1.3.1
Summary Of Product Characteristics (SPC)

1.3.1 Product information for health professionals

1.3.1.1 Invented Name of the Medicinal Product

1.3.1.2 Strength

Alpha-Beta Arteether 150 mg/ 2 ml

1.3.1.3 Dosage Form

Injection

1.3.1.4 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml contains:

α- β Arteether……150 mg

Oil Base……...…..q.s.

1.3.1.5 PHARMACEUTICAL FORM

Clear colourless to yellowish liquid.

1.3.1.6 CLINICAL PARTICULARS

1.3.1.6.1Therapeutic indications

α-β Arteether is indicated for use in severe P. falciparum malaria including cerebral malaria and as a second treatment in chloroquine resistant malaria. Not recommended to be used as first line treatment of malaria. No cross resistance detected with Chloroquine.

1.3.1.6.2 POSOLOGY AND METHOD OF ADMINISTRATION

α-β Arteether injection is for INTRAMUSCULAR USE ONLY.

ADULT: 150 mg of α-β Arteether once daily for 3 consecutive days.

CHILDREN: 3 mg/kg per day administered by intramuscular injection over a 3 days period.

The injection must be given in aseptic conditions, deep intramuscularly in the upper-external quadrant of the buttock. No other drug should be mixed in the same syringe.

1.3.1.6.3 CONTRAINDICATIONS

α-β Arteether injection is contra-indicated in patients hypersensitive to artemisinin derivatives.

1.3.1.6.4 WARNING AND PRECAUTIONS

Since no clinical data is available for the use of α-β Arteether during pregnancy, it should be used with caution in pregnant women, if the potential benefits justify the potential risk to the fetus.

1.3.1.6.5 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 artemisinin 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

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1.3.1.6.6 PREGNANCY AND LACTATION

Pregnancy: Since no clinical data is available of the use of α-β Arteether during pregnancy, it should be used with caution in pregnant women, if the potential benefits justify the potential risk to the fetus.

Nursing Mother:

It is not known whether α-β Arteether is excreted in human milk, because many drugs are excreted in human milk, a caution should be exercised while using a-ß Arteether.

1.3.1.6.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

There is no information on the effect of artesunate on the ability to drive or use machines. The patient's clinical status should be considered when assessing ability to drive or operate machinery.

1.3.1.6.8 UNDESIRABLE EFFECTS

Neurotoxicity is the common side effect associated with all artemisinin compounds in high doses. Neurotoxicity manifests as gait disturbances, loss of spinal cord pain responses, incoordination, respiratory depression, convulsions and cardio-respiratory arrest.

Other side effects are nausea, dizziness and depressed GIT activity. Clinical, neurological, electro-cardiographic and biochemical abnormality were seen.

In the metacentric trials of α-β Arteether involving 478 patients suffering from P. falciparum malaria, no significant side effects were observed.

1.3.1.6.9 OVERDOSE

Major & minor side effects for Arteether

Headache, Nausea or Vomiting, Persistent cough, Dizziness, Body pain.

Pain at the injection site, Stomach discomfort and pain, Chills and rigorsevererare.

1.3.1.7 PHARMACOLOGICAL PROPERTIES

1.3.1.7.1 Pharmacotherapeutic group: Antimalarial drugs

α-β Arteether is a synthetic derivative of artemisinin, a product of Chinese plant Artemisia annual. α-β Arteether is a fast acting blood schizonticide specifically indicated for the treatment of chloroquine resistant P.falciparum malaria and cerebral malaria cases.

Mechanism of Action:

α-β Arteether is a fast acting blood schizonticidal agent for P.falciparum malaria at the erythrocytic stage. Arteether is concentrated in parasitised erythrocytes.

The functional group responsible for antimalarial activity of Arteether is Endoperoxide Bridge. Iron from the digested hemoglobin of the parasite victim reduces the bridge, releasing a highly reactive free radical iron species, which causes lysis of the parasitic cell. Lysis of parasitic cell membrane occurs.

The damage includes swelling and deformity of food vacuole membrane, nuclear membrane, endoplasmic reticulum and formation of autophagy vacuoles. It is also proposed that Arteether inhibits the protein synthesis and alters the ribosomal organization and endoplasmic reticulum.

1.3.1.7.2 Pharmacokinetic properties

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

1.3.1.7.3 Preclinical safety data

Not applicable.

1.3.1.8. PHARMACEUTICAL PARTICULARS

1.3.1.8.1 List of excipients

Ingredients
Butylated Hydroxyanisole
Arachis oil

1.3.1.8.2 Incompatibilities:

Not applicable.

1.3.1.8.3 Shelf life:

24 Months.

1.3.1.8.4 Special precautions for storage:

Store below 30°C. Protected from light.

1.3.1.8.5 Nature and contents of container:

α-β Arteether Injection 150 mg is filled in 2 ml amber glass ampoule. Such 3 ampoules are packed in a tray. One tray is packed in a carton along with the package insert.

1.3.1.8.6 Special precautions for disposal and other Special handling:

None

1.3.1.9 Marketed by:

APHANTEE PHARMACEUTICAL NIGERIA LIMITED
SUIT FF 11, FIRST FLOOR, PACIFIC COMPLEX NO.9, AWKA ROAD, ONITSHA, ANAMBRA STATE, NIGERIA.

1.3.1.10 Manufactured by:

SHUKRA PHARMACEUTICALS LTD.
795, Rakanpur, Sola-Santej Road,
Ta. Kalol, Dist Gandhinagar-382721,
Gujarat, India