SUMMARY OF PRODUCT CHARACTERISTICS

GVITHER 40 Injection

Artemether Injection 40 mg

1. NAME OF THE MEDICINAL PRODUCT

Gvither 40 Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Artemether 40 mg

For full list of excipients refer 6.1

3. PHARMACEUTICAL FORM

The solution is sterile and colourless.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Gvither 40 Injection is indicated for the treatment of malaria caused by all forms of Plasmodium including severe malaria caused by multiple drug resistant strains of P. falciparum.

4.2 Posology and method of administration

For INTRAMUSCULAR use only

Formulations for intramuscular injection of Artemether are mostly used in case of severe malaria, but also in case of patients showing gastro-intestinal problems. The dosage depends on the patients' weight, the severity of the case and the clinical condition of the patient.

Loading dose: administered as one single injection.

Children: 3.2 mg/kg body weight on the first day.

Maintenance dose: administered as one single injection.

Children: 1.6 mg/kg body weight during the following four days.

Treatment can however also be continued by oral Artemisinin-based combination therapies (ACT), if the patient's condition does not require injections.

Note:

a) A full course therapy of five days is essential in order to avoid recrudescence.

b) In severe malaria it may be necessary to increase the loading dose and to prolong treatment for seven days if parasitaemia is not cleared during the first few days.

4.3 Contraindications

Gvither 40 injection is contraindicated in patients hypersensitive to the active substance (this has not been seen so far) or to any of the excipients.

4.4 Special warnings and precautions for use:

In cerebral malaria and complicated malaria, general supporting therapy may be required.

4.5 Interaction with other medicinal products and other forms of interaction:

Specific untoward drug interactions have not been found. Potentialisation of other antimalarial drugs is a common feature. Loading dose of Artemether followed by other antimalarial drugs have shown strong beneficial potentialisation effects.

4.6 Fertility, pregnancy and lactation

There are insufficient data on the use of Artemether in pregnant and lactating women. Artemether injection can be used during pregnancy or lactation only if benefits outweigh the risk under medical supervision.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Side effects:

At the therapeutic dose (700 mg) there are virtually no side effects.There are reports on laboratory abnormalities i.e. a decrease in reticulocytes count, an increase in transaminase and ECG changes (Sinus Bradycardia). However, these are transient. At high doses, transient abdominal pain, diarrhoea and tinnitus can occur.

4.9 Overdose:

Do not exceed the prescribed dose. In case of overdosage, symptomatic treatment in a specialized unit is recommended. The administration of several times the therapeutic dose was not reported to give serious side effects.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties:

Artemether acts essentially as a blood schizonticide. The presence of the endoperoxide bridge (generating singlet oxygen and free radicals) appears to be essential for antimalarial activity. Inhibition of protein synthesis as the basic mechanism of action is

suggested in studies which showed morphological changes in ribosomes as well as in the endoplasmic reticulum.

5.2 Pharmacokinetics:

Artemether, when injected through I.M route is rapidly absorbed reaching Cmax within 2-3 hours. It is metabolised in the liver to the demethylated derivative Dihydroartemisnin. The elimination is rapid, with a T1/2 of 4 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylated Hydroxy Anisole BP

Butylated Hydroxy Toluene BP

Ethyl Oleate BP

6.2 Incompatibilities

Not applicable

6.3 Shelf life:

3 years

6.4 Special precautions for storage

Store in cool, dry & dark place.

Keep out of reach and sight of children.

6.5 Nature and contents of container

1 ml/Ampoules, 10 such Ampoules packed in the hip tray which is packed in a monocarton along with insert, 10 such monocarton packed in PVC/PE shrink wrap.

6.6 Special precautions for disposal

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

7. MARKETING AUTHORISATION HOLDER

Bliss GVS Pharma Ltd.102, Hyde Park, Saki Vihar Road, Andheri (E), Mumbai – 400072, INDIA.