Bosch

For Healthcare Professionals only

Qmetem-P™

(Artemether)

Injection 80mg/mL

کیومیٹم-پی

(آرٹیمیتھر)

انجکشن ۸۰ ملی گرام/ملی لیٹر

QUALITATIVE AND QUANTITATIVE COMPOSITION
Qmetem-P Injection 80mg/mL
Each mL contains:
Artemether USP …… 80mg
(Product Specs: Ph.Int.)

PHARMACEUTICAL FORM
Injection

CLINICAL PARTICULARS
Therapeutic indications
Treatment of severe, complicated and uncomplicated malaria caused by *P.falciparum* both in adults and children in areas where there is multidrug resistance.

Posology and method of administration
Posology
Adults: First day: 80mg administered by IM route twice a day at a 12 hourly interval (=160mg/day).
Following 4 days: 80mg administered by IM route once a day.
The dose should not be exceeded 480mg in adults.

Children: First day: 1.6mg/kg of body weight administered by IM route twice a day at a 12 hourly (= 3.2mg /Kg body wt/day).

Following 4 days: 1.6mg/Kg of body weight administered by IM route once a day.
The dose should not be exceeded 9.6mg/kg in children.

Mode of Administration
Intramuscular Only

Contraindications
Hypersensitivity to artemether or other artemisinin compounds.

Interaction with other medicinal products and other forms of interaction
No known drug interaction has been recorded of Artemether.

Pregnancy and lactation
Pregnancy: Artemisinin and its derivatives can be used for treatment of uncomplicated malaria during the second and third trimester of pregnancy in areas of multidrug resistance. Owing to lack of data, use in the first trimester of pregnancy is not recommended.

Lactation: Artemisinin and its derivatives have not been measured in the milk to nursing mothers. It is very likely that these are present in milk and nursing mothers should not be given artemisinin if they are suffering from uncomplicated malaria either in multidrug resistance or drug sensitive situations. If the nursing mother is suffering from complicated and serious malaria induced by multidrug-resistant *P.falciparum* and artemisinin is indicated, breast-feeding should be stopped.

Effects on ability to drive and use machines
No Data Available

Undesirable effects
Artemether has been remarkably well-tolerated, and appears less toxic than quinine or chloroquine; adverse effects include bradycardia, electrocardiogram abnormalities, gastrointestinal disturbances (nausea, abdominal pain, diarrhea - oral therapy only), dizziness, injection site pain, skin reactions, and fever. Transient decreases in neutrophils and reticulocytes have been reported in some patients treated with artemether. Drug-induced fever has been observed with artemether. Mild reactions were seen in patients to whom artemether had been administered intramuscularly. These included nausea, hypotension, dizziness and tinnitus. These side effects were also reported: dark urine, sweating, somnolence, and jaundice. There were no deaths or any other side effects. No irreversible side effects were seen. Slight rise of SGOT and SGPT may occur in individual cases. Neurological side effects have not yet been observed in clinical use.

Overdose
There is no experience with overdosage with Artemether. There is no specific antidote known for the Artemisinin derivatives. Overdosage could bring on cardiac irregularities. An ECG should be taken before initiating treatment in cardiac patients.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Therapeutic Classification: Antimalarials, blood schizonticide

ATC code: P01BE02

Artemether is an antimalarial medicine. Artemisinin and its semisynthetic derivatives act essentially as blood schizonticides. The presence of the endoperoxide bridge appears to be essential for antimalarial activity: generation of singlet oxygen and formation of free radicals.

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. Morphological changes of the parasitic membranes induced by dihydroartemisinin have been described, being the result of free radical action. The observation that membranous structures are disrupted have lead, once again, to the hypothesis that the site of action of artemisinin could be the membranous structures. Other in vitro tests suggest that artemisinin causes a marked diminution of nucleic acid synthesis.

