SUMMARY OF PRODUCT CHARACTERISTICS

MEDOPHARM PRIVATE LIMITED, INDIA.

1. NAMEOFTHEMEDICINALPRODUCT

AmoxicillinOralsuspensionBP125mg/5ml. (MEDOMOX-125)

2. QUALITATIVEANDQUANTITATIVECOMPOSITION

Each 5 mL after reconstituted suspensioncontains:
AmoxicillintrihydrateBP Equivalent to Amoxicillin 125 mg
For the full list of excipients, see section 6.1.

3. PHARMACEUTICALFORM

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

4. CLINICALPARTICULARS

4.1 Therapeuticindications

- It is used to treat Acute streptococcal tonsillitis andpharyngitis
- It is used to treat Acute exacerbations of chronicbronchitis
- It is used to treat Community acquiredpneumonia
- It is used to treat Acute cystitis
- It is used to treat Asymptomatic bacteriuria inpregnancy
- It is used to treat Acutepyelonephritis
- It is used to treat Typhoid and paratyphoidfever
- It is used to treat Dental abscess with spreadingcellulitis
- It is used to treat Prosthetic jointinfections
- It is used to treat Helicobacter pylorieradication
- It is used to treat Lyme disease

4.2 Posology and method of administration<u>Posology</u>

ThedoseofAmoxicillinOralSuspensionthatisselectedtotreatanindividualinfection should take intoaccount:

• The expected pathogens and their likely susceptibility to antibacterialagents

• The severity and the site of theinfection

• The age, weight and renal function of the patient; as shownbelow

The duration of therapy should be determined by the type of infection and the responseof thepatient,andshouldgenerallybeasshortaspossible.Someinfectionsrequirelonger periods

of treatment (see section 4.4 regarding prolongedtherapy).

Adults and children ≥40kg

Indication*	Dose*
Acute bacterialsinusitis	250 mg to 500 mg every 8 hours or 750mg to 1 g every 12hours
Asymptomatic bacteriuria inpregnancy	
Acutepyelonephritis	For severe infections 750 mg to 1 g every8 hours
Dental abscess with spreadingcellulitis	
Acutecystitis	Acute cystitis may be treated with 3 gtwicedaily for oneday
Acute otitismedia	500 mg every 8 hours, 750 mg to 1 gevery
Acute streptococcal tonsillitis andpharyngitis Acute exacerbations of chronicbronchitis	12hours For severe infections 750 mg to 1 g every8 hours for 10days
Community acquiredpneumonia	500 mg to 1 g every 8hours
Typhoid and paratyphoidfever	500 mg to 2 g every 8hours
Prosthetic jointinfections	500 mg to 1 g every 8hours
Prophylaxis ofendocarditis	2 g orally, single dose 30 to 60minutes beforeprocedure
Helicobacter pylorieradication	750 mg to 1 g twice daily incombination with a proton pump inhibitor(e.g. omeprazole, lansoprazole) andanother antibiotic (e.g.clarithromycin, metronidazole) for 7days

Children < 40kg

Children may be treated with Amoxicillin Capsules, dispersible tablets suspensions orsachets

Amoxicillin Paediatric Suspension is recommended for children under six months ofage.

Children weighing 40 kg or more should be prescribed the adultdosage.

Recommendeddoses:

Indication+	Dose+
Acute bacterialsinusitis	20 to 90 mg/kg/day in divideddoses*
Acute otitismedia	
Community acquiredpneumonia	
Acutecystitis	
Acutepyelonephritis	
Dental abscess with spreadingcellulitis	

Acute streptococcal tonsillitis andpharyngitis	40 to 90 mg/kg/day in divideddoses*
Typhoid and paratyphoidfever	100 mg/kg/day in three divideddoses
Prophylaxis ofendocarditis	50 mg/kg orally, single dose 30 to60 minutes beforeprocedure
Lymedisease	Early stage: 25 to 50 mg/kg/day inthreedivided doses for 10 to 21days Late stage (systemic involvement):100 mg/kg/day in three divided doses for10 to 30days

+Consideration should begiven to theofficialtreatmentguidelinesforeach indication.

