SUMMARY OFPRODUCTCHARACTERISTICS

1. NAME OF THE MEDICINALPRODUCT

Amoxicillin Capsules BP 500 mg (MEDOMOX -500)

2. QUALITATIVE ANDQUANTITATIVE

Each Hard gelatin Capsules contains:
Amoxicillin Trihydrate BP Equivalent to Amoxicillin 500mg
Refer Excipients section 6.1

3. PHARMACEUTICALFORM:

Size 0, maroon cap and yellow bodyopaque capsules having linearprinting 'AMOXY'one part, '500'on the other part and filled withwhite granular powder.

4. CLINICALPARTICULARS

4.1 Therapeuticindications:

Amoxicillin capsules are indicated for the treatment of the following infections in adultsand children:

- Acute bacterialsinusitis
- Acute Otitismedia
- Acute streptococcal tonsillitis andpharyngitis
- Acute exacerbations of chronicbronchitis
- Community acquiredpneumonia
- Acute cystitis, Asymptomatic Bacteriuria inpregnancy
- Acutepyelonephritis
- Typhoid and paratyphoid fever Dental abscess with spreadingcellulitis
- Prosthetic jointinfections
- Helicobacter pylorieradication
- Lymedisease
- Amoxicillin is also indicated for the prophylaxis ofendocarditis

4.2 Posology and method of administration

ThedoseofAmoxicillinthatisselectedtotreatanindividualinfectionshouldtakeinto account:

- 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

Thedurationoftherapyshouldbedeterminedbythetypeofinfectionandtheresponseof

thepatient,andshouldgenerallybeasshortaspossible.Someinfectionsrequirelonger periods oftreatment

Adults and children ≥40kg

Indication*	Dose*
Acute bacterialsinusitis	250 mg to 500 mg every 8 hours or 750 mg to1 g every 12hours For severe infections 750 mg to 1 g every8 hours Acutecystitismaybetreatedwith3gtwice daily for oneday
Asymptomatic bacteriuria inpregnancy	
Acutepyelonephritis	
Dental abscess with spreadingcellulitis	
Acutecystitis	
Acute otitismedia	500 mg every 8 hours, 750 mg to 1 g every12 hours For severe infections 750 mg to 1 g every8 hours for 10days
Acute streptococcal tonsillitis andpharyngitis	
Acute exacerbations of chronicbronchitis	
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 60 minutesbefore procedure
Helicobacter pylorieradication	750 mg to 1 g twice daily in combination witha proton pump inhibitor (e.g.omeprazole, lansoprazole) and another antibiotic(e.g. clarithromycin, metronidazole) for 7days
Lymedisease	Early stage: 500 mg to 1 g every 8 hours up toa
	maximumof4g/dayindivideddosesfor14 days (10 to 21days) Late stage (systemic involvement): 500 mg to2 g every 8 hours up to a maximum of 6 g/dayin divided doses for 10 to 30days
*Consideration should be given to the official treatment guidelines for eachindication	

<u>Children <40kg</u>

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 inthree divided doses for 10 to 21days Late stage (systemic involvement):100 mg/kg/day in three divided doses for10 to 30 days
+Consideration should be given to the official treatment guidelines for eachindication. *Twice daily dosing regimens should only be considered when the dose is in the upperrange.	

Elderly

No dose adjustment is considerednecessary.

Renalimpairment

GFR(ml/min)	**Adults and children ≥ 40kg**	**Children < 40kg**[#]
greater than30	no adjustmentnecessary	no adjustmentnecessary
10 to 30	maximum 500 mg twicedaily	15 mg/kg given twice daily(maximum 500 mg
less than10	maximum 500mg/day.	15 mg/kg given as a singledaily dose (maximum 500mg)
[#] In the majority of cases, parenteral therapy ispreferred.		

In patients receivinghaemodialysis

Amoxicillin may be removed from the circulation byhaemodialysis.

	Haemodialysis
Adults and childrenover 40 kg	500 mg every 24h Priortohaemodialysisoneadditionaldoseof500mgshouldbe administered. In order to restore circulating drug levels,another dose of 500 mg should be administered afterhaemodialysis.
Children under 40kg	15 mg/kg/day given as a single daily dose (maximum 500 mg). Priortohaemodialysisoneadditionaldoseof15mg/kgshouldbe administered. In order to restore circulating drug levels,another dose of 15 mg/kg should be administered afterhaemodialysis.

In patients receiving peritonealdialysis

Amoxicillin maximum 500mg/day.

