SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

Cillinox Oral Powder for Suspension

2. Qualitative and quantitative composition

Each 5ml contains Ampicillin trihydrate equivalent Ampicillin: 125mg,Cloxacillin sodium equivalent to Cloxacillin:125mg

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Dry Suspension.
A white crystalline powder which forms on reconstitution a smooth pink suspension with characteristic odour and taste.

4. Clinical particulars

4.1 Therapeutic indications

Cillinox is also indicated in the treatment of infections of the respiratory tract, ear, urinary tract, skin and soft tissue septicaemia, pelvic infections endocarditis and orthopaedic infection.

4.2 Posology and method of administration

Children (3months to 2years): 2.5ml-5ml every 6 hours
2years to 12 years : 5ml-10ml every 6 hours

Condition of Administration

Administer half to one hour before meal or two hours after meal.

Preparation

Required water is provided.

To reconstitute shake the bottle to disperse the powder. Then add the purified water little at a time and shake, continue adding till all the water is added.That makes the required suspension. Once reconstituted the suspension should be used within seven days.

Method of Administration

Oral administration only

4.3 Contraindications

Cillinox is contra-indicated in patients with history of previous hypersensitivity reactions to any of the penicillins. The drug is also contra-indicated in patients with glandular fever and lymphatic lymphoma.

The drug is also contra-indicated in patients who show obvious bacterial resistances.

4.4 Special warnings and precautions for use

Cillinox should preferably not be given to patients with infectious mononucleosis since they are especially susceptible to skin rashes, patients with lymphatic leukaemia and patients with hyperuncaemia being treated with allopurinol may be at increased risk of developing skin rashes.

Ampicillin may decrease the efficacy of oestrogen containing oral contraceptives and it may also affect the absorption of other drugs due to its effect on the gastro-intestinal flora.

4.5 Interaction with other medicinal products and other forms of interaction

Ampicillin

Bacteriostatic drugs may interfere with the bactericidal action of ampicillin.

In common with other oral broad-spectrum antibiotics, ampicillin may reduce the efficacy of oral contraceptives and patients should be warned accordingly.

Probenecid decreases the renal tubular secretion of ampicillin. Concurrent use with ampicillin may result in increased and prolonged blood levels of ampicillin.

Concurrent administration of allopurinol during treatment with ampicillin can increase the likelihood of allergic skin reactions.

Cloxacillin interact with the following drugs:

- allopurinol
- amlodipine
- ampicillin
- ascorbic acid
- aspirin
- Ativan (lorazepam)
- atorvastatin
- beclomethasone
- cefepime
- cefotaxime

- ceftriaxone

4.6 Pregnancy and Lactation

Pregnancy

Cillinox may be used during pregnancy. Penicillin formulations have been well tolerated in pregnancy, neonates, infants and children. There have not been any reported cases of malformations or the complications in the mother, the foetus or the new-borne as a result of penicillin usage. Therefore Cillinox could be conveniently used in these circumstances as it has no teretogenic effects.

Lactation:

During lactation, trace quantities of penicillins can be detected in breast milk.

Adequate human and animal data on use of Ampicillin during lactation are not available

4.7 Effects on ability to drive and use machines

Adverse effects on the ability to drive or operate machinery have not been observed.

4.8 Undesirable effects

Cillinox is generally well tolerated. Adverse reactions are essentially the same as those observed with other penicillins. It may produce allergic reactions (rash, urticaria) epigastric fullness or abdominal discomfort, diarrhoea, nausea and vomiting. A few cases of eosinophilia, mild leucopoenia and elevated serum glutamic oxaloacetic transaminase (SGOT) levels have been reported.
Cillinox has little or no tendency to produce toxic effects on the liver, kidney or cell - forming elements of bone marrow. Super infections with gram-negative organisms have occurred occasionally, especially in patients being treated for pneumonia. If the super infection is severe, therapy must be discontinued.
In penicillin hypersensitivity, anaphylactic shock could occur. This shock could be associated with circulatory collapse and obstruction of breathing due to oedema and spasm of the bronchi.