*Twicedailydosingregimens should onlybe considered when thedoseisin theupper range

Elderly

No dose adjustment is considerednecessary.

Renalimpairment

GFR(ml/min)	Adults and children ≥ 40kg	Children < 40kg#
greater than30	No adjustmentnecessary	No adjustmentnecessary
10 to30	Maximum 500 mgtwicedaily	15 mg/kg given twicedaily (maximum 500 mgtwicedaily)
less than10	Maximum500mg/day.	15 mg/kg given as asingledailydose (maximum 500mg)
# In the majority of cases, parenteral therapy ispreferred.		

In patients receivinghaemodialysis

Amoxicillin may be removed from the circulation byhaemodialysis.

	Haemodialysis
Adults and children over 40kg	500mg every 24h Prior to haemodialysis one additional doseof 500mg should be administered. In orderto restore circulating drug levels, anotherdoseof 500 mg should be administeredafter haemodialysis.

Children under40kg	15 mg/kg/day given as a single dailydose(maximum 500mg). Prior to haemodialysis one additional doseof 15 mg/kg should be administered. In orderto restore circulating drug levels, anotherdoseof 15 mg/kg should be administeredafter haemodialysis

In patients receiving peritonealdialysisAmoxicillin maximum 500mg/day.

Hepaticimpairment

Dose with caution and monitor hepatic function at regularintervals.

Method ofadministration:

- Amoxicillin Oral Suspension is for oraluse.
- Absorption of Amoxicillin Oral Suspension is unimpaired byfood.
- Therapy can be started parenterally according to the dosing recommendations of theintravenous formulation and continued with an oralpreparation.
- For instructions on reconstitution of the medicinal product beforeadministration.

4.3 Contraindications

Hypersensitivitytotheactivesubstance,toanyofthepenicillinsortoanyoftheexcipients.History of a severe immediate hypersensitivity reaction (e.g. anaphylaxis) to anotherbeta-lactamagent (e.g. a cephalosporin, carbapenem ormonobactam).

4.4 Specialwarningsandprecautionsforuse

Hypersensitivityreactions

Before initiating therapy with amoxicillin, careful enquiry should be made concerningprevious hypersensitivity reactions to penicillins, cephalosporins or other beta-lactamagents.

Seriousandoccasionallyfatalhypersensitivityreactions(includinganaphylactoidandseverecutaneous adverse reactions) have been reported in patients on penicillin therapy. Thesereactions are more likely to occur in individuals with a history of penicillin hypersensitivityand in atopic individuals. If an allergic reaction occurs, amoxicillin therapy must be discontinuedand appropriate alternative therapyinstituted.

Non-susceptiblemicroorganisms

Amoxicillinisnotsuitableforthetreatmentofsometypesofinfectionunlessthepathogenis alreadydocumentedandknowntobesusceptibleorthereisaveryhighlikelihoodthatthepathogen would be suitable for treatment with amoxicillin. This particularly applieswhen considering the treatment

of patients with urinary tract infections and severe infections of theear, nose andthroat.

Convulsions

Convulsions may occur in patients with impaired renal function or in those receiving highdoses orinpatientswithpredisposingfactors(e.g.historyofseizures,treatedepilepsyormeningealdisorders.

Renalimpairment

Inpatientswithrenalimpairmentthedoseshouldbeadjustedaccordinglytothedegreeof impairment.

Skinreactions

Theoccurrenceatthetreatmentinitiationofafeverishgeneralisederythemaassociatedwith pustulamaybeasymptomofacutegeneralisedexanthemouspustulosis.Thisreactionrequiresamoxicilli n discontinuation and contra-indicates any subsequentadministration.

