SUMMARY OF PRODUCT CHARACTERISTICS

MEDOPHARM PRIVATE LIMITED, INDIA.

1. NAMEOFTHEMEDICINALPRODUCT

Cloxacillin Sodium for Oral Suspension USP 125 mg (M-CLOX DS 125)

2. QUALITATIVEANDQUANTITATIVECOMPOSITION

Each 5 mL after reconstituted suspensioncontains:
Cloxacillin sodiumUSP Equivalent to Cloxacillin125 mg
For the full list of excipients, see section 6.1.

3. PHARMACEUTICALFORM

Almost white granular powder havingpleasant odour. After constitution, yellow colour suspension having pleasant odour.

4. CLINICALPARTICULARS

4.1 Therapeuticindications

Itisuseinthetreatmentofinfectionscausedbystreptococciwhenassociatedwithsensitivepenicillinase-producing staphylococci; also in the treatment of all staphylococcalinfections, whether penicillin G-sensitive orresistant.

In infections suspected of being caused by penicillinase-producing staphylococci, cloxacillinmay be used for initial treatment after appropriate specimens have been taken for cultureand beforeresultsofmicrobialsusceptibilitytestsareknown.Iftheresultsofidentificationand susceptibility tests indicate that the infecting organism is not apenicillinase-producing staphylococcus susceptible to cloxacillin, cloxacillin should be discontinued and treatmentwithan appropriate alternative agentinstituted.

To reduce the development of drug-resistant bacteria and maintain the effectiveness andotherantibacterial drugs, Cloxacillin sodium should be used only to treat infections that are provenor strongly suspected to be caused by susceptible bacteria. When culture andsusceptibility

informationareavailable,theyshouldbeconsideredinselectingormodifyingantibacterialtherapy. In the absence of such data, local epidemiology and susceptibility patternsmay contribute to the empiric selection oftherapy.

4.2 Posology and method of administration

Adults:

Mild to moderate infections: 250 to 500 mg every 6 hours. It should be given l to 2 hoursbeforemealsasthepresenceoffoodinthestomachandsmallintestinereducesabsorption.Maintain therapy for a minimum of 5days.

Larger doses may be required for very

severeinfections. A daily dose of 6 g should not

beexceeded.

Children:

Up to 5 kg (11 lb) body weight: 250mg/day.

Over5kg(11lb)uptoapproximately40kg(85lb)bodyweight:50mg/kg/day.Totaldaily dosage must be divided into 4 doses, 1 dose given every 6hours.

In infections associated with streptococcus pyogenes, treatment should be continued for atleast10 days to reduce the risk of glomerulonephritis or rheumaticfever.

Powder for Oral Solution

After reconstitution, each 5 mL of pink, cherry flavoured solution contains cloxacillin sodium equivalent to 125 mg cloxacillin. Available in 60 mL, 100 mL and 200 mL bottles

4.3 Contraindications

A history of allergic reactions to penicillin or cephalosporins.

4.4 Specialwarningsandprecautionsforuse

Warnings:

Seriousandoccasionallyfatalhypersensitivity(anaphylactoid)reactionshavebeenreportedin patients receiving penicillin therapy. These reactions are more apt to occur in individuals withahistory of sensitivity to multiple allergens. Careful inquiry should be made concerningprevious hypersensitivity reactions to penicillins, cephalosporins or other allergens. If an allergicor anaphylactic reaction occurs, discontinue treatment and administer the usual agents,e.g. antihistamines, pressor amines,corticosteroids.

Safety for use in pregnancy has not beenestablished.

Susceptibility/Resistance

Development of Drug ResistantBacteria

PrescribingCloxacillinintheabsenceofaprovenorstronglysuspectedbacterialinfectionis unlikely to provide benefit to the patient and risks the development of drug-resistantbacteria.

