

## **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Amoxicillin Tablets for Oral Suspension USP 125 MG (MEDOMOX 125 DT)

## 2. QUALITATIVE & QUANTITATIVE COMPOSITION:

Each dispersible tablet contains:

Amoxicillin Trihydrate USP Equivalent to Amoxicillin 125mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM:

- Dispersible Tablet
- White to off-white flat circular tablets with beveled edges and scored in the middle on one side and having a pleasant odour

## 4. CLINICAL PARTICULARS

### 4.1 INDICATIONS

- Amoxicillin is indicated for the treatment of the following bacterial infections caused by amoxicillin-sensitive gram-positive and gram-negative pathogens.
- Infections of the upper respiratory tract, including infections of the ears, nose and throat: Acute otitis media, acute sinusitis and bacterial pharyngitis.
- Infections of the lower respiratory tract: Acute exacerbation of chronic bronchitis, community-acquired pneumonia.
- Infections of the lower urinary tract: Cystitis
- Prophylaxis of endocarditis in patients at risks - for example those undergoing dental procedures.
- Considerations should be given to official guidance on the appropriate use of antibacterial agents.
- Susceptibility of the causative organism to the treatment should be tested (if possible), although therapy may be initiated before the results are available.

### 4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Adult dosage (including elderly patients): Standard dosage:

Standard dosage:

- The usual dosage covers a range from 750 mg to 3g amoxicillin daily in divided doses. In some areas 1500mg amoxicillin daily in divided doses are recommended as the upper usual dose.

Special dosage recommendation

- Acute exacerbation of chronic bronchitis in adults: 2 x 1 g

per day Children's dosage (under 40kg)

➤ The daily dosage for children is 40-

90 mg/kg/day in two to three divided doses\* (not exceeding 3g/day) depending on the indication, the severity of the disease and the susceptibility of the pathogen.

\*PK/PD data indicate that dosing three times daily is associated with enhanced efficacy, thus twice daily dosing is only recommended when the dose is in the upper range.

Children weighing more than 40kg should be given the usual adult dosage. Special dosage recommendation

➤ Tonsillitis: 50 mg/kg/day in two divided doses.

➤ Acute otitis media: In areas with high prevalence of pneumococci with reduced susceptibility to penicillins, dosage regimens should be guided by national/local recommendations.

Dosage in impaired renal function:

The doses should be reduced in patients with severe renal function impairment. In patients with a renal clearance of less than 30 ml/min an increase in the dosage interval and a reduction in the total daily dose are recommended.

*Adults (including elderly patients):*

<b>Creatinine clearance ml/</b>	<b>Dose</b>	<b>Interval between administration</b>
>30	No adjustment necessary.	
10 –30	500mg	12h
<10	500mg	24h

In case of hemo dialysis: 500 mg should be administered at the end of the procedure.

*Renal impairment in children under 40kg:*

<b>Creatinine clearance ml/</b>	<b>Dose</b>	<b>Interval between administration</b>
>30	Usual dose	No adjustment necessary.
10 –30	Usual dose	12 h (corresponding to 2/3 of the dose)
<10	Usual dose	24 h (corresponding to 1/3 of the dose)

*Dosage in impaired hepatic function*

➤ No dose reduction is necessary as long as the renal function is

not impaired. Method of administration:

➤ The preparation is administered orally with a measuring spoon. The measuring spoon is included in the package. The ready-for-use suspensions should be taken with a glass of water.

- The absorption of amoxicillin is not reduced by food intake.
- Administration to babies: The prescribed dosage is administered undiluted to the baby; milk or tea should be given afterwards.

#### Prophylaxis for endocarditis:

- For the prevention of endocarditis, in patients not having general anaesthetic, 3 g amoxicillin are given orally in the hour preceding the surgical procedure, followed by (6 hours later) a further 3 g dose, if considered necessary.
- For children: 50 mg amoxicillin/kg body weight given as a single dose one hour preceding the surgical procedure.
- For further details and description of patients at risk local official guidelines for the prevention of endocarditis should be consulted.

