

# **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE MEDICINAL PRODUCT

Amoxicillin Oral suspension BP 125 mg/5 ml. (MEDOMOX-125)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL after reconstituted suspension contains:

Amoxicillin trihydrate BP Equivalent to Amoxicillin 125 mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

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

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

- It is used to treat Acute streptococcal tonsillitis and pharyngitis
- It is used to treat Acute exacerbations of chronic bronchitis
- It is used to treat Community acquired pneumonia
- It is used to treat Acute cystitis
- It is used to treat Asymptomatic bacteriuria in pregnancy
- It is used to treat Acute pyelonephritis
- It is used to treat Typhoid and paratyphoid fever
- It is used to treat Dental abscess with spreading cellulitis
- It is used to treat Prosthetic joint infections
- It is used to treat Helicobacter pylori eradication
- It is used to treat Lyme disease

### 4.2 Posology and method of

#### administration Posology

The dose of Amoxicillin Oral Suspension that is selected to treat an individual infection should take into account:

- The expected pathogens and their likely susceptibility to antibacterial agents
- The severity and the site of the infection
- The age, weight and renal function of the patient; as shown below

The duration of therapy should be determined by the type of infection and the response of the patient, and should generally be as short as possible. Some infections require longer periods

of treatment (see section 4.4 regarding prolonged therapy).

**Adults and children  $\geq 40$ kg**

<b>Indication*</b>	<b>Dose*</b>
Acute bacterial sinusitis	250 mg to 500 mg every 8 hours or 750mg to 1 g every 12 hours
Asymptomatic bacteriuria in pregnancy	
Acute pyelonephritis	For severe infections 750 mg to 1 g every 8 hours
Dental abscess with spreading cellulitis	
Acute cystitis	Acute cystitis may be treated with 3 g twice daily for one day
Acute otitis media	500 mg every 8 hours, 750 mg to 1 g every 12 hours
Acute streptococcal tonsillitis and pharyngitis	For severe infections 750 mg to 1 g every 8 hours for 10 days
Acute exacerbations of chronic bronchitis	
Community acquired pneumonia	500 mg to 1 g every 8 hours
Typhoid and paratyphoid fever	500 mg to 2 g every 8 hours
Prosthetic joint infections	500 mg to 1 g every 8 hours
Prophylaxis of endocarditis	2 g orally, single dose 30 to 60 minutes before procedure
Helicobacter pylori eradication	750 mg to 1 g twice daily in combination with a proton pump inhibitor (e.g. omeprazole, lansoprazole) and another antibiotic (e.g. clarithromycin, metronidazole) for 7 days

**Children < 40kg**

Children may be treated with Amoxicillin Capsules, dispersible tablets suspensions or sachets

Amoxicillin Paediatric Suspension is recommended for children under six months of age.

Children weighing 40 kg or more should be prescribed the adult dosage.

Recommended doses:

<b>Indication+</b>	<b>Dose+</b>
Acute bacterial sinusitis	20 to 90 mg/kg/day in divided doses*
Acute otitis media	
Community acquired pneumonia	
Acute cystitis	
Acute pyelonephritis	
Dental abscess with spreading cellulitis	

Acute streptococcal tonsillitis and pharyngitis	40 to 90 mg/kg/day in divided doses*
Typhoid and paratyphoid fever	100 mg/kg/day in three divided doses
Prophylaxis of endocarditis	50 mg/kg orally, single dose 30 to 60 minutes before procedure
Lyme disease	Early stage: 25 to 50 mg/kg/day in three divided doses for 10 to 21 days Late stage (systemic involvement): 100 mg/kg/day in three divided doses for 10 to 30 days

+Consideration should be given to the official treatment guidelines for each indication.

\*Twice daily dosing regimens should only be considered when the dose is in the upper range

### Elderly

No dose adjustment is considered necessary.

### Renal impairment

GFR (ml/min)	Adults and children $\geq$ 40kg	Children < 40kg#
greater than 30	No adjustment necessary	No adjustment necessary
10 to 30	Maximum 500 mg twice daily	15 mg/kg given twice daily (maximum 500 mg twice daily)
less than 10	Maximum 500 mg/day.	15 mg/kg given as a single daily dose (maximum 500 mg)

# In the majority of cases, parenteral therapy is preferred.

In patients receiving haemodialysis

Amoxicillin may be removed from the circulation by haemodialysis.

	Haemodialysis
Adults and children over 40kg	500mg every 24h Prior to haemodialysis one additional dose of 500mg should be administered. In order to restore circulating drug levels, another dose of 500 mg should be administered after haemodialysis.