Hepaticimpairment

- Dose with caution and monitor hepatic function at regularintervals
- Method ofadministration

Oral:

- Amoxicillin is for oraluse.
- Absorption of Amoxicillin is unimpaired byfood.
- Swallow with water without openingcapsule.

4.3 Contra-indications

Hypersensitivity to the active substance, to any of the penicillins or to any of theexcipients section 6.1.

Historyofasevereimmediatehypersensitivityreaction(e.g.anaphylaxis)toanotherbeta-lactam agent (e.g. a cephalosporin, carbapenem ormonobactam)

4.4 Interaction with other medicaments and other forms of interaction Probenecid:

Concomitant use of probenecid is not recommended. Probenecid decreases the renaltubular secretion of amoxicillin. Concomitant use of probenecid may result in increasedand prolonged blood levels ofamoxicillin.

Allopurinol:

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

Tetracyclines:

Tetracyclinesandotherbacteriostaticdrugsmayinterferewiththebactericidaleffectsof amoxicillin.

Oralanticoagulants:

Oralanticoagulantsandpenicillinantibioticshavebeenwidelyusedinpracticewithout reportsofinteraction.However,intheliteraturetherearecasesofincreasedinternational normalisedratioinpatientsmaintainedonacenocoumarolorwarfarinandprescribeda course of amoxicillin. If co-administration is necessary, the prothrombin timeor international normalised ratio should be carefully monitored with the addition orwithdrawal of amoxicillin. Moreover, adjustments in the dose of oral anticoagulants may be necessary

Methotrexate

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

4.5 Pregnancy, Lactation and Fertility:

Pregnancy

Animal studies do not indicate direct or indirect harmful effects with respect toreproductive toxicity. Limited data on the use of amoxicillin during pregnancy in humans do notindicate an increased risk of congenital malformations. Amoxicillin may be used in pregnancywhen the potential benefits outweigh the potential risks associated withtreatment.

Lactation:

Amoxicillin is excreted into breast milk in small quantities with the possible riskof sensitisation.Consequently,diarrhoeaandfungusinfectionofthemucousmembranesare possible in the breast-fed infant, so that breast-feeding might have to bediscontinued. Amoxicillin should only be used during breast-feeding after benefit/risk assessment bythe physician incharge.

Fertility:

There are no data on the effects of amoxicillin on fertility in humans.

Reproductivestudies in animals have shown no effects onfertility.

4.6 Effects on ability to drive and use machines

Nostudiesontheeffectsontheabilitytodriveandusemachineshavebeenperformed.However, undesirableeffectsmayoccur(e.g.allergicreactions,dizziness,convulsions), which may influence the ability to drive and usemachines.

4.7 Undesirable effects

- The most commonly reported adverse drug reactions (ADRs) are diarrhoea,nausea and skinrash.
- The ADRs derived from clinical studies and post-marketing surveillancewith amoxicillin, presented by MedDRA System Organ Class are listedbelow.

The following terminologies have been used in order to classify the occurrenceof undesirableeffects.

- Very common(≥1/10)
- Common(≥1/100to<1/10)
- Uncommon (≥1/1,000to<1/100)
- Rare(≥1/10,000to<1/1,000)
- Veryrare(<1/10,000)
- Not known (cannot be estimated from the availabledata)

General

The most commonly reported adverse drug reactions (ADRs) are diarrhoea, nausea andskin rash.

Infections andinfestations

Very rare :Muco-cutaneouscandidiasis

Blood and lymphatic systemdisorders

Very rare: Reversible leucopenia (including severe neutropenia oragranulocytosis), reversible thrombocytopenia and haemolyticanaemia. Prolonged prothrombin andbleeding times

Nervoussystem

Veryrare:Hyperkinesia,dizzinessandconvulsions.Convulsionsmayoccurinpatients with impaired renal function or those receiving highdoses.

Gastrointestinal

Common: Diarrhoea andnausea.

Uncommon:Vomiting.

Very rare : Antibiotic associated colitis (including pseudomembranous colitisand hemorrhagiccolitis

Black hairytongue

Immune systemdisorders

Very rare: Angioneuroticoedema, anaphylaxis, Serum sickness and hypersensitivity vasculitis.

Not known: Jarisch-Herxheimerreaction

Hepato-biliarydisorders

Very rare: Hepatitis and cholestatic jaundice. A moderate rise in AST and/orALT.

Skin and subcutaneous tissuedisorders Common: Skinrash

Uncommon: Vomiting.

Very rare: Skin reactions such as erythema multiforme, Stevens-Johnson syndrome,toxic epidermalnecrolysis,bullousandexfoliativedermatitis,acutegeneralisedexanthematouspustulosis (AGEP) and drug reaction with eosinophilia and systemic symptoms(DRESS).