Pharmacokinetic properties

Pharmacokinetics:

Intramuscular β-Artemether is rapidly absorbed reaching Cmax Within 4-9 hours. It is metabolized in the liver to the demethylated derivative dihydroartemisinin. The elimination is rapid, with a $T_{1/2}$ of 4 hours.

Dihydroartemisinin has a $T_{1/2}$ of more than 10 hours.

The degree of binding to plasma proteins varied markedly according to the species considered. The binding of β-Artemether with plasma protein is of the order of 50%. Radioactivity of free β-Artemether in plasma was found to be equal to that in red blood cells indicating an equal distribution of free drug between cells and plasma.

Artemisinin and related compounds are difficult to assay in body fluids. Measurement can be done by high-performance liquid chromatography with UV detection and electrochemical detection. These drugs bind avidly and irreversibly to membranes, including those of normal erythrocytes and may also bind covalently to plasma proteins. In view of these difficulties, some groups have developed bio-assays as useful, if imprecise, measures of biological activity.

Distribution and Excretion:

Artemisinin and its derivatives are metabolized rapidly in vivo to dihydroartemisinin. This active metabolize may be eliminated more slowly than the parent compound. Intramuscular β-Artemether is rapidly absorbed reaching Cmax within 4 - 9 hours. Oral, β-Artemether is rapidly absorbed reaching Cmax within 2 - 3 hours. The elimination is rapid, with a $T_{1/2}$ of 4 hours.

β-Artemether undergoes rapid and extensive conversion to dihydroartemisinin. The active metabolize, dihydroartemisinin, reached Cmax at the median time of 6h, attaining higher plasma concentrations than the parent drug.

In the patients β-Artemether was rapidly absorbed; median absorption half-life was 0.29h Cmax of 199ng/mL was reached at 2.3h after the first dose. Steady state was reached after the third dose (24h). The plasma levels indicate high bioavailability.

Metabolism:

Artemether is rapidly metabolised in the liver, primarily by CYP3A4, to the demethylated derivative dihydroartemisinin (DHA). Dihydroartemisinin is further converted to inactive metabolites.

The antimalarial activity of artemether and DHA has been attributed to endoperoxide moiety. The presence of the endoperoxide bridge (generating singlet oxygen and free radicals) appears to be essential for the antimalarial activity.

Special populations:

Patients with acute renal failure might reach higher maximal concentrations; in these patients the elimination half-life of artemether could be longer.

PHARMACEUTICAL PROPERTIES

Shelf life

02 years

Special precautions for storage and instructions

Protect from heat, light & moisture, store below 30°C.

The expiration date refers to the product correctly stored at the required condition.

Keep out of the reach of children.

To be sold on the prescription of a registered medical practitioner only.

Nature and contents of the container / Presentation

Qmetem-P Injection 80mg/mL: Pack of 5 ampoules.

REGISTRATION HOLDER / MARKETING AUTHORIZATION HOLDER

Head Office:

Bosch Pharmaceuticals (Pvt.) Ltd.,
8, Modern Society, Tipu Sultan Road, Karachi-Pakistan

Manufacturer:

Bosch Pharmaceuticals (Pvt.) Ltd.,
221-223, Sector 23, Korangi Industrial Area, Karachi-Pakistan

REGISTRATION / MARKETING AUTHORIZATION NUMBER

055640

DATE FROM WHICH MARKETING IS AUTHORIZED/RENEWAL OF THE AUTHORIZATION

02-04-2009/01-04-2024

DATE OF REVISION OF THE TEXT

15-05-2024

صرف پٹھوں میں استعمال کے لئے۔

ہدایات:

روشنی، گرمی اور نمی سے محفوظ ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

بچوں کی پہنچ سے دُور رکھیں۔

صرف معتمد ڈاکٹر کے نسخے پر فروخت کے لئے۔

Manufactured by:
Bosch Pharmaceuticals (Pvt.) Ltd.
221-223, Sector 23, Korangi Industrial Area,
Karachi - Pakistan