Children under 40kg	15 mg/kg/day given as a single daily dose (maximum 500mg). Prior to haemodialysis one additional dose of 15 mg/kg should be administered. In order to restore circulating drug levels, another dose of 15 mg/kg should be administered after haemodialysis
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In patients receiving peritoneal dialysis Amoxicillin maximum 500mg/day.

### **Hepatic impairment**

Dose with caution and monitor hepatic function at regular intervals.

#### **Method of administration:**

- Amoxicillin Oral Suspension is for oral use.
- Absorption of Amoxicillin Oral Suspension is unimpaired by food.
- Therapy can be started parenterally according to the dosing recommendations of the intravenous formulation and continued with an oral preparation.
- For instructions on reconstitution of the medicinal product before administration.

### **4.3 Contraindications**

Hypersensitivity to the active substance, to any of the penicillins or to any of the excipients. History of a severe immediate hypersensitivity reaction (e.g. anaphylaxis) to another beta-lactam agent (e.g. a cephalosporin, carbapenem or monobactam).

### **4.4 Special warnings and precautions for use** **Hypersensitivity reactions**

Before initiating therapy with amoxicillin, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other beta-lactam agents.

Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and in atopic individuals. If an allergic reaction occurs, amoxicillin therapy must be discontinued and appropriate alternative therapy instituted.

#### **Non-susceptible microorganisms**

Amoxicillin is not suitable for the treatment of some types of infection unless the pathogen is already documented and known to be susceptible or there is a very high likelihood that the pathogen would be suitable for treatment with amoxicillin. This particularly applies when considering the treatment

of patients with urinary tract infections and severe infections of the ear, nose and throat.

### **Convulsions**

Convulsions may occur in patients with impaired renal function or in those receiving high doses or in patients with predisposing factors (e.g. history of seizures, treated epilepsy or meningeal disorders).

### **Renal impairment**

In patients with renal impairment the doses should be adjusted according to the degree of impairment.

### **Skin reactions**

The occurrence at the treatment initiation of a feverish generalised erythema associated with pustules may be a symptom of acute generalised exanthematous pustulosis. This reaction requires amoxicillin discontinuation and contra-indicates any subsequent administration.

Amoxicillin should be avoided if infectious mononucleosis is suspected since the occurrence of a morbilliform rash has been associated with this condition following the use of amoxicillin.

### **Jarisch-Herxheimer reaction**

The Jarisch-Herxheimer reaction has been seen following amoxicillin treatment of Lyme disease. It results directly from the bactericidal activity of amoxicillin on the causative bacteria of Lyme disease, the spirochaete *Borrelia burgdorferi*. Patients should be reassured that this is a common and usually self-limiting consequence of antibiotic treatment of Lyme disease.

### **Overgrowth of non-susceptible microorganisms**

Prolonged use may also occasionally result in overgrowth of non-susceptible organisms. Antibiotic-associated colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhoea during, or subsequent to, the administration of any antibiotics. Should antibiotic-associated colitis occur, amoxicillin should immediately be discontinued, a physician consulted and an appropriate therapy initiated. Anti-peristaltic medicinal products are contra-indicated in this situation.

### **Prolonged therapy**

Periodic assessment of organ system functions; including renal, hepatic and haematopoietic function is advisable during prolonged therapy. Elevated liver enzymes and changes in blood counts have been reported.

### **Anticoagulants**

Prolongation of prothrombin time has been reported rarely in patients receiving amoxicillin. Appropriate monitoring should be undertaken when anticoagulants are prescribed concomitantly. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of 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

advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of amoxicillin crystalluria. In patients with bladder catheters, a regular check of patency should be maintained.

### **Interference with diagnostic tests**

Elevated serum and urinary levels of amoxicillin are likely to affect certain laboratory tests. Due to the high urinary concentrations of amoxicillin, false positive readings are common with chemical methods.

It is recommended that when testing for the presence of glucose in urine during amoxicillin treatment, enzymatic glucose oxidase methods should be used.

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

### **Important Information about excipients**

This medicinal product contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This medicinal product contains sodium benzoate (E211) which is a mild irritant to the eyes, skin and mucous membrane. May increase the risk of jaundice in newborn babies.

## **4.5 Interaction with other medicinal products and other forms of interaction**

### **Probenecid**

Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin. Concomitant use of probenecid may result in increased and prolonged blood levels of amoxicillin.

### **Allopurinol**

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

### **Tetracyclines**

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

### **Methotrexate**

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

### **Oral typhoid vaccine**

The oral typhoid vaccine is inactivated by antibiotics.