Amoxicillin should be avoided if infectious mononucleosis is suspected since the occurrence ofamorbilliform rash has been associated with this condition following the use ofamoxicillin.

Jarisch-Herxheimerreaction

The Jarisch-Herxheimer reaction has been seen following amoxicillin treatment of Lymedisease.It results directly from the bactericidal activity of amoxicillin on the causative bacteria ofLymedisease, the spirochaeteBorreliaburgdorferi. Patients should be reassured that this is acommon and usually self-limiting consequence of antibiotic treatment of Lymedisease.

Overgrowth of non-susceptiblemicroorganisms

Prolonged use may also occasionally result in overgrowth of non-susceptibleorganisms. Antibiotic-associated colitis has been reported with nearly all antibacterial agents and may rangeinseverityfrommildtolifethreatening.Therefore,itisimportanttoconsiderthisdiagnosisinpatients who present with diarrhoea during, or subsequent to, the administration ofany antibiotics. Should antibiotic-associated colitis occur, amoxicillin should immediatelybediscontinued, a physician consulted and an appropriate therapy initiated. Anti-peristaltic
medicinal products are contra-indicated in thissituation.

Prolongedtherapy

Periodic assessment of organ system functions; including renal, hepatic andhaematopoieticfunctionisadvisableduringprolongedtherapy.Elevatedliverenzymesandchangesi nblood counts have beenreported.

Anticoagulants

Prolongationofprothrombintimehasbeenreportedrarelyinpatientsreceivingamoxicillin. Appropriate monitoring should be undertaken when anticoagulants are prescribedconcomitantly. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired levelof anticoagulation

Crystalluria

In patients with reduced urine output, crystalluria has been observed very rarely,predominantly with parenteral therapy. During the administration of high doses of amoxicillin, it is

advisabletomaintain adequate fluid intake and urinary output in order to reduce the possibility ofamoxicillin crystalluria. In patients with bladder catheters, a regular check of patency should bemaintained.

Interference with diagnostictests

Elevated serum and urinary levels of amoxicillin are likely to affect certain laboratory tests.Dueto the high urinary concentrations of amoxicillin, false positive readings are commonwith chemicalmethods.

Itisrecommendedthatwhentestingforthepresenceofglucoseinurineduringamoxicillin treatment, enzymatic glucose oxidase methods should beused.

The presence of amoxicillin may distort assay results for oestriol in pregnantwomen.

Important Information aboutexcipients

This medicinal product contains sucrose. Patients with rare hereditary problems offructoseintolerance, glucose-galactosemalabsorption or sucrase-isomaltase insufficiency should nottakethismedicine.

This medicinal product contains sodium benzoate (E211) which is a mild irritant to the eyes,skinand mucous membrane. May increase the risk of jaundice in new bornbabies.

4.5 Interaction with other medicinal products and other forms of interaction

Probenecid

Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubularsecretionofamoxicillin.Concomitantuseofprobenecidmayresultinincreasedandprolongedb loodlevels ofamoxicillin

Allopurinol

Concurrent administration of allopurinol during treatment with amoxicillin can increasethelikelihood of allergic skinreactions.

Tetracyclines

Tetracyclines and other bacteriostatic drugs may interfere with the bactericidal effectsof amoxicillin.

Methotrexate

Penicillins may reduce the excretion of methotrexate causing a potential increase intoxicity.

Oral typhoidvaccine

The oral typhoid vaccine is inactivated byantibacterials.