Precautions:

Candidiasis and other superinfections may occur, especially in debilitated andmalnourished patients,orthosewithlowresistancetoinfectionduetocorticosteroids,immunosuppressiveagents or irradiation. If superinfection occurs, institute appropriatemeasures.

During long-term therapy, renal, hepatic and hematopoietic functions should bechecked periodically.

Experienceinprematureandnewborninfantsislimited.Cautiousadministrationofthedrugto such patients and frequent evaluation of organ system function isrecommended.

The passage of any penicillin from blood into brain is facilitated by inflamed meningesand duringcardiopulmonarybypass.Inthepresenceofsuchfactors,particularlyinrenalfailurewhen high serum concentrations can be attained, central nervous system adverse effects including myoclonia, convulsive seizures and depressed consciousness can beexpected. Although this complication has not been reported with cloxacillin, it should beanticipated.

4.5 Interaction with other medicinal products and other forms of interaction

Probenecid:

Aswithotherpenicillin's,concurrentadministrationofprobenecidenhancestheserumconcentration ofcloxacillin.

4.6 Fertility, pregnancy and lactation

Pregnancy

Cloxacillin has been assigned to pregnancy category B. There are no controlled data in human pregnancies; however, there are no literature reports of congenital abnormalities associated with it. Cloxacillin should only be given during pregnancy when need has been clearly established.

Breastfeeding

There are no data on the excretion of cloxacillin into human milk. Other penicillins are excreted into human milk in small amounts. Adverse effects in the nursing infant are unlikely.

4.7 Effectsonabilitytodriveandusemachines

Nostudiesontheeffectsontheability todriveandusemachineshavebeenperformed.However, undesirable effects may occur (e.g. allergic reactions, dizziness, convulsions), whichmayinfluencetheabilityto driveand usemachines.

4.8 Undesirableeffects

Gastrointestinaldisturbances,suchasnausea,vomiting,epigastricdiscomfort,flatulenceand loosestools,havebeennotedinsomepatients.Rarely,mildleukopeniahasoccurred.Mildly elevatedSGOTlevels(lessthan100units)havebeenreportedinafewpatientsforwhompre- therapeutic determinations were not made. Fever, anaphylaxis and allergicreactions(rash, urticaria) including wheezing and sneezing, have occasionally beenencountered.

Eosoinophilia,withorwithoutovertallergicmanifestations,hasbeennotedinsomepatients during therapy. Thrombophlebitis has occurred occasionally I.V.therapy.

Reportingofsuspectedadversereactions

Reportingsuspectedadversereactionsafterauthorisationofthemedicinalproductisimportant.It

allows continued monitoring of the benefit/risk balance of the medicinal product.Healthcareprofessionalsare askedto reportany suspectedadverse reactions via theYellow CardSchemeat:www.mhra.gov.uk/yellowcard.

4.9 Overdose

When penicillin reaches a certain (as yet undetermined) concentration in the cerebrospinalfluid, neurotoxic symptoms may occur consisting of myoclonia, convulsive seizures, anddepressed consciousness. Unless administration of the drug is stopped or its dosage reduced, thesyndromemayprogresstocomaanddeath.Penicillindoesnotnormallycrosstheblood-brainbarrierto any substantial extent, but when massive doses are used (several grams a day) in the presenceof inflamed meninges and/or impaired renal function, or in elderly patients, the drug may causetheabove- mentioned toxic reactions. No antidote isrequired.

Treatment ofoverdose:
Stop administration temporarily - promote excretion (dialysis,etc.). Toxic serum levels and the lethal serum level of cloxacillin in man are notknown

5. PHARMACOLOGICALPROPERTIES

Pharmacotherapeutic group: penicillin's, incl. beta-lactamase inhibitors;
ATC code:J01CF02.

Sodiumcloxacillinmonohydrateisrapidlybutincompletelyabsorbedfromthegastrointestinaltrac t after oraladministration.

Whenadoseof500mgcloxacillinsodium(2x250mgcloxacillinsodiumcapsules)was administeredtofastingadultvolunteersameanpeakplasmalevelof8.5mcg/mLwasobtained with a Tmax of 0.88hr.