## **Oral Anticoagulants**

Oral anticoagulants and penicillin antibiotics have been widely used in practice without reports of interaction. However, in the literature there are cases of increased international normalised ratio in patient maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of amoxicillin. Moreover, adjustments in the dose of oral anticoagulants may be necessary.

### **4.6 Fertility, pregnancy and lactation**

#### **Pregnancy**

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. Limited data on the use of amoxicillin during pregnancy in humans do not indicate an increased risk of congenital malformations. In a single study in women with preterm, premature rupture of the foetal membrane it was reported that prophylactic treatment with amoxicillin may be associated with an increased risk of necrotizing enterocolitis in neonates. Use should be avoided during pregnancy, unless considered essential by the physician.

#### **Breastfeeding**

Both substances are excreted into breast milk. Consequently, diarrhoea and fungus infection of the mucous membranes are possible in the breast-fed infant, so that breast-feeding might have to be discontinued. The possibility of sensitization should be taken into account. Amoxicillin should only be used during breast-feeding after benefit/risk assessment by the physician in charge.

### **4.7 Effect 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.

### **4.8 Undesirable effects**

- The most commonly reported adverse drug reactions (ADRs) are diarrhoea, nausea and skin rash.
- The ADRs derived from clinical studies and post-marketing surveillance with amoxicillin, presented by MedDRA System Organ Class are listed below.

The following terminologies have been used in order to classify the occurrence of undesirable effects.



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

Not known (cannot be estimated from the available data)

<b>Infections and infestations</b>	
Very rare	Mucocutaneous candidiasis
<b>Blood and lymphatic system disorders:</b>	
Very rare	Reversible leucopenia (including severe neutropenia and agranulocytosis), reversible thrombocytopenia and haemolytic anaemia.  Prolongation of bleeding time and prothrombin time
<b>Immune system disorders</b>	
Very rare	Severe allergic reactions including angioedema, anaphylaxis, serum sickness and hypersensitivity vasculitis
Not Known	Jarisch-Herxheimer reaction
<b>Nervous system disorders</b>	
Very rare	Hyperkinesia, dizziness and convulsions
<b>Gastrointestinal disorders</b>	
Clinical trial data	
*Common	Diarrhoea and nausea
*Uncommon	Vomiting
<b>Post-marketing data</b>	
Very rare	Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis).  Black hairy tongue Superficial tooth discoloration <sup>#</sup>
<b>Hepatobiliary disorders</b>	
Very rare	Hepatitis and cholestatic jaundice. A moderate rise in AST and/or ALT.

<b>Skin and subcutaneous tissue disorders</b>	
Clinical Trial Data	
*Common:	Skin rash
*Uncommon:	Urticaria and pruritus
<b>Post-marketing data</b>	
Very rare	Skin reactions such as erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous and exfoliative dermatitis, acute generalised exanthematous pustulosis (AGEP) and drug reaction with eosinophilia and systemic symptoms (DRESS).
<b>Renal and urinary tract disorders</b>	
Very rare	Interstitial nephritis Crystalluria
<p>*The incidence of these AEs was derived from clinical studies involving a total of approximately 6,000 adult and paediatric patients taking amoxicillin.</p> <p>#Superficial tooth discolouration has been reported in children. Good oral hygiene may help to prevent tooth discolouration as it can usually be removed by brushing.</p>	

### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

## **4.9 Overdose**

### **Symptoms and signs of overdose**

Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. 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 high doses.

### **Treatment of intoxication**

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

Amoxicillin can be removed from the circulation by haemodialysis.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

**Pharmacotherapeutic group:** penicillins, incl. beta-lactamase inhibitors; ATC code: J01CR02.

#### Mechanism of action

Amoxicillin is a semisynthetic penicillin (beta-lactam antibiotic) that inhibits one or more enzymes (often referred to as penicillin-binding proteins, PBPs) in the biosynthetic pathway of bacterial peptidoglycan, which is an integral structural component of the bacterial cell wall. Inhibition of peptidoglycan synthesis leads to weakening of the cell wall, which is usually followed by cell lysis and death.

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

#### Pharmacokinetic/pharmacodynamic relationship

The time above the minimum inhibitory concentration ( $T > MIC$ ) is considered to be the major determinant of efficacy for amoxicillin.

#### Mechanisms of resistance

The two main mechanisms of resistance to amoxicillin are:

- Inactivation by those bacterial beta-lactamases that are not themselves inhibited by including class B, C and D.

