SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Cloxacillin capsules 250mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains Cloxacillin sodium eq.to 250mg Cloxacillin.

For excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard capsules.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This product is mainly used to treat mild and moderate infections caused by Staphylococcus which producing penicillinase and sensitive to methicillin, such as infections on bone, respiratory tract and skin, soft tissue, etc.

4.2 Posology and method of administration

For adults:

Take 0.5g per time, total 4 times a day.

For children:

Take 25~50mg/kg as per body weight every day, divided into 4 times to use.

Method of administration

Cloxacillin capsule is for oral use.

4.3 Contraindications

Cloxacillin should not be given to patients with a history of penicillin allergy or administered to neonates born of mothers hypersensitive to penicillin.

Patients allergic to cephalosporins may also be allergic to penicillins.

Cloxacillin is incompatible with aminoglycosides, tetracyclines, erythromycin and polymyxin B.

4.4 Special warnings and precautions for use

Use with caution in patients with a known history of allergy to penicillins.

When administered to a patient with penicillin sensitivity anaphylactic shock may occur.

Adrenaline, corticosteroids and antihistamines should be used to treat anaphylaxis.

Due to the variability in intestinal absorption, oral administration is not a suitable substitute for the parenteral treatment of serious infections.

4.5 Interaction with other medicinal products and other forms of interaction

Chloramphenicol, erythromycin, tetracycline, sulfonamide and other bacteriostasis drugs can interfere with the bactericidal activity of penicillin, so it is not suitable to be used with this product and other penicillin drugs, especially in the treatment of meningitis or serious infection in urgent need of fungicide.

AFP, aspirin, indopidacin, betasone, and sulfonamide can reduce the excretion of the product in the renal tubules, increase the blood concentration of the drug, prolong the serum half-life, and also increase the toxicity.

4.6 Fertility, pregnancy and lactation

Pregnancy: Reproduction studies performed in the mouse, rat, and rabbit have revealed no evidence of impaired fertility or harm to the fetus due to the penicillinase-resistant penicillins.

Human experience with the penicillins during pregnancy has not shown any positive evidence of adverse effects on the fetus. There are, however, no adequate or well-controlled studies in pregnant women showing conclusively that harmful effects of these drugs on the fetus can be excluded. Because animal reproduction studies are not always predictive of human response, this product should be used during pregnancy only if no alternatives are available.

Lactation: Cloxacillin is excreted in breast milk. Caution should be exercised when cloxacillin are administered to a nursing woman.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. However, undesirable effects may occur (e.g. allergic reactions, dizziness, convulsions), which may influence the ability to drive and use machines (see section 4.8).

4.8 Undesirable effects

Sensitivity reactions may include skin rashes, angioedema, bronchospasm, serum sickness and anaphylaxis, and sometimes death within minutes. Treatment with adrenaline, corticosteroids, aminophyllin or antihistamines may be necessary. A generalised sensitivity reaction can develop within a few hours or weeks of commencing treatment, including urticaria, fever, joint pains and eosinophilia. Other allergic reactions include exfoliative dermatitis and maculopapular rashes, interstitial nephritis and vasculitis. Haemolytic anaemia, leucopenia, prolonged bleeding time and defective platelet function can occur.

Oral administration may produce diarrhoea, heartburn and nausea, and hepatitis and cholestatic jaundice have been reported. A sore mouth or tongue, and a black hairy tongue have also been reported.

Supra-infection with C.albicans, other fungi or organisms resistant to cloxacillin may occur. Care should be taken when administrering high doses of cloxacillin especially to patients with impaired renal function as there is a risk of neuro-toxicity and congestive heart failure.

Disturbance of electrolyte blance may occur following administration of large doses. Incrwases in liver enzyme values have been reported.

Renal and haematological systems should be monitored during prolonged and high dose therapy, patients with syphilis may exhibit the Jarish-Herxheimer reaction and should also therefore be monitored.

A skin test for sensitivity may be used to determine those patients most likely to develop allergic reactions to penicillins.

4.9 Overdose

Convulsions and other signs of toxicity to the central nervous system may occur with very high doses, particularly when administered intravenously to patients with renal failure. Nephrotoxicity may occur in patients with diminished renal function. Treatment of overdosage is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Semisynthetic penicillin; ATC code: J01CF02.

Mechanism of action

Cloxacillin is a semi-synthetic penicillin, resistant to penicillinase, and is therefore active against penicillinase-producing staphylococci.

Cloxacillin is in general less effective against organisms susceptible to benzylpenicillin, such as streptococci, pneumococci and non-penicillinase-producing staphylococci, and is not useful against gram-negative bacteria.

5.2 Pharmacokinetic properties

Take this product 500mg by oral on an empty stomach, reach the peak blood concentration (Cmax) at 1hour, is 9.1mg/ml. The absorption of oral administration is about 35%. The food affects the absorption of this product in the gastrointestinal tract, and the blood concentration of the users after eating is only half of those taken on an empty stomach. The serum protein binding rate of this product is 94%, can penetrate into the bone tissue, pus and joint cavity effusion of patient with acute osteomyelitis, and also has higher concentrations in the pleural effusion. It can also cross the placenta into the fetus, but not through the normal blood-brain barrier. After taking this product by oral, about 9%-22% is metabolismed in the body, the blood elimination half-life (t1/2) is 0.5-1.1hour. Mainly through glomerular filtration and tubular secretion, from urine, a few from bile.

5.3 Preclinical safety data

Unknown.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate, Purified talc

6.2 Incompatibilities

None known

6.3 Shelf life

Unopened – Three years.

6.4 Special precautions for storage

Protect from light, heat and moisture.

Keep out of reach of children.

6.5 Nature and contents of container

Aluminum foil and PVC sheet are used as primary package materials. Each 10 capsules packed in a blister and 10 blisters packed in a box.

Or,

HDPE jar is used as primary package materials. Each 1000 capsules packed in a jar and 40 jars packed in a carton.

6.6 Special precautions for disposal and other handling

None

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

Marketing Authorisation Holder: Farmasino Co., Ltd.

Address: Building 5, No. 9 Weidi Road, Nanjing (210033), China

Manufacturer: Reyoung Pharmaceutical Co., Ltd.

Manufacturing site(s) physical address: No.1 Ruiyang Road, Yiyuan County, Zibo City, Shandong Province, China

8. MARKETING AUTHORIZATION NUMBER

NA.

9. DATE OF FIRST <REGISTRATION> / RENEWAL OF THE <REGISTRATION>

NA.

10. DATE OF REVISION OF THE TEXT

NA.