4.9 Overdose

Ampicillin

Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be

treated symptomatically.

Ampicillin may be removed from the circulation by haemodialysis.

Cloxacillin

Symptoms of overdose may include: severe vomiting, persistent diarrhea.

Treatment

Control of the reactions may be attempted by the administration of antihistamins. At the first sign of an immediate allergic reaction, 0.3 to 1ml of Adrenaline injection should be given intramuscularly
or in severe cases 0.2ml well diluted intravenously followed by a further dose if no improvement occurs.
Urticaria may be treated with corticosteroids by mouth.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Ampicillin is broad spectrum penicillin, indicated for the treatment of a wide range of bacterial infections caused by ampicillin sensitive organisms.

Cloxacillin is a semisynthetic antibiotic in the same class as penicillin. Cloxacillin is for use against staphylococci that produce beta-lactamase.

Mechanism of action

By binding to specific penicillin-binding proteins (PBPs) located inside the bacterial cell wall, cloxacillin inhibits the third and last stage of bacterial cell wall synthesis. Cell lysis is then mediated by bacterial cell wall autolytic enzymes such as autolysins; it is possible that cloxacillin interferes with an autolysin inhibitor.

Mechanism of Action:

Both Ampicillin and Cloxacillin are bacterial agents.

They act by interfering with synthesis of the peptidoglycan layer of the cell wall,
which normally protects the bacterium from its environment. Defective wall synthesis renders the
cell incapable of withstanding the osmotic gradient between the cell and its environment so that it swells and explodes.

Synergy has been demonstrated between Ampicillin and Cloxacillin against some beta lactamase producing organisms.

5.2 Pharmacokinetic properties

Ampicillin:

Ampicillin is moderately well absorbed from the gastro-intestinal tract after oral administration. Food can interfere with the absorption of Ampicillin so doses should be taken 30 minutes to an hour before meals.

Peak concentration in plasma are obtained in about 1 to 2 hours and following a dose of 500mg by mouth are
reported to range from 2 to 6 g/ml. It diffuses across the placenta into the foetal circulation and concentration can be detected in the milk of nursing mothers. There is little diffusion into the cerebrospinal fluid except when the meninges are inflamed, when higher concentration can be achieved.

About 20% is bound to plasma protein and the plasma half-life is a bout 1-2 hours, but this may increase
in neonates and the elderly. In renal failure half-lives of 7 to 20 hours have been reported. Renal clearance of Ampicillin occurs partly by glomerular filtration and partly by tubular secretion.
About 20 to 40% of an orally administered doses is excreted unchanged in the urine in 6 hours, urinary
concentration ranges from 0.25 to 1mg/ml following a dose of 500mg.

Cloxacillin:

Cloxacillin sodium is incompletely absorbed from the gastrointestinal tract after oral administration;
the absorption is further reduced by the presence of food in the stomach.
After oral dose of 500mg, a peak plasma concentration of 7 to 14g/ml is obtained in fasting subject
in 1 to 2 hours. About 94% of Cloxacillin in the circulation is bound to the plasma proteins.

Cloxacillin has been reported to have a plasma half-life is prolonged in neonates.
Cloxacillin diffuses across the placenta into the foetal circulation and is excreted
in breast milk. Cloxacillin is metabolised to a limited extend, and the unchanged drug
and metabolites are excreted in the urine by glomerular filtration and renal tubular secretion.

5.3 Preclinical safety data

None stated

6. Pharmaceutical particulars

6.1 List of excipients

Sodium benzoate
Lactose powder

Sodium chloride
Aerosil 200
Talcum powder
Sodium CMC
Vanilla essence
Methyl paraben
Allura red colour
Aspartame

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 30 ° C.

6.5 Nature and contents of container

Transparent glass bottle of 100ml and amber plastic bottle of 85ml purified water

6.6 Special precautions for disposal and other handling

No special requirements for disposal

7. APPLICANT/MANUFACTURER

Afrab Chem Limited
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