1.3 Product Information

1.3.1 Summary of Product Characteristics

Enclosed

National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1. NAME OF THE MEDICINAL PRODUCT

NURAMAL 80

(Artemether Injection 80mg/ml)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Contains:

Artemether 80mg

Benzyl alcohol BP……1%V/V

Arachis Oil BP .....QS

3. PHARMACEUTICAL FORM

Controlled (Psychotropic) medicine;

A Sterile colourless solution for Injection

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of severe and complicated malaria caused by Plasmodium falciparum in adults and in children in areas where there is a multidrug resistance.

Treatment of malaria uncomplicated in situations where the prevalence of MDR infection by Plasmodium falciparum is widespread

4.2 Posology and Method of Administration

Route of administration: IM use only

Dosage:

Adults: 160 mg IM the first day followed by 80 mg IM once per day of the 2nd to 5th day. If the treatment can be carried out during 5 days, 80 mg may be administered twice per day IM over a period of three days. The total dose is 480 mg for adults.

Children: 2 intramuscular injections of 1.6 mg / kg must be administered day 1 (0.1 ml / 5 kg), followed by 1.6 mg / kg IM between the 2nd and the 5th day. The total dose recommended for children is 9.6 mg / kg

4.3 Contraindications

The pregnant women with malaria uncomplicated in the first trimester of pregnancy.

Prior to the dihydroartemisinin hypersensitivity.

4.4 Special Warnings and Precautions for Use

Artemether prolongs the PQ and QT intervals in laboratory animals. Adverse drug interactions can be induced when they are administered with other drugs or antimalarials who also have heart action.

Use in neonates: There is no information on the use of artemisinin in newborns. Use in children: Artemisinin can be administered to children with severe and complicated malaria caused by Plasmodium falciparum multidrug. The total dose of artemether is 9.6 mg / kg Use in the elderly: No special precautions are required during administration of artemisinin to seniors.

Use in concomitant illness:

Heart: given that artemisinin induces cardio-toxiques effects in laboratory animals and transient first degree block was observed in four patients, artemisinin should be used with caution in patients suffering from chronic heart problems. At present, there is no indication to retain or to reduce the dose of the drug. It should not be administered parenterally to patients with serious coronary heart disease, unless an intensive surveillance can be ensured.

Renal and hepatic insufficiency: there is no information available on the use of artemisinin in patients of malaria with concomitant liver or kidney failure. Until more information is available, the drug should be administered at the same dose as in adult patients.

4.5 Interaction with Other Drugs, Other Forms of Interactions

Since electrocardiographic QT prolongation has been reported in some patients treated with artemether, it is recommended to avoid prescription of medications known to produce prolongation of QT interval or patients receiving such medication: erythromycin, terfenadine, astemizole, probucol, Class 1a antiarrhythmic agents (quinidine, procainamide, disopyramide),Class III antiarrhythmic agents (amiodarone, bretylium), bepridil, sotalol, tricyclic antidepressants, some neuroleptics and phenothiazines are to be monitored closely.

4.6 Fertility, pregnancy and lactation

In view of the serious health consequences of malaria in pregnancy in the case of multidrug resistance, artemisinin and its derivatives should not be denied to patients with no complicated malaria in the second and third quarters of the pregnancy. When there is severe and complicated malaria caused by Plasmodium falciparum multidrug during pregnancy, the use of artemisinin could also be seriously considered, even during the first trimester of pregnancy, in taking into account the benefit-risk ratio and the intensity of the resistance. intravenous quinine. Breast-feeding: Artemisinin and its derivatives have not been measured in the milk of nursing mothers. It is very likely that these are present in milk and breastfeeding women should not receive combination therapy if they suffer no complicated malaria, either in the multidrug resistance or drug-sensitive situations. If the nursing mother suffers from a severe and complicated malaria caused by Plasmodium falciparum multidrug, and artemisinin is indicated, breast-feeding should be stopped

4.7 Effects on ability to drive and operate machine

Not Applicable

4.8 Undesirable effects

A fever induced by drugs and a fall in the number of reticulocytes have been reported. Nausea, hypotension, dizziness, tinnitus, dark urines, sweats, fatigue and jaundice have been reported.

Artemether prolongs the PQ and QT intervals in laboratory animals. Adverse drug interactions can be induced when they are administered with other drugs or antimalarials who also have heart action.

4.9 Overdose

At present, there is no information on the effect of the overdose of artemisinin or the lethal dose. There is no specific antidote known for artemisinin derivatives.

5. Pharmacological properties

5.1 Pharmacodynamics properties

Artemether: Anti-malarial,

Code ATC: P01BE02

Pharmacodynamics properties: Artemether essentially acts as a blood schizonticide. The presence of the endoperoxide bridge (producing the singlet oxygen and free radicals) seems to be essential for the antimalarial activity. The inhibition of the synthesis of proteins as the basic action mechanism is suggested in studies that showed morphological changes in the ribosomes as well as in the endoplasmic reticulum.

The morphological changes of the parasitic membranes induced by Artemether have been described, being the result of the action of free radicals. Other tests in vitro suggest that Artemether provokes a marked decrease in the synthesis of nucleic acids. All used artemisinins today are prodrugs of the metabolite biologically active dihydroartemisinin, active at the point where the parasite is located in red blood cells.

5.2 Pharmacokinetic properties

Intramuscular artemether is quickly absorbed and reaches therapeutic levels during the first hour. Cmax is achieved within 4-6 hours. It is metabolized in the liver by dihydroartemisinin, a metabolite derivative. The elimination is fast, with a t1 / 2 of 2-4 hours. Dihydroartemisinin, being itself a powerful

5.3 Pre-clinical safety data

No specific information on the preclinical safety data of the drug was obtained.

6. Pharmaceutical particulars

6.1 List of excipients

Benzyl Alcohol

Refined Ground Nut Oil/ Arachis Oil

6.2 Shelf life

36 months from the date of manufacturing.

6.3 Special precautions for storage

Store below 30°C in a cool & dry place. Protect from Light.

Keep all medicines out of the reach of children.

6.4 Nature and contents of container

1 ml A clear colourless to pale yellow coloured solution filled in 1ml, Amber Blue Snap Off Ampoule. Such 6 ampoules are packed in a Tray, which is further packed in a printed Primary Carton along with the Pack Insert

6.5 Special precautions for disposal and other handling

Any unused portion should be discarded as per local regulations

7. MANUFACTURER

M/s FARBE FIRMA Pvt Ltd

Address: Plot No: 1508, Near Atique Bakery, GIDC Estate,

Ankleshwar-393002, Gujarat, INDIA