Renal and urinary tractdisorders

Very rare: Interstitial nephritis &Crystalluria

4.8 Overdose

Symptoms and signs ofoverdose:

Gastrointestinal symptoms (such as nausea, vomiting and diarrhoea) and disturbance ofthe fluid and electrolyte balances may be evident. Amoxicillin crystalluria, in somecases leading to renal failure, has been observed. Convulsions may occur in patients withimpaired renal function or in those receiving highdoses

Treatment ofintoxication:

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

Amoxicillin may be removed from the circulation byhaemodialysis.

5. PHARMACOLOGICALPROPERTIES

5.1 Pharmacodynamicproperties

Pharmacotherapeutic classification: Penicillin's with extendedspectrum;

ATC code: J01CA04

- Amoxicillin is a semisynthetic penicillin (beta-lactam antibiotic) that inhibits oneor more enzymes (often referred to as penicillin-binding proteins, PBPs) inthe biosynthetic pathway of bacterial peptidoglycan, which is an integralstructural componentofthebacterialcellwall.Inhibitionofpeptidoglycansynthesisleadsto weakening of the cell wall, which is usually followed by cell lysis anddeath.
- Amoxicillinissusceptibletodegradationbybeta-lactamasesproducedbyresistant bacteria and therefore the spectrum of activity of amoxicillin alone does notinclude organisms which produce theseenzymes.

5.2 Pharmacokineticproperties

Absorption

- AmoxicillinfullydissociatesinaqueoussolutionatphysiologicalpH.Itisrapidly and well absorbed by the oral route of administration. Following oraladministration, amoxicillin is approximately 70% bioavailable. The time to peakplasma concentration (T_{max}) is approximately onehour.
- Thepharmacokineticresultsforastudy,inwhichanamoxicillindoseof250mg three times daily was administered in the fasting state to groups of healthy volunteers are presentedbelow.

C_{max}	T_{max}*	$AUC_{(0-24h)}$	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)			

In the range 250 to 3000 mg the bioavailability is linear in proportion to dose (measuredas C_{max} and AUC). The absorption is 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 apparentvolume of distribution is around 0.3 to 0.4l/kg.
- Following intravenous administration, amoxicillin has been found in gallbladder, abdominaltissue,skin,fat,muscletissues,synovialandperitonealfluids,bileand pus. Amoxicillin does not adequately distribute into the cerebrospinalfluid.

- Fromanimalstudiesthereisnoevidenceforsignificanttissueretentionofdrug-derived material. Amoxicillin, like most penicillins, can be detected in breastmilk
- Amoxicillin has been shown to cross the placentalbarrier.

Metabolism

Amoxicillinispartlyexcretedintheurineastheinactivepenicillinacidinquantities equivalent to 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 amean total clearance of approximately 25 l/hour in healthy subjects. Approximately 60to 70%oftheamoxicillinisexcretedunchangedinurineduringthefirst6hoursafter administrationofasingle250mgor500mgdoseofamoxicillin.Variousstudies have found the urinary excretion to be 50-85% for amoxicillin over a 24 hourperiod.

5.3 Preclinical safetydata

- Non-clinicaldatarevealnospecialhazardforhumansbasedonstudiesofsafety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproductionand development.
- Carcinogenicity studies have not been conducted withamoxicillin.

6. PHARMACEUTICALPARTICULARS

6.1 List ofexcipients

Magnesiumstearate
Sodium LaurylSulphate
Sodium StarchGlycolate
HEGCapsules

6.2 Incompatibilities

Not applicable

6.3 Shelflife

36 months from the date ofmanufacturing

6.4 Special precautions forstorage

Not applicable

6.5 Nature and contents ofcontainer

Presentation:MEDOMOX500 are available as 10x10’s, 50 x 10's, 100x10’sPVC blister pack.

Primary Container(s):

MEDOMOX 500are available as strip pack. Each blister of 10x10’s, 50 x 10's, 100x10’sPVC blister pack contains 10 capsulesrespectively.

SecondaryContainer:

Suchblisterpacksarepackedinaprintedcarton.PrintedCartonsareprintedwithrelevant batchdetails.

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.

6.6 Special precautions for disposal and otherhandling

No specialrequirements.

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 renewal – 3388/2869/NMR/2016

Renewal registration - 06455/08038/REN/2021

9. Date of first authorization/renewal of theauthorization

First authorization – 14.08.2017

Renewal authorization - 05.08.2021

10. Date of revision of thetext

13.07.2023