

# Biapenem for Injection

## Drug names

Generic name: Biapenem for Injection

Trade name: Newanti<sup>®</sup>

Pinyin: Anxin Zhusheyong Bi'apeinan

## Drug description

It occurs as a white to yellowish white crystalline powder.

## Indication

Strains sensitive to this product include: staphylococcus, streptococcus, pneumococcus, enterococcus (enterococcus faecium is not included), moraxella, coliform bacilli, citrobacter, klebsiella, enterobacter, serratia, proteus, haemophilus influenzae, pseudomonas aeruginosa, actinomyces, peptostreptococcus, bacteroides, prevotella, fusiformis, etc.

This product is applicable to the treatment of a variety of infections caused by sensitive bacteria: septicemia, pneumonia, lung abscess, secondary infections resulting from chronic respiratory disease, cystitis, pyelonephritis, peritonitis, appendagitis, etc.

## Specification

Biapenem is supplied in glass vials each containing 0.3g Biapenem dry powder

## Dosage and administration

For I.V. injection, every 0.3g Biapenem dry powder should be dissolved in 100ml physiological saline (0.9% Sodium Chloride solution), shake to dissolve and let stand until clear. Freshly prepared solutions of Biapenem I.V. should be used by intravenous infusion. The recommended dose of Biapenem I.V. for adults is 0.6g/d, given over approximately 30-60 minutes in twice administration per day. Dosage can be adjusted according to the physical condition such as age and symptom of each individual, but should not exceed 1.2g/d.

## Side effects and Adverse reactions

According to foreign literatures, side effects including rash or itch of skin, nausea, vomiting, diarrhea, etc may occur. In one study where 2348 clinical cases were

investigated, adverse events were observed in 64 cases (2.7%), among which skin rash (1.0%) and diarrhea (0.7%) were the most common ones, etc. In another study investigated on 2287 cases, 522 abnormal clinical parameter changes in 304 cases (13.3%) were reported, among which the increase of ALT(GPT) (144 cases, 6.3%), the increase of AST (GOT) (93 cases, 4.1%) , and the increase of eosinophilic granulocyte (77 cases, 3.4%) were the most common ones.

Serious adverse reactions from this product include:

1. Allergy and anaphylactic Shock (<0.1%),;
2. Interstitial pneumonia, (0.1%~5%), PIE syndrome;
3. Serious enteritis such as colitis pseudomembranous, etc;
4. Myospasm and mental disorder;
5. Impairment of liver function, jaundice;
6. Acute renal insufficiency;

### **Contraindications**

1. Biapenem is contraindicated in patients with known hypersensitivity to any component of this product or to other drugs in the same class ;
2. Patients who are concurrently taking sodium valproate are prohibited to use this product.

### **Precautions**

1. This product should be used with caution by patients who are allergic to carbopenems, penicillins and cephalosporins;
2. This product should be used with caution by patients who or whose direct relatives are susceptible to induced hypersensitivities including bronchial asthma, rash, urticaria and so on;
3. Patients with severe renal inadequacy take precautions before using this product;
4. Senile patients should use this product with cautions (see “Medication for senile patients”);
5. When this product is used by the patients with eating difficulty and poor body condition, symptoms of Vitamin k Deficiency may occur;
6. Patients with history of epilepsy and illness of central nervous system shall use this

product with caution;

7. False positive findings may occur during clinical Urine Glucose Test, Benedict's test and Fehling's test for reducing sugar;

8. Positive findings may occur in Kveim test.

### **Use in pregnant and lactating women**

Its safety of use in **pregnant and lactating women** remains unclear.

### **Use in children**

Its safety of use in children remains unclear.

### **Use in elderly patients**

Due to degeneration of physiological function, it is necessary to adjust the dosage and treatment interval in elderly patients.

### **Drug Interactions**

A clinically significant reduction in serum valproic acid concentration has been reported in patients receiving carbapenem antibiotics and may result in loss of seizure control. Patients concurrently taking valproic acid concentrations should be monitored frequently after initiating carbapenem therapy. Alternative antibacterial or anticonvulsant therapy should be considered if serum valproic acid concentrations drop below the therapeutic range or a seizure occurs

### **Overdose**

Symptom of an overdose is not known. If an overdose happens, seek routine monitoring symptomatic treatment.

### **Pharmacological effects**

Biapenem is a carbopenems antibiotic which suppresses bacterial growth by inhibiting the enzymes responsible for bacterial cell wall synthesis, and shows broad-spectrum antibacterial activity both against gram-positive bacteria and gram-negative bacteria. Biapenem is stable to dehaloperoxidase-I (DHP-I) and can not be administered together with DHP-I inhibitor.

### **Pharmacokinetics**

1. serum drug level

In a clinical study where health volunteers (5 cases) are injected with Biapenem intravenously 3 times, with a dose of 150mg, 300mg and 600mg respectively each time over 60 minutes, and there is a linear relationship observed between serum drug level and dose.

## 2. in vivo distribution

When 300mg Biapenem is injected over 30 minutes or 60 minutes intravenously once, the maximum concentration in blood is 9.6ug/ml. 6 hours after administration, drug concentration detected in saliva is 0.1-2.5µg/g.

## 3. Metabolism

In healthy adults (5 cases) injected with 150mg, 300mg and 600mg Biapenem intravenously only once, or doses of 300mg and 600mg Biapenem intravenously in separate injections repeatedly, there are no metabolite detected in the blood.

9.7%-23.4% of the metabolite is excrete by urine, and metabolite exerts no bacteriostatic activity.

## 4. Excretion

In health adult (5 cases) received injections of 150mg, 300mg and 600mg Biapenem intravenously only once over 60 minutes, the average concentration of Biapenem in urine 0-2 hours after injection is 325.5, 584.8 and 1105.1µg/ml respectively, and the concentration had dropped to 2.4, 4.7 and 21.4µg/ml respectively 8-12 hours after injection. Its total excretory rate 0-12 hours after injection is 62.1%, 63.4% and 64.0% respectively.

## 5. Serum drug level of patients with renal inadequacy

Three cases of patients with renal inadequacy are injected with 300mg Biapenem intravenously over 60 minutes every time, the results indicate that the impairment of renal function has resulted in prolonged half-life of Biapenem .

**Storage** Store the dry powder at room temperature against light and moisture.

**Package** Packed with glass vial, one bottle in one cardboard box.

**Shelf life** 24 months