#### Method of administration:

- The preparation is administered orally with a measuring spoon. The measuring spoon is included in the package. The ready-for-use suspensions should be taken with a glass of water.
- The absorption of amoxicillin is not reduced by food intake.
- Administration to babies: The prescribed dosage is administered undiluted to the baby; milk or tea should be given afterwards.

### 4.3 CONTRAINDICATIONS

Amoxicillin is contraindicated in patients with:

- Hypersensitivity to penicillin; a cross-allergy to other beta-lactams such as cephalosporins should be taken into account.
- Hypersensitivity to any of the excipients.

### 4.4 SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE

- Before initiating therapy with amoxicillin, careful enquiry should be made concerning previously hypersensitivity reactions to penicillins and cephalosporins. The possibility of cross-hypersensitivity (10 % - 15 %) with cephalosporins should be taken into account.
- Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of hypersensitivity to beta-lactam antibiotics.
- In patients with renal function impairment the excretion of amoxicillin will be delayed and, depending on the degree of the impairment, it may be necessary to reduce the total daily dosage.
- Precautions should be taken in premature children and during neonatal period: renal, hepatic and haematological functions should be monitored.
- The prolonged use of amoxicillin may occasionally result in an overgrowth of non-susceptible

bacteria or yeasts. Patients should therefore carefully be watched for superinfections.

- The occurrence of anaphylactic shock and other severe allergic reactions is rare following the oral administration of amoxicillin. However, if such reactions occur, appropriate emergency treatment measures must be taken.
- The presence of high urinary concentrations of amoxicillin can cause precipitation of the product in urinary catheters. Therefore, catheters should be visually inspected at intervals.
- At high doses, adequate fluid intake and urinary output must be maintained to minimize the possibility of amoxicillin crystalluria.
- Amoxicillin should not be used for the treatment of bacterial infections in patients with viral infections, acutelymphatic leukaemia, or infectious mononucleosis as erythematous (morbilliform) rashes have been associated with glandular fever in patients receiving amoxicillin.
- Antibiotic-associated colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life threatening (see section 4.8). 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 be consulted and appropriate therapy initiated. Anti-peristaltic medicinal products are contraindicated in this situation.
- As with other beta-lactams, the blood formula should be checked regularly during high-dose therapy.
- Periodic assessment of organ system functions, including renal, hepatic and haematopoietic function is advisable during prolonged therapy.
- High dose therapy with beta-lactams for patients with renal insufficiency or seizure history, treated epilepsy and meningeal affection, could exceptionally lead to seizures.
- The occurrence of a generalized erythema with fever and pustules at the beginning of treatment should make you suspect a generalized acute exanthematic pustulosis; this necessitates the interruption of therapy and contraindicates any further administration of amoxicillin.
- All Amoxicillin powders for oral suspension contain aspartame (E951) and should be used with care in patients with phenylketonuria. In homozygotic patients with phenylketonuria, the amount of phenylalanine that is supplied by aspartame must be included in the calculation for the dietary regulations.

## 4.5 DRUG INTERACTION

Concomitant use not recommended

### **Allopurinol**

Concomitant administration of allopurinol may promote the occurrence of allergic cutaneous reactions

and is therefore not advised.

### **Digoxin**

An increase in the absorption of digoxin is possible on concurrent administration with amoxicillin. A dose adjustment of digoxin may be necessary.

### **Anticoagulants**

Concomitant administration of amoxicillin and anticoagulants from the coumarin class, may prolong the bleeding time. A dose adjustment of anticoagulants may be necessary. A large number of cases showing an increase of oral anticoagulant activity has been reported in patients receiving antibiotics. The infectious and inflammatory context, age and the general status of the patient appear as risk factors. In these circumstances, it is difficult to know the part of the responsibility between the infectious disease and its treatment in the occurrence of INR disorders. However, some classes of antibiotics are more involved, notably fluoroquinolones, macrolides, cyclines, cotrimoxazole and some cephalosporins.

### **Methotrexate**

Interaction between amoxicillin and methotrexate leading to methotrexate toxicity has been reported. Serum methotrexate levels should be closely monitored in patients who receive amoxicillin and methotrexate simultaneously. Amoxicillin decreases the renal clearance of methotrexate, probably by competition at the common tubular secretion system.

