Summary of Product Characteristics (SmPC)

1. N AME OF THE MEDICINAL PRODUCT

Cimetidine Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule contains:Cimetidine

Inactive ingredients: None

3. PHARMACEUTICAL FORM

This product is colorless, clear liquid.

4. CLINICAL PARTICULARS

【Chemical composition】Cimetidine

5. PHARMACOLOGICAL ACTION:

Pharmacological toxicology

1.Pharmacological effects mainly act on H2 receptors on parietal cells, competitively inhibit histamine, inhibit basic gastric acid secretion, and also inhibit the gastric acid secretion stimulated by food, netamine gastrin, caffeine and insulin. And 300mg after injection, 4-5 hours later. Inhibition of basal gastric acid secretion by up to 80%, can inhibit basal gastric acid by 50% up to 4-5 hours。

2.The subacute and chronic toxicity tests in rats and dogs showed that this product had mild antiandrogenic effects, causing the prostate, seminal vesicles and milk secretion, but disappeared after drug withdrawal. No mutagenic, carcinogenic, teratogenic effect, and no soft and tolerance.

pharmacokinetics

After absorption, this product is widely distributed in the whole body tissue except the brain. This product can cross the placental barrier, and the concentration of this product in the milk can be higher than the plasma concentration. The protein binding rate is 15% – 20%, and it is partially metabolized in the liver. The metabolites are Sulphoxide and hydroxymelhylcimeliding, which are mainly excreted through the kidney. After 24 hours, about 75% of the injection volume is excreted from the kidney; 10% can be excreted from feces。It can be eliminated by hemodialysis, t1 / 2 is 2 hours for normal renal function, creatinine clearance is 2.9 hours at 20-50ml / minute (t1 / 2), 3.7 hours at <20ml / minute, and 5 hours for renal insufficiency.

6. PHARMACOLOGICAL PROPERTIES

Indication

For digestive tract ulcers.

usage and dosage

Injection: 0.2g with 5% glucose injection or 0.9% sodium oxide injection or glucose sodium chloride injection 250~500ml diluted after intravenous infusion, at the rate of l-4mg / kg per hour, 0.2-0.6g per time。Intravenous injection: dilute 20ml of the above solution and slowly intravenous injection (2-3 minutes), once for 6 hours, 0.2g each. Intramuscular injection: 0.2g once, once in 6 hours.

untoward effect

1.The digestive system reaction. More common diarrhea, abdominal distension, dry mouth, serum amino transferase mild elevated, occasionally see severe hepatitis, liver damage, liver fatty change. The application of acute pancreatitis has been reported in both animal experiments and clinical practice.Sudden withdrawal of medication may lead to chronic peptic discharge perforation。

2.Urinary system reaction. Acute interstitial nephritis has been reported, but this toxic reaction is reversible.

3.The hematopoietic system response. It has some inhibitory effect on the bone. A small number of patients develop a reversible moderate degree of leukocytic or granulocytopenia.

4.Central nervous system response. There is no certain neurotoxicity through the blood and brain. More common have dizziness, headache, fatigue, drowsiness and so on. A few can appear uneasy, feel late bell, the language ambiguity, sweating or epileptic seizure, hallucinations, delusion and other symptoms, the blood concentration of poisoning symptoms is more in 2 u g/ml, and more occur in the elderly, young children or patients with liver and kidney insufficiency. After the occurrence of neurotoxicity, the dose can disappear, and the symptoms can be improved with choline drug stigmine.

5.Blood praise system reaction, can have bradycardia, facial flushing, etc. Distant blood pressure, premature atrial beats, cardiac and respiratory arrest, shortness of breath or difficulty in breathing during intravenous injection.

6.Impact on endocrine and skin, this drug has the effect of antimale cream, which can cause male breast development, female breast overflow, sexual loss, Yang fistula, sperm

count reduction, etc., and disappear after withdrawal; can inhibit sebum secretion, induce exfoliative dermatitis, alopecia, oral ulcer, etc.

Taboo

1. Pregnant women and lactating women are prohibited.2. Those who are allergic to this product are prohibited.

matters need attention

].Should not be used for acute pancreatitis.

2.Attention should be paid to the renal function and blood routine during medication.

3.The use of this product with central anticholindrugs should be avoided to prevent the aggravation of central nervous toxicity.

4.Caffeine and caffeinated beverages should be prohibited when using this product.

5.Sudden withdrawal of medication may lead to chronic perforation of peptic ulcer, which is estimated to be caused by high acidity of rebound after withdrawal. Therefore, the treatment should continue to be taken (400mg per night) for 3 months.

6.Interference to diagnosis: the gastric cult blood test can be false positive; the concentration of salicylic acid, creatinine, prolactin and aminotransferase may grow taller; the concentration of parathyroid hormone may decrease.

7.The following symptoms should be used with caution: (1) severe cardiac and respiratory diseases; used with caution in patients with hepatic and renal insufficiency.(2) Chronic inflammation, such as systemic lupus erythematosus (SLE), and the bone marrow toxicity of xidetidine may be increased.(3) organic encephalopathy. (4) Renal function impairment (moderate or severe).

8.In case of discoloration, crystallization, muddy oil, foreign body should be prohibited.

Women's medication

This product can cross the placental barrier, and can enter the milk, causing fetal and infant liver dysfunction, so it is prohibited.折叠

Children's medication Children with caution.

Old age medication

Use it with caution in elderly patients. The medication interval can be extended and the dose can be reduced.

drug interaction

1. Associated with acid production. It has pain relief for duodenal ulcers, but the absorption of cimetidine may be reduced, so it is generally not mentioned.

2.The combination of this product and aluminum may reduce the efficacy of aluminum (because the eurolysis of aluminum can only be hydrolysis by xiao acid), aggravate the symptoms of sedation and other central nervous depression, and can develop into respiratory and circulatory failure. If it must be used together with antacids, they should be at least 1 hour apart.

3.When used with coumarin anticoagulants, the prothrombin time can be further extended, so it is necessary to pay close attention to the changes in the disease, and adjust the dosage of anticoagulant drugs.

4.It should be used with caution with other intrahepatic metabolic drugs.

5.When used with phenytoin sodium, the blood concentration of the latter increases, the toxicity may be enhanced, pay attention to the regular peripheral blood image.

6. This product can nearly double the absolute bioavailability of verapamil.

7.When patients take both digoxin and quinidine, they should not be used again.

8.This product can attenuate the effect of tetracycline and enhance the effect of aspirin.

9.Can interfere with the absorption of ketoconazole and reduce its antifungal activity.

10.Combination of this product with captopril may cause psychotic symptoms.

11.Due to its similar myonerve blocking effect with aminoglycosides, this effect is not opposed by neostigmine but only by calcium chloride, which may lead to respiratory inhibition or arrest when combined with aminoglycoside antibiotics.

12.When associated with propranolol, metoprolol and metronidazole.

13.When used with theophylline, caffeine, aminophylline and other yellow drug drugs, the liver metabolism is reduced, which can lead to the removal level, the blood concentration increases, and the toxic reaction may occur.

overdose

Common signs of excess are shortness of breath or dyspnea and tachycardia.Treatment: First, remove the unabsorbed drugs in the gastrointestinal tract, and give clinical monitoring and support therapy. In patients with respiratory failure, artificial respiration was performed immediately, and those with tachycardia were given β adrenaline block drugs.

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

MANUFACTURED BY:

Shandong Xier Kangtai Pharmaceutical Co., Ltd

Private Economy Garden, Xinyan Town, Yanzhou City, Shandong China

IMPORTED BY:

ECNU PHARM CO. LIMITED

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