

1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

(1) Name of the medicinal product

Paracetamol Injection

(2) Qualitative and quantitative composition

Each 2ml ampoule contains:

Approved name	Quantity/dose	Function
Paracetamol	300mg	Active Ingredient
PEG-400	840mg	Non-ionic surfactant.
Anhydrous sodium sulfite	4mg	Antioxidant
Benzyl alcohol	20mg	Local anesthetics
Lidocaine	20mg	Local anaesthetic

(3)Pharmaceutical form

Sterile small volume injection

2ml of Colourless or almost colourless slightly viscous clear liquid is filled in the glass ampoule（2ml）.

(4) Clinical particulars

①Therapeutic indications

This product is used for fever, and can also be used to relieve mild and moderate pain, such as headache, muscle pain, arthralgia, neuralgia, dysmenorrhea, cancer pain and postoperative pain relief. This product can be used in patients who are allergic or intolerable to aspirin. This product has no effect on all kinds of acute pain and visceral smooth muscle colic.eroidal anti-inflammatory drugs are contra-indicated.

② Posology and method of administration

Intramuscular injection, 0.15g~0.25g at a time. This product should not be used for a long time. The course of antipyretic treatment should not exceed 3 days, and the duration of analgesia should not exceed 10 days.

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③ Contraindications

It is forbidden for those who are allergic to this product and have severe liver and kidney insufficiency.

(5) Special warnings and precautions for use

1. Cross-allergic reaction: people who are allergic to aspirin generally do not have allergic reaction to this product, but it is reported that a few (<; 5%) of the patients who have asthma due to aspirin allergy can have mild bronchospasm reaction after using this product.

2. The following situations should be used with caution:

① In case of alcoholism, liver disease or viral hepatitis, there is a risk of increasing liver toxicity;

② Renal insufficiency can be used occasionally, but if it is used for a long time, it will increase the risk of renal toxicity.

3. During long-term treatment, blood picture and liver function should be checked regularly.

4. Interference to laboratory inspection:

① In the determination of blood glucose, the false low value can be obtained by using glucose oxidase method, but it has no effect when using hexokinase/6-phosphate dehydrogenase method;

② Determination of serum uric acid can be false when using phosphotungstic acid method

(6) Interaction with other medicinal products and other forms of interaction

1. In patients who drink or use other liver enzyme inducers for a long time, especially those who use barbiturates or anticonvulsants, there is a greater risk of liver toxicity when using this product for a long time.

2. The combination of this product and chloramphenicol can prolong the half-life of the latter and enhance its toxicity.

3. Combined with anticoagulants can enhance the anticoagulant effect, so the dosage of anticoagulants should be adjusted.

4. When combined with aspirin and other non-steroidal anti-inflammatory drugs for a

long time, there is a risk of significantly increasing renal toxicity.

5. When used together with the antiviral drug Zidovudine, it can increase its toxicity, and should not be used at the same time.

(7) Pregnancy and lactation

This product can pass through the placenta, so the possible adverse effects on the fetus after the use of this product by pregnant women should be considered. Although this product can reach a certain concentration in milk after being used by lactating women, the product or its metabolites have not been found in the urine of lactating infants. It is not recommended for pregnant women and lactating women.

(8)Child medication

Children under 3 years of age should avoid using because of liver and kidney dysfunction.

(9) Elderly medication

Due to the deterioration of liver and kidney functions in elderly patients, the half-life of this product is prolonged, and adverse reactions are likely to occur. It should be used with caution or reduced dosage.

(10)Adverse effects

Under the conventional dose, acetaminophen has few adverse reactions, occasionally causing nausea, vomiting, sweating, abdominal pain, skin pallor, etc. In a few cases, allergic dermatitis (rash, skin itching, etc.), agranulocytosis, thrombocytopenia, anemia, liver function damage, etc., rarely causing gastrointestinal bleeding.

(11)Overdose

Overdose of drugs, including toxic amount, can cause nausea, vomiting, stomachache, diarrhea, anorexia, hyperhidrosis and other symptoms quickly, and can last for 24 hours. Liver function damage occurs within 2 to 4 days, which is manifested as liver pain, hepatomegaly, jaundice, or renal function damage, such as oliguria and elevated serum creatinine. The abnormal liver function can reach the peak on the 3rd to 5th day, and obvious liver failure, renal tubular necrosis and even renal failure can occur on the 4th to 6th day. For rescue, the antagonist N-acetylcysteine should be given in time (140mg/kg orally at the beginning according to the body weight, then 70mg/kg once every 4 hours, a total of 17 times; if the disease is serious, the drug can be administered intravenously, and dissolved in 200ml of 5% glucose solution) or oral methionine, which has protective effect on the liver. Antagonists should be used as soon as possible, and the effect is satisfactory when administered within 12 hours, but

the effect is poor when administered more than 24 hours. Other treatments should also be given, such as intravenous infusion and/or diuresis to promote excretion, and hemodialysis.

(12)Pharmacology and toxicology

This product is acetanilide antipyretic and analgesic. The antipyretic effect is achieved by inhibiting the synthesis and release of prostaglandin PGE1 in the hypothalamic thermoregulation center, leading to peripheral vascular dilation and sweating, and its antipyretic effect is similar to that of aspirin; It can relieve pain by inhibiting the synthesis and release of prostaglandin PGE1, bradykinin and histamine, and raising the pain threshold. It is a peripheral analgesic, with weaker effect than aspirin, and is only effective for mild and moderate pain. This product has no obvious anti-inflammatory effect.

The results of acute toxicity test: the LD50 of mice was 338 mg/kg orally and 500 mg/kg intraperitoneally.

(13)Pharmacokinetics

The plasma protein binding rate was 25%. 90%~95% are metabolized in the liver, mainly combined with glucuronic acid, sulfuric acid and cysteine. Intermediate metabolites have toxic effects on liver. T1/2 is generally 1 to 4 hours (2 hours on average), and remains unchanged when renal function is incomplete, but it may be prolonged in some patients with liver disease, extended in the elderly and newborns, and shortened in children. This product is mainly excreted from the kidney in the form of glucuronic acid binding, and about 3% of it is excreted in the urine in its original form within 24 hours.

(14) Storage

Shading and airtight storage.

(15) Shelf life

36 months.