OralAnticoagulants

Oralanticoagulantsandpenicillinantibioticshavebeenwidelyusedinpracticewithoutreports ofinteraction.However,intheliteraturetherearecasesofincreasedinternationalnormalisedratioinpatient smaintainedonacenocoumarolorwarfarinandprescribedacourseof amoxicillin. If co-administration is necessary, the prothrombin time or internationalnormalised ratioshouldbecarefullymonitoredwiththeadditionorwithdrawalofamoxicillin.Moreover, adjustments in the dose of oral anticoagulants may benecessary

4.6 Fertility, pregnancy and lactation

Pregnancy

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy,embryonal/foetaldevelopment, parturitionorpostnatal development. Limited data on the use of amoxicillin during pregnancy in humans do notindicateanincreasedriskofcongenitalmalformations.Inasinglestudyinwomenwithpreterm, premature rupture of the foetal membrane it was reported that prophylactic treatmentwithamoxicillin maybeassociatedwithanincreasedriskofnecrotizingenterocolitis in neonates.Use shouldbe avoidedduring pregnancy, unless considered essentialbythephysician.

Breastfeeding

Bothsubstancesareexcretedintobreastmilk. Consequently, diarrhoea and fungus infection of the mucousmembranesarepossibleinthe breast-fedinfant,sothatbreast-feedingmighthave tobediscontinued.The possibility of sensitization should be taken into account.Amoxicillin should only be used during breast-feeding after benefit/riskassessmentbythephysician incharge.

4.7 Effectsonabilitytodriveandusemachines

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

4.8 Undesirableeffects

- Themostcommonlyreportedadversedrugreactions(ADRs)arediarrhoea,nauseaand skin rash.
- The ADRs derived from clinical studies and post-marketing surveillance withamoxicillin, presented by MedDRA System Organ Class are listedbelow.

Thefollowingterminologieshavebeenusedinordertoclassifytheoccurrenceofundesirableeffects.

- Very common(≥1/10)
- Common (≥1/100 to<1/10)
- Uncommon (≥1/1,000 to<1/100)
- Rare (≥1/10,000 to<1/1,000)
- Very rare(<1/10,000)

Not known (cannot be estimated from the availabledata)

Infections andinfestations	
Veryrare	Mucocutaneouscandidiasis
Blood and lymphatic systemdisorders:	
Veryrare	Reversible leucopenia(including severe neutropeniaand agranulocytosis),reversiblethrombocytopenia andhaemolyticanaemia. Prolongation of bleeding timeand prothrombintime
Immune systemdisorders	
Veryrare	Severe allergic reactionsincluding angioneuroticoedema,anaphylaxis, serum sickness andhypersensitivity vasculitis
NotKnown	Jarisch-Herxheimerreaction
Nervous systemdisorders	
Veryrare	Hyperkinesia, dizziness and convulsions
Gastrointestinaldisorders	
Clinical trialdata	
*Common	Diarrhoea andnausea
*Uncommon	Vomiting
Post-marketingdata	
Veryrare	Antibiotic-associatedcolitis (including pseudomembranouscolitis and haemorrhagiccolitis). Black hairytongue Superficial toothdiscolouration[#]
Hepatobiliarydisorders	
Veryrare	Hepatitis and cholestaticjaundice. A moderate rise in AST and/orALT.

Skin and subcutaneous tissuedisorders	
Clinical TrialData	
*Common:	Skinrash
*Uncommon:	Urticaria andpruritus
Post-marketingdata	
Veryrare	Skin reactions such aserythemamultiforme,Stevens-Johnson syndrome, toxic epidermalnecrolysis, bullous and exfoliativedermatitis, acute generalisedexanthematouspustulosis (AGEP) and drugreaction with eosinophilia andsystemic symptoms(DRESS).
Renal and urinary tractdisorders	
Veryrare	InterstitialnephritisCrystalluria
*The incidence of these AEs was derived from clinical studies involving a totalof approximately 6,000 adult and paediatric patients takingamoxicillin. #Superficial tooth discolouration has been reported in children. Good oral hygiene mayhelp to prevent tooth discolouration as it can usually be removed bybrushing	

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

Symptomsandsignsofoverdose

Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may beevident. Amoxicillin crystalluria, in some cases leading to renal failure, has been observed.Convulsions may occur in patients with impaired renal function or in those receiving highdoses.