### **Caution is recommended when amoxicillin is given concomitantly with: Oral hormonal contraceptives**

Administration of amoxicillin can transiently decrease the plasma level of estrogens and progesterone, and may reduce the efficacy of oral contraceptives. It is therefore recommended to take supplemental non-hormonal contraceptive measures.

### **Other forms of interactions:**

- Forced diuresis leads to a reduction in blood concentrations by increased elimination of amoxicillin.
- It is recommended that when testing for the presence of glucose in urine during amoxicillin treatment, enzymatic glucose oxidase methods should be used. Due to the high urinary concentrations of amoxicillin, false positive readings are common with chemical methods.
- Amoxicillin may decrease the amount of urinary estriol in pregnant women.
- At high concentrations, amoxicillin may diminish the results of serum glycemia levels.
- Amoxicillin may interfere with protein testing when colorimetric methods are used.

## **4.6 Uses during Pregnancy & Lactation**

Use in pregnancy

Amoxicillin has been assigned to pregnancy category B by the FDA. Animal studies using 10 times the

human dose have failed to reveal any evidence of teratogenicity. Although no controlled data in human pregnancy are available, literature reports of adverse fetal effects are lacking. Amoxicillin is only recommended during pregnancy when benefit outweighs risk. In the Collaborative Perinatal Project involving 50,282 mother-child pairs, there were 3,546 mother-child pairs exposed to penicillin derivatives in the first trimester. As a group, there was no significant increase in the risk of malformations. In the Michigan Medicaid Birth Defects Study involving 229,101 pregnancies from 1985 to 1992, there were 8,538 first trimester exposures to amoxicillin. Overall, 317 cases of birth defects were observed (363 expected). There was no evidence of an association between first trimester use of amoxicillin and major groups of malformations. A Danish study of 401 women exposed to amoxicillin during pregnancy from 1991 to 2000 did not find an increased risk of birth defects or adverse outcomes compared to women who had taken no medication. Transient decreases in total conjugated estradiol, estradiol-glucuronide, conjugated estrone, and estradiol plasma concentrations have been reported in pregnant women who received ampicillin and this may also occur with amoxicillin. In one study, six women were administered a single 1000 mg dose of amoxicillin on the third postpartum day. Amoxicillin milk concentrations ranged from 0.10 to 0.81 mcg/mL, with a peak concentration measured at 5 hours post-dose. The milk to maternal serum concentration ratio ranged from 0.013 to 0.043. Amoxicillin is excreted in human milk in small amounts. Sensitization of the infant may occur. The American Academy of Pediatrics considers the use of amoxicillin to be compatible with breastfeeding. The manufacturer recommends that caution be used when administering amoxicillin to nursing women.

#### 4.7 EFFECTS ON ABILITY TO DRIVE AND TO 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 SIDE EFFECTS / ADVERSE REACTIONS

In this section undesirable effects are defined as follows:

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	$< 1/10,000$ ,

## Infections and infestations

### *Uncommon*

- Superinfections and colonization with resistant organisms or yeasts such as oral and vaginal candidiasis after prolonged and repeated use of amoxicillin.

## Blood and the lymphatic system disorders

- *Rare*  
Eosinophilia and haemolytic anaemia.
- *Very rare*  
Leucopenia, neutropenia, granulocytopenia, thrombocytopenia, pancytopenia, anaemia, myelosuppression, agranulocytosis, prolongation of bleeding time, and prolongation of prothrombin time. All were reversible on discontinuation of therapy.

## Immune system disorders

- *Rare*  
Laryngeal oedema, serum sickness, allergic vasculitis, anaphylaxis and anaphylactic shock.

## Nervous system disorders

- *Rare*  
CNS effects including hyperkinesia, dizziness and convulsions. Convulsions may occur in patients with impaired renal function, epilepsy, meningitis or in those receiving high doses.

