orally once a day for 10 days

Comments: Recommended as alternative therapy

Case Reports of Hepatic Capillariasis (n=2)

At least 18 months: 400 mg/day for 21 days, up to 100 days

Usual Pediatric Dose for Cutaneous Larva Migrans

US CDC and AAP recommendations:

Older than 2 years: 400 mg orally once a day for 3 days

Comments (US CDC): This drug is contraindicated in children younger than 2 years; may use topical agents in such patients

Case Report (n=1)

11 months: 2.5 mL (suspension: 200 mg/5 mL) orally twice a day for 3 days

Usual Pediatric Dose for Cysticercus cellulosae (Cysticercosis)

Some experts recommend: 15 mg/kg/day orally in divided doses twice a day

Maximum dose: 800 mg/day

Duration of therapy: 8 to 30 days

Comments:

-May repeat as necessary

-Therapy for at least 30 days recommended in patients with subarachnoid cysts or giant cysts in the fissures.

-Surgical intervention (especially neuroendoscopic removal) or CSF diversion followed by treatment with this drug and steroids recommended for obstructive hydrocephalus.

-With prednisone or dexamethasone, recommended for arachnoiditis, vasculitis, or cerebral edema

Usual Pediatric Dose for Echinococcus Infection

US CDC and AAP recommendations: 10 to 15 mg/kg/day orally in divided doses twice a day

Maximum dose: 800 mg/day

Duration of therapy: 1 to 6 months

Comments:

-Recommended for cystic echinococcosis in patients with small cysts or multiple cysts in several organs; treatment depends on the WHO classification of the cysts; this drug is not appropriate for all forms of the infection.

-This drug has been administered before surgery to facilitate safe surgical manipulation of cysts by inactivating protoscolices, altering cyst membrane integrity, and reducing cyst turgidity.

Usual Pediatric Dose for Ascariasis

US CDC and AAP recommendations: 400 mg orally as a single dose

Usual Pediatric Dose for Pinworm Infection (Enterobius vermicularis)

AAP recommendations:

-Children less than 20 kg: 200 mg orally as a single dose; repeat in 2 weeks

-Children at least 20 kg: 400 mg orally as a single dose; repeat in 2 weeks

Some experts recommend: 400 mg orally as a single dose; repeat in 2 weeks

Comments: Some clinicians recommend all household contacts of infected patients receive treatment, especially when multiple or repeated symptomatic infections occur, since such contacts commonly also are infected; retreatment after 14 to 21 days may be needed.

Usual Pediatric Dose for Filariasis

Some experts recommend: 400 mg orally twice a day for 10 days

Comments: Recommended for infection due to M perstans

Usual Pediatric Dose for Hookworm Infection (Necator or Ancylostoma)

US CDC and AAP recommendations: 400 mg orally as a single dose

Comments: Recommended for infection due to A duodenal or N americanus

Usual Pediatric Dose for Enterocolitis

Some experts recommend: 400 mg orally once as a single dose

Comments: Recommended for eosinophilic enterocolitis due to A caninum

Usual Pediatric Dose for Loiasis

US CDC and AAP recommendations: 200 mg orally twice a day for 21 days

Comments:

-Recommended for symptomatic infection with microfilariae of L loa/mL less than 8000 and 2 rounds of diethylcarbamazine failed; or recommended for symptomatic loiasis with microfilariae of L loa/mL at least 8000 to reduce level to less than 8000 before diethylcarbamazine therapy

-Treatment of this infection is complex; experts with experience treating this disease and preventing complications of therapy should be consulted.

Usual Pediatric Dose for Visceral Larva Migrans (Toxicariasis)

US CDC and AAP recommendations: 400 mg orally twice a day for 5 days

Comments:

-Recommended for visceral toxocariasis

-Optimum duration of therapy is unknown; some clinicians recommend 20 days therapy.

Usual Pediatric Dose for Strongyloidiasis

Some experts recommend: 400 mg orally twice a day for 7 days

Comments:

-Recommended as alternative therapy

-May be necessary to repeat or prolong therapy or use other agents in immunocompromised patients or patients with disseminated disease

Usual Pediatric Dose for Trichinosis

US CDC and AAP recommendations: 400 mg orally twice a day for 8 to 14 days

Usual Pediatric Dose for Trichostrongylosis

Some experts recommend: 400 mg orally as a single dose with food

Comments: Recommended as an alternative therapy

Usual Pediatric Dose for Whipworm Infection (Trichuris trichiura)

US CDC and AAP recommendations: 400 mg orally once a day for 3 days

Usual Pediatric Dose for Gnathostomiasis

US CDC and AAP recommendations: 400 mg orally twice a day for 21 days

Comments: Recommended for cutaneous symptoms

Usual Pediatric Dose for Clornorchis sinensis (Liver Fluke)

US CDC and AAP recommendations: 10 mg/kg/day orally for 7 days

Comments: Recommended as alternative therapy

Usual Pediatric Dose for Microsporidiosis

Some experts recommend: 15 mg/kg/day orally in divided doses twice a day

Maximum dose: 800 mg/day

Comments:

-Recommended for disseminated infection due to E hellem, E cuniculi, E intestinalis, Pleistophora species, Trachipleistophora species, or A vesicularum

-Recommended for intestinal infection due to E intestinalis

-With fumagillin, recommended for ocular infection due to E hellem, E cuniculi, or V corneae US CDC, NIH, HIVMA/IDSA, Pediatric Infectious Diseases Society, and AAP recommendations for HIV-exposed and HIV-infected children: 15 mg/kg/day orally in divided doses twice a day

Maximum dose: 800 mg/day

US CDC, NIH, and HIVMA/IDSA recommendations for HIV-infected adolescents: 400 mg orally twice a day

Comments:

-Recommended as preferred therapy (including treatment and secondary prophylaxis)

-Recommended for intestinal and disseminated (not ocular) infection due to Microsporidia other than E bieneusi and V corneae

-With fumagillin, recommended for ocular infection for management of systemic infection

Renal Dose Adjustments

Data not available

Liver Dose Adjustments

Data not available

4.3. Contra-indications

Albendazole is contraindicated in patients with:

• BLISZOLE 400 is contraindicated in patients with known hypersensitivity to the benzimidazole class of compounds or any components of BLISZOLE 400.

• It is known to be teratogenic and embryotoxic in animals. The safety of albendazole during pregnancy has not been established, and BLISZOLE 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.

4.4. Special warnings and special precautions for use

Special warnings

It has been noted that leucopaenia has occurred when used for periods longer than recommended.

In order to avoid administering albendazole during early pregnancy, women of childbearing age should initiate treatment during the first week of menstruation or after a negative pregnancy test.

Albendazole has been shown to cause bone marrow suppression, aplastic anemia, and agranulocytosis in patients with and without underlying hepatic dysfunction. Blood counts should be monitored at the beginning of each 28day cycle of therapy, and every 2 weeks while on therapy with albendazole in all patients. Patients with liver disease, including hepatic echinococcosis, appear to be more at risk for bone marrow suppression leading to pancytopenia, aplastic anemia, agranulocytosis, and leukopenia attributable to albendazole and warrant closer monitoring of blood counts. Albendazole should be discontinued in all patients if clinically significant decreases in blood cell counts occur.

Albendazole should not be used in pregnant women except in clinical circumstances where no alternative management is appropriate. Patients should not become pregnant for at least 1 month following cessation of albendazole therapy. If a patient becomes pregnant while taking this drug, albendazole should be discontinued immediately. If pregnancy occurs while taking this drug, the patient should be apprised of the potential hazard to the fetus.

Special precautions

General

Before taking Albendazole a, tell your doctor or pharmacist if you are allergic to it; or to other benzimidazole anthelmintic drugs (e.g., mebendazole); or if you have any other

allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver disease, biliary tract problems (e.g., blockage), blood / bone marrow disorders.

This medication may cause liver problems. Because drinking alcohol increases the risk of liver problems, limit alcoholic beverages while using this medication. Check with your doctor or pharmacist for more information.

Use In 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 breast-feeding.

Interactions

Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

4.5. Interactions with other Drug products and other forms of interaction

Dexamethasone

Steady-state trough concentrations of albendazole sulfoxide were about 56% higher when 8 mg dexamethasone was coadministered with each dose of albendazole (15 mg/kg/day) in 8 neurocysticercosis patients.

Praziquantel

In the fed state, Praziquantel (40 mg/kg) increased mean maximum plasma concentration and area under the curve of albendazole sulfoxide by about 50% in healthy subjects (n = 10) compared with a separate group of subjects (n = 6) given albendazole alone. Mean Tmax and mean plasma elimination half-life of albendazole sulfoxide were unchanged. The

pharmacokinetics of praziquantel were unchanged following coadministration with albendazole (400 mg).

Cimetidine

Albendazole sulfoxide concentrations in bile and cystic fluid were increased (about 2-fold) in hydatid cyst patients treated with cimetidine (10 mg/kg/day) (n = 7) compared with albendazole (20 mg/kg/day) alone (n = 12). Albendazole sulfoxide plasma concentrations were unchanged 4 hours after dosing.

Theophylline

The pharmacokinetics of theophylline (aminophylline 5.8 mg/kg infused over 20 minutes) were unchanged following a single oral dose of albendazole (400 mg) in 6 healthy subjects.

4.6. 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 breast-feeding.

4.7. Effects on ability to drive and use machines

Adverse effects on the ability to drive or operate machinery have not been observed.

4.8. Undesirable effects

The most common adverse reactions are headache, dizziness and upper gastrointestinal symptoms (e.g. epigastric or abdominal pain, nausea, vomiting) and diarrhoea, particularly in patients with intestinal infections and cutaneous larva migrans. Data from large clinical studies were used to determine the frequency of very common to rare undesirable reactions. The frequencies assigned to all other undesirable reactions (i.e. those occurring at < 1/1000) were mainly determined using post-marketing data as frequency cannot be estimated from this data a frequency category of “Not known” is assigned. Treatment related adverse reactions, all grades, are listed below by MedDRA body system organ class and frequency. The following convention has been utilised 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 to < 1/1,000; very rare < 1/10,000.

