Summary of Product Characteristics (SmPC)

1. N AME OF THE MEDICINAL PRODUCT

Artemether Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule contains:Artemether

Inactive ingredients: None

3. PHARMACEUTICAL FORM

This product is Colorless or pale yellow clear-cut oil solution.

4. CLINICAL PARTICULARS

【Chemical composition】Artemether

5. PHARMACOLOGICAL ACTION:

Pharmacological toxicology

Pharmacological artemether is a derivative of artemisinin, which has a strong and rapid killing effect on plasmodium red internal stage, and can quickly control clinical attacks and symptoms。The mechanism of action of artemisinin is not very clear, mainly interfering with the surface membrane-mitochondrial function of Plasmodium. Artemisinin changes the membrane structure of Plasmodium by affecting the ultrastructure of the red inner stage. Due to the effect of food bubble membrane, blocked the nutrient intake of Plasmodium, when the Plasmodium loses a lot of cytosol and nutrients, but can not supplement, so quickly died。Its mode of action is mediated by its internal peroxide (dioxygen) bridge, produced by free iron after hemoglobin decomposition, producing unstable organic free radicals and / or other electrophilic mediators, and then forming a covalent adduct with the proteins of Plasmodium to killing the Plasmodium. The antimalarial activity of artemether was six times greater than that of artemisinin。The LD50 of artemether was 895 to 977 mg / kg, and the LD50 of artemether oil was 597mg / kg. Subacute toxicity test showed that after 14 days of 18mg / kg daily, except for a decrease in reticulocyte count. This drug has certain embryological toxicity, manifested as embryonic resorption.

Pharmacokinetics

Fast and complete absorption after intramuscular injection. After 10mg / kg, the peak time was 7 hours, the peak could reach about 0.8 mg/L, and T1 / 2 was about 13 hours. In the body distribution is very wide, with the most brain tissue, liver, kidney second. It is mainly excreted through the intestinal tract, followed by urinary excretion.

6. **PHARMACOLOGICAL PROPERTIES**

indication

It is suitable for various types of malaria, but mainly used for anti-chloroquine falciparum malaria treatment and emergency treatment of dangerous falciparum malaria。

usage and dosage

1. Adult common dosage, intramuscular injection, the first dose of 160mg, once daily from the second day, 80mg, even for 5 days。

2. Children, intramuscular injection, the first dose weight 3.2mg / kg; from day 2 to 5, each weight 1.6mg / kg, once a day.

untoward effect

However, some patients had a mild elevation in aspartate aminotransferase and alanine aminotransferase, and a transient decrease in reticulocytes

matters need attention

If this product is solidified when cold, it can be used after dissolving at micro-temperature。

pharmacy

Pregnant women and lactating women should use drugs with caution in pregnant women。

7.PHARMACEUTICAL PARTICULARS

7.1List of excipients

None

7.2Incompatibilities

Not applicable

7.3Shelf-life

3 years

7.4Special precautions for storage

Store in a dry place below 30°C

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

7.5Nature and contents of container

Ampoule

7.6 Special precautions for disposal and other handling

No special requirements

8.MARKRTING AUTHORISATION HOLDER

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