- Alteration of PBPs, which reduce the affinity of the antibacterial agent for the target.

Impermeability of bacteria or efflux pump mechanisms may cause or contribute to bacterial resistance, particularly in Gram-negative bacteria.

#### Breakpoints

Organism	MIC breakpoint (mg/L)	
	Susceptible	Resistant
<i>Haemophilus influenzae</i>	$\leq 2^1$	$> 2^1$
<i>Moraxella catarrhalis</i>	$\leq 1^1$	$> 1^1$
<i>Staphylococcus spp</i>	$\leq 0.125^{2,3,4}$	$> 0.125^{2,3,4}$
<i>Enterococcus</i>	$\leq 4^1$	$> 8^1$
<i>Streptococcus A, B, C, G</i>	$\leq 0.25^2$	$> 0.25^2$

<i>Streptococcus pneumoniae</i>	$\leq 0.5^{1,5}$	$> 1^{1,5}$
Enterobacterales	$\leq 8^{1,6}$	$> 8^6$
Enterobacterales in	$\leq 32^{1,6}$	$> 32^6$
Gram-negative Anaerobes	$\leq 4^1$	$> 8^1$
Gram-positive Anaerobes (except	$\leq 4^1$	$> 8^1$
Non-species related	$\leq 2^1$	$> 8^1$

<sup>1</sup>Wild type Enterobacteriaceae are categorised as susceptible to aminopenicillins. Some countries prefer to categorise wild type isolates of *E. coli* and *P. mirabilis* as intermediate. When this is the case, use the MIC breakpoint  $S \leq 0.5 \text{ mg/L}$

<sup>2</sup>Most staphylococci are penicillinase producers, which are resistant to amoxicillin. Methicillin resistant isolates are, with few exceptions, resistant to all beta-lactam agents.

<sup>3</sup>Susceptibility to amoxicillin can be inferred from ampicillin

<sup>4</sup>The susceptibility of streptococcus groups A, B, C and G to penicillins is inferred from the benzylpenicillin susceptibility

<sup>5</sup>Breakpoints relate only to non-meningitis isolates. For isolates categorised as intermediate to ampicillin avoid oral treatment with amoxicillin. Susceptibility inferred from the MIC of ampicillin.

<sup>6</sup>Breakpoints are based on intravenous administration. Beta-lactamase positive isolates should be reported resistant.

<sup>7</sup>Beta lactamase producers should be reported resistant

<sup>8</sup>Susceptibility to amoxicillin can be inferred from benzylpenicillin.

<sup>9</sup>The breakpoints are based on epidemiological cut-off values (ECOFFs), which distinguish wild-type isolates from those with reduced susceptibility.

<sup>10</sup>The non-species related breakpoints are based on doses of at least  $0.5 \text{ g} \times 3$  or  $4$  doses daily ( $1.5$  to  $2 \text{ g/day}$ )

The prevalence of resistance may vary geographically and with time for selected species, and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infections is questionable.

Commonly susceptible species

Aerobic Gram-positive micro-organisms

*Enterococcus*

*faecalis* *Gardnerella*

*aginalis*

*Staphylococcus aureus* (methicillin-

susceptible) £ Coagulase-negative staphylococci

(methicillin-susceptible) *Streptococcusagalactiae*

*Streptococcus pneumoniae*<sup>1</sup>

*Streptococcus pyogenes* and other beta-haemolytic streptococci

*Streptococcus viridans* group

Aerobic Gram-negative micro-organisms

*Capnocytophaga* spp. *Eik*

*enella* *corrodens* *Haemop*

*hilus*

*influenzae*<sup>2</sup> *Moraxella* *cat*

*arrhalis*

*Pasteurella multocida* Anaer

obic micro-

organisms *Bacteroides fragil*

*is* *Fusobacterium nucleatum*

*Prevotella* spp.

Species for which acquired resistance may be a problem

Aerobic Gram-positive micro-organisms

*Enterococcus faecium* \$

Aerobic Gram-negative micro-organisms

*Escherichia coli*

Inherently resistant organisms

Aerobic Gram-negative micro-organisms

*Acinetobacter* sp. *Cit*

*robacterfreundii* *Ent*

*erobacter* sp.

*Legionella pneumophila*

*Morganella morganii* *Pr*

*ovidencia* sp.

*Pseudomonas* sp.

*Serratia* sp. *Stenotrophomonas*

*maltophilia* Other micro-

organisms *Chlamydia pneumoniae*

*Chlamydia psittaci*

*Coxiella burnetii*

*Mycoplasma pneumoniae*

\$ Natural intermediate susceptibility in the absence of acquired mechanism of resistance.