Treatmentofintoxication

Gastrointestinal symptoms may be treated symptomatically, with attention to thewater/electrolytebalance.

Amoxicillincanberemovedfrom thecirculationbyhaemodialysis.

5. PHARMACOLOGICALPROPERTIES

5.1 Pharmacodynamicproperties

Pharmacotherapeutic group: penicillin's, incl. beta-lactamase inhibitors;ATC code:J01CR02.

Mechanismof action

Amoxicillin is a semisynthetic penicillin (beta-lactam antibiotic) that inhibits one or moreenzymes (often referred to as penicillin-binding proteins, PBPs) in the biosynthetic pathwayof bacterial peptidoglycan, which is an integral structural component of the bacterial cellwall. Inhibition of peptidoglycan synthesis leads to weakening of the cell wall, which isusuallyfollowed bycell lysisand death.

Amoxicillin is susceptible to degradation by beta-lactamases produced by resistant bacteria andtherefore the spectrum of activity of amoxicillin alone does not include organisms which produce theseenzymes.

Pharmacokinetic/pharmacodynamicrelationship

The time above the minimum inhibitory concentration (T>MIC) is considered to be the majordeterminantofefficacyfor amoxicillin.

Mechanismsofresistance

Thetwomainmechanismsofresistancetoamoxicillin are:

•Inactivation by those bacterial beta-lactamases that are not themselves inhibited byincludingclassB, C andD.

•AlterationofPBPs,whichreducethe affinityoftheantibacterialagentforthetarget.

Impermeability of bacteria or efflux pump mechanisms may cause or contribute to bacterial resistance,particularlyin Gram-negativebacteria.

Breakpoints

Organism	MIC breakpoint(mg/L)	
	Susceptible	Resistant
Haemophilusinfluenzae	$\leq 2^{1}$	$>2^{1}$
Moraxellacatarrhalis	$\leq 1^{1}$	$>1^{1}$
Staphylococcusspp	$\leq 0.125^{2,3,4}$	$>0.125^{2,3,4}$
Enterococcus	$\leq 4^{1}$	$>8^{1}$
StreptococcusA,B,C,G	$\leq 0.25^{2}$	$>0.25^{2}$

Streptococcuspneumoniae	≤0.5[1,5]	>1[1,5]
Enterobacterales	≤8[1,6]	>8[6]
Enterobacterales in	≤32[1,6]	>32[6]
Gram-negativeAnaerobes	≤ 4[1]	>8[1]
Gram-positiveAnaerobes(except	≤ 4[1]	>8[1]
Non-species related	≤ 2[1]	>8[1]

[1]Wild type Enterobacteriaceae are categorised as susceptible to aminopenicillins. Somecountriesprefer to categorise wild type isolates of E. coli and P. mirabilis as intermediate. When this isthecase, use the MIC breakpoint S ≤ 0.5mg/L

[2]Moststaphylococciarepenicillinaseproducers,whichareresistanttoamoxicillin.Methicillinresistant isolates are, with few exceptions, resistant to all beta-lactamagents.

[3]Susceptibility to amoxicillin can be inferred fromampicillin

[4]ThesusceptibilityofstreptococcusgroupsA,B,CandGtopenicillinsisinferredfromthe benzylpenicillin susceptibility

[5]Breakpointsrelateonlytonon-meningitisisolates.Forisolatescategorisedasintermediatetoampicillin avoid oral treatment with amoxicillin. Susceptibility inferred from the MIC of ampicillin.

[6]Breakpoints are based on intravenous administration. Beta-lactamase positive isolates shouldbereportedresistant.

[7]Beta lactamase producers should be reportedresistant

[8]Susceptibility to amoxicillin can be inferred frombenzylpenicillin.

[9]The breakpoints are based on epidemiological cut-off values (ECOFFs), whichdistinguish wild-type isolates from those with reducedsusceptibility.