## Gastrointestinal disorders:

- *Common*  
Gastric complaints, nausea, loss of appetite, vomiting, flatulence, soft stools, diarrhoea, enanthem as (particularly in the region of the mouth), dry mouth, taste disturbances. These effects on the gastrointestinal system are mostly mild and frequently disappear either during the treatment or very soon after completion of therapy. The occurrence of these side effects can generally be reduced by taking amoxicillin during meals.
- *Rare*  
Superficial discoloration of the teeth (especially with the suspension). Usually the discoloration can be removed by teeth brushing.
- *Very rare*  
If severe and persistent diarrhoea occurs, the very rare possibility of pseudomembranous colitis should be considered. The administration of anti-peristaltic drug is contraindicated. Development of a black tongue.

## **Hepato-biliary disorders:**

### *Uncommon*

Moderate and transient increase of liver enzymes.

- *Rare*



Hepatitis and  
cholestatic jaundice. Skin and subcutaneous  
tissue disorders: **Common**

Cutaneous reactions such as exanthema, pruritus, urticaria; the typical morbilliform exanthema occurs 5-11 days after start of therapy. Immediate appearance of urticaria indicates an allergic reaction to amoxicillin and therapy should therefore be discontinued.

➤ *Rare*

Angioneurotic oedema (Quincke's oedema), Erythema multiforme exsudativum, acute generalised pustulosis, Lyell's syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous and exfoliative dermatitis.

**Renal disorders**

➤ *Rare*

Acute interstitial nephritis. Crystalluria.

General disorders and administration site conditions

➤ *Rare*

Drug fever.

## 4.9 OVERDOSE

Symptoms of overdose:

- Amoxicillin is not generally associated with acute toxic effects, even when accidentally consumed in high doses. Overdose can lead to symptoms such as gastrointestinal, renal and neuro-psychic disturbances and fluid and electrolyte imbalance. In patients with severely impaired renal function, large overdoses can result in signs of renal toxicity; crystalluria is possible.

Management of overdose:

- There is no specific antidote for an overdose of amoxicillin.
- Treatment consists primarily of administration of activated charcoal (if gastric lavage is usually not necessary), or symptomatic measures. Particular attention should be paid to the water and electrolyte balance of the patients.
- Amoxicillin can be eliminated via haemodialysis.

## 5. PHARMACOLOGY:

### 5.1 PHARMACODYNAMIC PROPERTIES

ATC-Code: J01CA04

Pharmacotherapeutic group: Beta-lactam antibacterials, Penicillins with extended spectrum.

**Mechanism of resistance**

Bacteria may be resistant to amoxicillin due to production of beta-

lactamases which hydrolyse aminopenicillins, due to alteration in penicillin-binding proteins, due to impermeability to the drug, or due to drug efflux pumps. One or more of these mechanisms may co-exist in the same organism, leading to a variable and unpredictable cross-resistance to other beta-lactams and to antibacterial drugs of other classes.

### **Mechanism of Action**

Amoxicillin is similar to penicillin in its bactericidal action against susceptible bacteria during the stage of active multiplication. It acts through the inhibition of cell wall biosynthesis that leads to the death of the bacteria.

### **Breakpoints (EUCAST)**

Organism	Susceptibility Breakpoints (µg/ml)		
	Susceptible	Intermediate	Resistant
<i>Haemophilus influenzae</i>	≤1	-	>1
<i>Moraxella catarrhalis</i>	≤1	-	>1
<i>Enterococcus</i>	≤4	8	>8
<i>Streptococcus A, B, C, G</i> <sup>1</sup>	≤0.25	-	>0.25
<i>Streptococcus pneumoniae</i> <sup>2</sup>	≤0.5	1-2	>2
Enterobacteriaceae <sup>3</sup>	-	-	>8
Gram-negative anaerobes	≤0.5	-	>2
Gram-positive Anaerobes	≤4	8	>8
Non-species related	≤2	4-8	>8

<sup>1</sup> Breakpoint values in the table are based on Benzylpenicillin breakpoints.

<sup>2</sup> Breakpoint values in the table are based on ampicillin breakpoints.

<sup>3</sup> The resistant breakpoint of R > 8 mg/L ensures that all isolates with resistance mechanisms are reported resistant.

