Summary of Product Characteristics (SmPC)

1. Name of the medicinal product
α-β Arteether Injection 150 mg /2 ml

2. Qualitative and quantitative composition
Each 2 ml contains:
α-β Arteether ……..…150 mg
Tea-Seed Oil……Q.S

3. Pharmaceutical form
Oily Solution for Injection
A clear colorless to slightly yellowish, oily solution 2 ml amber coloured glass ampoule.

4. Clinical particulars

4.1 Therapeutic indications
Severe malaria including cerebral malaria and as a second line drug in chloroquine resistant malaria cases only.

4.2 Posology and method of administration
ARH is for intramuscular use only.
Children - 3mg/Kg per day administered by intramuscular injection over a 3-day period
The injection must be given under aseptic conditions, deep intramuscularly in the upper lateral quadrant of the buttock. No other drug should be mixed in the same syringe

4.3 Contraindications
α-β Arteether injection is contraindicated in patients hypersensitive to artemisinin derivatives.

4.4 Special warnings and precautions for use

When treating children, particular care should be taken to ensure the correct doses are given and retained.

4.5 Interaction with other medicinal products and other forms of interaction

Prolonged QT interval has been reported in some studies with high dosage of artemisinin derivatives. The cardiac effects of artemisinins are not very important from a clinical point of view, except that caution should be exercised against combinations with other drugs that prolong the QT interval, such as quinine and halofantrine.

4.6 Fertility, pregnancy and lactation

Pregnancy: Adequate studies regarding safe use of artemisinin derivatives during pregnancy are not available. Artemisinin derivatives should not be used in pregnancy as primary drugs for uncomplicated malaria cases but these can be used for treatment of severe or complicated P. Falciparum malaria infection in patients of multiple drug resistance, if the potential benefit

justifies the potential risk to the fetus.
Lactation: It is not known whether α-β Arteether is secreted in human milk. Caution should be exercised when α-β Arteether injection used in lactating mother.

4.7 Effects on ability to drive and use machines

There have been no studies to investigate the effect of α-β Arteether on driving performance or the ability to operate machinery.

4.8 Undesirable effects

While neurotoxicity has been reported in experimental animals, there is no evidence of neurotoxicity in human beings with artemisinin derivatives. a-b Arteether is usually well tolerated. However, nausea, dizziness and depressed GIT activity can occur. Clinical, neurological, electrocardiographic and biochemical monitoring did not reveal significant toxicity. Apart from some increase in eosinophil numbers, no haematological abnormality was seen.

4.9 Overdose

Overdose treatment should be symptomatic and supportive.

5. Pharmacological properties

5.1 Pharmacodynamic properties

α-β Arteether is a fast acting blood schizonticidal agent for P. falciparum malaria at the erythrocytic stage.
α-β Arteether is concentrated in parasitized erythrocytes. The functional group responsible for antimalarial activity of a-b Arteether is endoperoxide bridge. Iron from the digested haemoglobin of the parasite's victim reduces this bridge, releasing a highly reactive free radical iron species which causes lysis of the parasitic cell. It is also proposed that
α-β Arteether inhibits the protein synthesis and alters the ribosomal organization and endoplasmic reticulum.

5.2 Pharmacokinetic properties

α-β Arteether is transformed into dihydroartemisinin. It has a half life of 20 hours. It is eliminated by hepatic metabolism. The elimination is much slower compared to other artemisinin compounds.

5.3 Preclinical safety data

Not Applicable

6. Pharmaceutical particulars

6.1 List of excipients

Tea-Seed Oil Ch. P 2020

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C. Protect from light. Do not freeze.

6.5 Special precautions for disposal and other handling

A clear to colorless to slight yellowish oily solution filled in 2 ml amber colored glass ampoule. 3 ampoules are packed in tray pack and 1 tray pack is packed in mono carton with package insert.

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

7. APPLICANT/MANUFACTURER

Applicant name: DANNYFAITH PHARMACY LIMITED.
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