- **Immune system disorders, including hypersensitivity reactions (Not known):** Hypersensitivity reactions including rash, pruritus and urticarial
- **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(Not known):** Elevations of hepatic enzymes
- **Skin and subcutaneous tissue disorders (Not known):** Erythema multiforme, Stevens-Johnson syndrome.

Systemic helminth infections (longer duration of treatment at higher doses) The most common adverse reactions are headache, mild to moderate elevations of hepatic enzymes, dizziness, gastrointestinal disturbances (abdominal pain, nausea, vomiting), reversible alopecia (thinning of hair, and moderate hair loss) and fever, particularly in patients with systemic helminth infections. Patients with liver disease, including hepatic echinococcosis, appear to be more susceptible to bone marrow suppression (see Dosage and Administration and Warnings and Precautions). Gastrointestinal disturbances have been associated with albendazole when treating patients with echinococcosis. Data from large clinical studies were used to determine the frequency of very common to rare undesirable reactions. The frequencies assigned to all other undesirable reactions (i.e. those occurring at < 1/1000) were mainly determined using post-marketing data as frequency cannot be estimated from this data a frequency category of "Not known" is assigned. Treatment related adverse reactions, all grades, are listed below by MedDRA body system organ class, frequency and grade of severity. The following convention has been utilized for the classification of frequency: very common ≥ 1/10; common ≥ 1/100 to < 1/100; rare ≥ 1/10,000 to < 1/1,000; very rare < 1/10,000.

Blood and lymphatic system disorders (Not known): Leukopenia Pancytopenia, aplastic anaemia, agranulocytosis

Immune system disorders, including hypersensitivity reactions (Uncommon): Hypersensitivity reactions including rash, pruritus and urticaria

Nervous system disorders (Very common): Headache

(Common): Dizziness

Gastrointestinal disorders (Common): Gastrointestinal disturbances (abdominal pain, nausea, vomiting)

Hepatobiliary disorders (Very common): Mild to moderate elevations of hepatic enzymes **(Uncommon):** Hepatitis

Skin and subcutaneous tissue disorders (Common): Reversible alopecia (thinning of hair, and moderate hair loss)

General disorders and administration site conditions (Common): Fever

4.9 Overdose

All indications Further management should be as clinically indicated or as recommended by the national poisons centre, where available. In case of overdosage, symptomatic therapy (gastric lavage) and general supportive measures should be undertaken.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Inhibits effect on tubulin polymerization, resulting in loss of cytoplasmic microtubules.

Albendazole is a benzimidazole carbamate anthelmintic drug similar to mebendazole. It is a broad-spectrum anthelmintic, which is highly effective against a wide range of intestinal helminths including a variety of intestinal nematodes, cestodes, and trematodes. It is also effective against tissue helminth infections, such as cutaneous larva migrans and 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 due to low absorption (less than 5%) after oral administration. However, at higher albendazole doses, sufficient amount 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

Absorption: Albendazole is poorly absorbed from the GI tract; however, it is rapidly converted to its primary active metabolite, albendazole sulfoxide, prior to reaching systemic circulation. Fatty meals enhance bioavailability, as indicated by up to a 5-fold increase in plasma concentration in albendazole sulfoxide. Albendazole sulfoxide plasma concentrations

are dose dependent. C max is achieved in 2 to 5 h and ranges from 0.46 to 1.58 mcg/mL, with a fatty meal.

Distribution: Albendazole sulfoxide is 70% protein bound and widely distributed throughout the body.

Metabolism After metabolism in the liver to albendazole sulfoxide, it is further metabolized to albendazole sulfone and other oxidative metabolites.

Elimination: Albendazole sulfoxide elimination is 8 to 12 h. Biliary elimination of albendazole sulfoxide results in biliary concentrations similar to plasma concentration. Urinary excretion is a minor elimination pathway (less than 1%).

Special Populations: Hepatic Function Impairment Systemic availability of albendazole sulfoxide is increased in patients with extrahepatic obstruction.

5.3. Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Maize Starch
Lactose
Sucrose
Sodium Saccharin
Sodium Lauryl Sulphate
Sodium Benzoate
Sunset Yellow FCF
PVPK 30
Purified water
Talcum
Colloidal Silicon Dioxide
Orange Flavour
Magnesium Stearate
Sodium Starch Glycolate

6.2. Incompatibilities

Not applicable

6.3. Shelf life

36 Months

6.4 Special precautions for storage

Storage below 30^{o}C, Protected from the sunlight.

Keep out of reach and sight of children.

6.5. Nature and contents of container

25 x 1 Tablets in Alu-Pvc Blister Pack

6.6. Instruction for use and handling

No special requirements

7. MARKETING AUTHORISATION HOLDER

Not Applicable

8. MARKETING AUTHORISATION NUMBER

Not Applicable

9. DATE OF FIRST AUTHORISATION /RENEWAL OF THE AUTHORISATION

Not Applicable

10. DATE OF REVISION OF THE TEXT

Not Applicable