### **Susceptibility:**

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** *Corynebacterium diptheriae*  
*Enterococcus faecalis*<sup>s</sup>  
*Listeria monocytogenes*  
*Streptococcus agalactiae*  
*Streptococcus bovis*  
*Streptococcus pyogenes*\*

**Aerobic Gram-negative** *Helicobacter pylori*  
**Anaerobes** *Peptostreptococci*  
**Others**

**Species for which acquired resistance may be a problem**

**Aerobic Gram-positive** *Corynebacterium* spp  
*Enterococcus faecium*<sup>s</sup>  
*Streptococcus pneumoniae* \*  
<sup>+</sup> *Streptococcus viridans*  
**Aerobic Gram-negative** *Escherichia coli* + *Haemophilus influenzae*  
\**Haemophilus parainfluenzae* \*  
*Moraxella catarrhalis* + *Proteus mirabilis*  
**Anaerobes** *Prevotella* spp  
*Fusobacterium* spp

**Inherently resistant organisms**

**Aerobic Gram-positive** *Staphylococcus aureus*  
**Aerobic Gram-negative** *Acinetobacter* spp  
*Citrobacter* spp  
*Enterobacter* spp  
*Klebsiella* spp  
*Legionella*  
*Morganella morganii*  
*Proteus vulgaris*  
*Providencia* spp  
*Pseudomonas* spp  
*Serratia* spp  
**Anaerobes** *Bacteroides fragilis*

**Others** *Chlamydia*  
*Mycoplasma*  
*Rickettsia*

\* Clinical efficacy has been demonstrated for susceptible isolates in approved clinical indications

+ pathogens resistance prevalence is >50%

\$ Naturally intermediate species

### **Clinical efficacy and safety:**

H. pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence

Randomized, double-

blind clinical studies performed in the United States in patients with H. pylori and duodenal ulcer disease (defined as an active ulcer or history of an ulcer within 1 year) evaluated the efficacy of lansoprazole in combination with Amoxicillin capsules and clarithromycin tablets as a triple 14-day therapy, or in combination with Amoxicillin capsules as a dual 14-day therapy, for the eradication of H. pylori. Based on the results of these studies, the safety and efficacy of 2 different eradication regimens were established: Triple Therapy: Amoxicillin 1 gram twice daily/clarithromycin 500 mg twice daily/lansoprazole 30 mg twice daily (see Table 6). Dual Therapy: Amoxicillin 1 gram three times daily/lansoprazole 30 mg three times daily (see Table 7). All treatments were for 14 days. H. pylori eradication was defined as 2 negative tests (culture and histology) at 4 to 6 weeks following the end of treatment. Triple therapy was shown to be more effective than all possible dual therapy combinations. Dual therapy was shown to be more effective than both monotherapies. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence.

**Pediatric population** Because of incompletely developed renal function in neonates and young infants, the elimination of Amoxicillin may be delayed. Dosing of Amoxicillin should be modified in pediatric patients 12 weeks or younger ( $\leq 3$  months)

## **5.2 PHARMACOKINETIC PROPERTIES**

### ***Absorption:***

The absolute bioavailability of amoxicillin depends on the dose and ranges between 75 and 90%. In the dose range between 250 mg and 1000 mg the bioavailability (parameters: AUC and  $C_{max}$ ) is linearly proportional to the dose. At higher doses the extent of absorption decreases. The absorption is not affected by concomitant food intake. Oral administration of a single dose of 500 mg amoxicillin results in plasma concentrations of 6 - 11 mg/l. After administration of a single dose of 3 g amoxicillin, the plasma concentrations reach 27 mg/l. Peak plasma concentrations are present about 1-2 hours after administration.

### ***Distribution:***

Protein binding for amoxicillin is approximately 17%. Therapeutic drug levels are rapidly achieved in serum, lung tissue, bronchial secretions, middle ear fluid, bile and urine. In healthy meninges amoxicillin diffuses badly in liquor or cerebrospinalis. Amoxicillin crosses the placenta and a small percentage is excreted into the breast milk.