A dose of 500 mg cloxacillin sodium reconstituted granules for oral solution yielded peakplasmalevels of 13.3 mcg/mL with a Tmax of 0.58 hr. in fasting adultvolunteers.

Oral doses of 250 mg sodium cloxacillin to adult fasting volunteers resulted in 4.8 mcg/mLpeak serum levels with a Tmax of 1hr.

Mean urinary excretion of cloxacillin after an oral dose of 500 mg was found to be 37%.8Totalurinary excretion in healthy volunteers was 62% of an intravenously injected dose of 750mg (250 mg/hr for threehours).

Fooddelaystheabsorptionofcloxacillinsodium.cloxacillin.9,10Sodiumcloxacillinisbound to serum proteins to the extent of94%.

Theplasmahalf-lifeofcloxacillinisreportedtobe25minutesinhealthyvolunteersfollowing infusion of 750 mg over a 3 hour period.12 The plasma half-life in uremic patients wasincreasedto 49minutes.

Cloxacillin passage across the CNS barrier is insufficient for practical purposes unlessthemeninges are inflamed. Cloxacillin passes the placental barrier as do the penicillins to theextentof about 50% of the mothers plasmalevel.
Serum concentrations are enhanced if probenecid is givenconcomitantly

6. PHARMACEUTICALPARTICULARS

6.1 Listof excipients

- Saccharin Sodium
- Sucrose (Castor sugar)
- Sodium Citrate
- Sodium benzoate
- Di Sodium Edetate (EDTA)
- Citric acid anhydrous
- Pineapple dry powder
- Sunset yellow supra

6.2 Incompatibilities

Notapplicable

6.3 Shelf life

24months.

6.4 Specialprecautionsforstorage

Storeinacooldryplace,between15-30°C.Protectfrom light.

6.5 Natureandcontents ofcontainer

PrimaryContainer(s): Cloxacillin sodium for oral suspension(M-CLOX 1 25) isavailable in 100mlHDPEbottle.

SecondaryContainer:

Each bottle is labelled and packed in a Printed Carton with relevant batch details along withleaflet.

- Carton: ITCCyber XLwithaquavarnishsideopenwith300GSMmulti-colours.

- Leaflet:60GSMMaplithopaper.

OuterContainer:

Such cartons are packed in Export Worthy 5/7 Ply Shippers. These shippers are labeled with product name and relevant batch details and sealed with BOPP tape. Shippersare then strapped with Polypropylenetapes.

6.6Specialprecautionsfordisposalandotherhandling

- Use cloxacillin suspension as ordered by your doctor. Read all information given toyou. Follow all instructions closely. Take on an empty stomach. Take 1 hour before or 2hours aftermeals.Keepusingcloxacillinsuspensionasyouhavebeentoldbyyourdoctoror other health care provider, even if you feel well. Shake well beforeuse.

7. Marketing authorizationholder

NameandPermanentaddressoftheMarketingauthorizationholder:

Medopharm, Private limited

"MEDOHOUSE"
25, Puliyur II Mainroad,Trustpuram, Chennai-600024,
Tamil Nadu,India.
PH: +9144-30149992/30149955

Fax: 260211286283

Manufacturing Siteaddress:

Medopharm Private Limited,

No. 50, KayarambeduVillage,
Guduvanchery- 603 202, Tamil Nadu,India.

8. Number (s) in the National register of finished pharmaceuticalproducts

Firstregistration No.: MEDO/IND/002 Certificate No.: 025/05

Second registration No.: MEDO/IND/002 Certificate No.: RV/218/09

Renewal registration - 05817/07735/REN/2020

9. Date of first authorization/renewal of theauthorization

First authorization – 24/09/2012

Second authorization – 12/01/2017

Renewal authorization - 30.03.2021

10. Date of revision of thetext

13.07.2023