[10]The non-species related breakpoints are based on doses of at least 0.5 g x 3or 4 doses daily(1.5 to 2g/day)

Theprevalenceofresistancemayvarygeographicallyandwithtimeforselectedspecies,andlocalinformation onresistanceisdesirable,particularlywhentreatingsevereinfections.Asnecessary,expertadviceshould besoughtwhenthelocalprevalenceofresistanceissuchthattheutilityoftheagentin at least sometypes ofinfections isquestionable.

Commonlysusceptiblespecies
AerobicGram-positivemicro-organisms *Enterococcus* *faecalisGardnerellav* *aginalis* *Staphylococcusaureus*(methicillin- susceptible)£Coagulase-negative staphylococci (methicillin-susceptible)*Streptococcusagalactiae* *Streptococcuspneumoniae*[1] *Streptococcuspyogenes*andotherbeta-haemolyticstreptococci *Streptococcusviridans*group AerobicGram-negativemicro-organisms *Capnocytophaga*spp.*Eik* *enellacorrodensHaemop* *hilus* *influenzae*[2]*Moraxellacat* *arrhalis* *Pasteurellamultocida*Anaer obic micro- organisms*Bacteroidesfragil* *isFusobacteriumnucleatum* *Prevotella*spp.
Species forwhich acquired resistance maybeaproblem
AerobicGram-positivemicro-organisms *Enterococcusfaecium*$
AerobicGram-negativemicro-organisms *Escherichiacoli*
Inherentlyresistantorganisms

AerobicGram-negativemicro-organisms *Acinetobacter*sp.*Cit* *robacterfreundiiEnt* *erobacter*sp. *Legionellapneumophila* *MorganellamorganiiPr* *ovidencia*spp. *Pseudomonas*sp. *Serratia*sp.*Stenotrophomonas* *maltophilia*Other micro- organisms*Chlamydophilapneu* *moniaeChlamydophilapsittaci* *Coxiellaburnetti* *Mycoplasmapneumonia*
$Naturalintermediate susceptibilityintheabsence of acquired mechanismofresistance. £ All methicillin-resistant staphylococci are resistant to amoxicillin[1]*Streptococcuspneumoniae*thatareresistanttopenicillinshouldnotbetreatedwiththispresentationofamoxicillin(seesections 4.2 and4.4). [2]StrainswithdecreasedsusceptibilityhavebeenreportedinsomecountriesintheEUwithafrequencyhigherthan10%.

5.2 Pharmacokineticproperties

Absorption

Amoxicillin and clavulanic acid, are fully dissociated in aqueous solution at physiological pH.Bothcomponentsarerapidlyandwellabsorbedbytheoralrouteofadministration.Followingoral administration,amoxicillinandclavulanicacidareapproximately70%bioavailable. The plasma profiles of both components are similar and the time to peak plasmaconcentration (Tmax)ineachcaseis approximatelyonehour.

The pharmacokinetic results for a study, in which amoxicillin/clavulanic acid (500 mg/125 mgtabletsthreetimesdaily)wasadministeredinthefastingstatetogroupsofhealthyvolunteersarepresentedbelow.

Cmax	Tmax*	AUC(0-24h)	T½
(μg/ml)	(h)	((μg.h/ml)	(h)
3.3 ±1.12	1.5(1.0-2.0)	26.7 ±4.56	1.36 ±0.56
*Median(range)			

Intherangeof250to3000mgthebioavailabilityislinearinproportiontodose(measuredasC_{max} and AUC). The absorption in not influenced by simultaneous foodintake. Haemodialysis can be used for elimination ofamoxicillin.

Distribution

- About 18% of total plasma amoxicillin is bound to protein and the apparent volume of distribution is around 0.3 to 0.4 l/kg.
- Following intravenous administration, amoxicillin has been found in gall bladder, abdominal tissue, skin, fat, muscle tissues, synovial and peritoneal fluids, bile and pus. Amoxicillin does not adequately distribute into the cerebrospinal fluid.
- From animal studies there is no evidence for significant tissue retention of drug-derived material. Amoxicillin, like most penicillins, can be detected in breast milk.
- Amoxicillin has been shown to cross the placental barrier.