£ All methicillin-resistant staphylococci are resistant to

amoxicillin<sup>1</sup> *Streptococcus pneumoniae* that are resistant to penicillins should not be treated with this presentation of amoxicillin (see sections 4.2 and 4.4).

<sup>2</sup> Strains with decreased susceptibility have been reported in some countries in the EU with a frequency higher than 10%.

## 5.2 Pharmacokinetic properties

### Absorption

Amoxicillin and clavulanic acid, are fully dissociated in aqueous solution at physiological pH. Both components are rapidly and well absorbed by the oral route of administration. Following oral administration, amoxicillin and clavulanic acid are approximately 70% bioavailable. The plasma profiles of both components are similar and the time to peak plasma concentration (T<sub>max</sub>) in each case is approximately one hour.

The pharmacokinetic results for a study, in which amoxicillin/clavulanic acid (500 mg/125 mg tablet three times daily) was administered in the fasting state to a group of healthy volunteers are presented below.

C <sub>max</sub>	T <sub>max</sub> *	AUC(0-24h)	T <sub>1/2</sub>
(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 of 250 to 3000 mg the bioavailability is linear in proportion to dose (measured as C<sub>max</sub> and AUC). The absorption is not influenced by simultaneous food intake. Haemodialysis can be used for elimination of amoxicillin.

### **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 quantities equivalent to up to 10 to 25% of the initial dose.

### **Elimination**

The major route of elimination for amoxicillin is via the kidney.

Amoxicillin has a mean elimination half-life of approximately one hour and a mean total clearance of approximately 25 l/hour in healthy subjects. Approximately 60 to 70% of the amoxicillin is excreted unchanged in urine during the first 6 hours after administration of a single 250 mg or 500 mg dose of amoxicillin. Various studies have found the urinary excretion to be 50-85% for amoxicillin over a 24 hour period.

Concomitant use of probenecid delays amoxicillin excretion.

### **Age**

The elimination half-life of amoxicillin is similar for children aged around 3 months to 2 years and older children and adults. For very young children (including preterm newborns) in the first week of life the interval of administration should not exceed twice daily administration due to immaturity of the renal pathway of elimination.

Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

### **Gender**

Following oral administration of amoxicillin/clavulanic acid to healthy males and female subjects, gender has no significant impact on the pharmacokinetics of either amoxicillin or clavulanic acid.

### **Renal impairment**

The total serum clearance of amoxicillin/clavulanic acid decreases proportionately with decreasing renal function. The reduction in drug clearance is more pronounced for amoxicillin 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 of amoxicillin while maintaining adequate levels of clavulanic acid.

### **Hepatic impairment**

Hepatically impaired patients should be dosed with caution and hepatic function monitored at regular intervals

## **5.3 Preclinical safety data**

Non-clinical data reveal no special hazard for humans based on studies of safety pharmacology, genotoxicity and toxicity to reproduction.

Carcinogenicity studies have not been conducted with amoxicillin or its components

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of 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

Not applicable

## 6.3 Shelf life

36 months.

## 6.4 Special precautions for storage

Store in a cool dry place, between 15-30°C. Protect from light.

## 6.5 Nature and contents of container

**Primary Container(s):** Amoxicillin for oral suspension BP 125mg/5ml (MEDOMOX 125) is available in 100ml HDPE bottle.

### **Secondary Container:**

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

- Carton: ITCCyber XL with a quavarnish side open with 300 GSM multi-colours.
- Leaflet: 60 GSM Map litho paper.

### **Outer Container:**

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. Shippers are then strapped with Polypropylene tapes.

## 6.6 Special precautions for disposal and other handling

- Amoxicillin can be taken with or without food. Capsules should be swallowed whole with a glass of water, milk or squash (but not juice). Your child should not chew the capsules. Liquid medicine: Shake the medicine well.

## 7. Marketing authorization holder

### **Name and Permanent address of the Marketing authorization holder:**

Medopharm, Private limited

“MEDOHOUSE”

25, Puliur II Mainroad, Trustpuram, Chennai-600024,

Tamil Nadu, India.

PH: +9144-30149992/30149955

Fax: 260211286283

**Manufacturing Siteaddress:**

Medopharm Private Limited,

No. 50, Kayarambedu Village,

Guduvanchery- 603 202, Tamil Nadu, India.

**8. Number (s) in the National register of finished pharmaceutical products**

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 the authorization**

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 the text**

12.07.2023