Biotransformation

Amoxicillin is partly excreted in the urine as the inactive penicilloic acid in quantitiesequivalentto up to 10 to 25% of the initialdose.

Elimination

The major route of elimination for amoxicillin is via thekidney.

Amoxicillin has a mean elimination half-life of approximately one hour and a meantotalclearance of approximately 25 l/hour in healthy subjects. Approximately 60 to 70% oftheamoxicillin is excreted unchanged in urine during the first 6 hours after administration of asingle250mgor500mgdoseofamoxicillin.Variousstudieshavefoundtheurinaryexcretiontobe50-85% for amoxicillin over a 24 hourperiod

Concomitant use of probenecid delays amoxicillinexcretion.

Age

Theeliminationhalf-lifeofamoxicillinissimilarforchildrenagedaround3monthsto2 years and older children and adults. For very young children (including pretermnewborns)in thefirstweekoflifetheinterval of administration should notexceedtwicedaily

administration due to immaturity of the renal pathway of elimination.

Becauseelderlypatientsaremorelikelytohavedecreasedrenalfunction,careshouldbetakenindoses election, and it maybeuseful to monitorrenalfunction.

Gender

Followingoraladministrationofamoxicillin/clavulanicacidtohealthymalesandfemale subjects,genderhasnosignificantimpactonthepharmacokineticsofeitheramoxicillinorclavulanic acid.

Renalimpairment

The total serum clearance of amoxicillin/clavulanic acid decreases proportionatelywithdecreasingrenalfunction.Thereductionindrugclearanceismorepronouncedf oramoxicillin than for clavulanic acid, as a higher proportion of amoxicillin is excreted *via*the renal route. Doses in renal impairment must therefore prevent undue accumulation ofamoxicillinwhilemaintainingadequatelevels ofclavulanicacid.

Hepaticimpairment

Hepaticallyimpairedpatientsshouldbedosedwithcautionandhepaticfunctionmonitoredat regularintervals

5.3Preclinicalsafetydata

Non-clinicaldatarevealnospecialhazardforhumansbasedonstudiesofsafetypharmacology,genotoxici tyandtoxicitytoreproduction.

Carcinogenicitystudieshavenotbeenconductedwithamoxicillinoritscomponents

6. PHARMACEUTICALPARTICULARS

6.1 Listof excipients

- Sodium carboxy methyl cellulose (HVP grade)
- Sodium benzoate
- Colloidal anhydrous silica (Aerosil)
- Dry powder orange
- Dry powder vanilla
- Tartrazine
- Castor sugar

6.2 Incompatibilities

Notapplicable

6.3 Shelf life

36 months.

6.4 Specialprecautionsforstorage

Storeinacooldryplace,between15-30°C.Protectfrom light.

6.5 Natureandcontents ofcontainer

PrimaryContainer(s): AmoxicillinfororalsuspensionBP 125mg/5ml(MEDOMOX 125) 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

- Amoxicillincanbetakenwithorwithoutfood.Capsulesshouldbeswallowedwholewithaglassof water,milkorsquash(butnotjuice).Yourchildshouldnotchewthecapsules. Liquid medicine: Shake the medicinewell.

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

First registration No. MEDO/IND/002 certificate No.: 171/01

First registration No. MEDO/IND/002 certificate No.: 084/02 (Shelf life extension)

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

Renewal registration - 05831/07746/REN/2020

9. Date of first authorization/renewal of theauthorization

First authorization – 11/02/2009

First authorization - 18/11/2009 (Shelf life extension)

Second authorization – 12/01/2017

Renewal authorization – 05.04.2021

10. Date of revision of thetext

12.07.2023