### ***Biotransformation and elimination:***

The main route of excretion of amoxicillin is the kidney. About 60-80% of an oral dose of amoxicillin is excreted in unchanged active form in the urine within 6 hours of administration, and a small fraction is excreted in the bile. Approximately 7-25% of the administered dose is metabolized to inactive penicilloic acid. The serum half-life in patients with normal renal function is approximately 1-1.5 hours. In patients with end-stage renal failure the half-life ranges between 5 to 20 hours. The substance is haemodialysable.

### ***Pediatric population***

In preterm infants with gestational age 26-33 weeks, the total body clearance after intravenous dosing of amoxicillin, day 3 of life, ranged between 0.75-2 ml/min, very similar to the inulin clearance (GFR) in this population. Following oral administration, the absorption pattern and the bioavailability of amoxicillin in small children may be different to that of adults. Consequently, due to the decreased CL, the exposure is expected to be elevated in this group of patients, although this increase in exposure may in part be diminished by decreased bioavailability when given orally.

## **5.3 PRECLINICAL SAFETY DATA**

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction.

### **TOXICOLOGY**

#### **An Unusual Case of Amoxicillin/Clavulanic Acid-Related Hepatotoxicity**

M.G. Nathani, M.D.a, M.G. Mutchnick, M.D., F.A.C.G.a, D.J. Tynes, M.D.a, and M.N. Ehrinpreis, M.D., F.A.C.G.a

Amoxicillin/clavulanic acid is a widely used antibiotic. Hepatic dysfunction is a rare adverse reaction associated with this combination antibiotic. We report the case of a 40-year-old woman with a somewhat unusual presentation of amoxicillin/clavulanate-related cholestatic hepatotoxicity and multiple duodenal erosions whose diagnosis was delayed until an inadvertent challenge with the antibiotic combination. The relevant literature is also reviewed and discussed. The diagnosis may be missed because the onset of signs/symptoms may occur several weeks after the cessation of the therapy. The hepatic dysfunction, which may be severe and is more prevalent in elderly patients, is usually reversible, although chronic liver disease and death have been reported. Immunological hypersensitivity is considered to be the most likely mechanism resulting in liver injury. Amoxicillin/clavulanate should be used with caution in patients with underlying liver disease and in the elderly.

#### **Carcinogenesis, Mutagenesis, Impairment of Fertility**

Long-term studies in animals have not been performed to evaluate carcinogenic potential. The mutagenic

potential of Coamoxiclav was investigated in vitro with an Ames test, a human lymphocyte cytogenetic assay, a yeast test, and a mouse lymphoma forward mutation assay, and in vivo with mouse micronucleus tests and a dominant lethal test. All were negative apart from the in vitro mouse lymphoma assay, where weak activity was found at very high, cytotoxic concentrations.

## **6. PHARMACEUTICAL PROPERTIES**

### **6.1 List of Excipients**

- Microcrystalline Cellulose (PH 112)BP
- Colloidal anhydrous silicaBP
- Maize starchBP
- Sodium saccharineBP
- Flavour orange dry powder INH
- Magnesium stearateBP
- Crosspovidone NF
- Purified waterBP

### **6.2 Incompatibilities**

We evaluated the compatibility of these excipients with the active and found no evidence of incompatibility.

### **6.3 Shelf Life**

36 months from the date of manufacture

### **6.4 Special Precautions for storage**

Store in a dry place at a temperature of less than 25°C. Protect from light.

### **6.5 Nature and Contents of Container**

**Presentation:** MEDOMOX 125 DT are available as 2 x 10's, 3x10's & 10x10's PVDC blister pack.

#### **Primary Container (s):**

MEDOMOX 125 DT are available as strip pack. Each strip of 2 x 10's 3x10's & 10x10's PVDC blister pack contains 10 tablets respectively.

#### **Secondary Container:**

Such strip packs are packed in a printed carton. Printed Cartons are printed with relevant batch details.

#### **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**

Dispersible tablets should be stirred into a little water before taking. No special requirements.

## **7. Marketing authorization holder**

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

Medopharm, Private limited

“MEDOHOUSE”

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

Tamil Nadu, India.

PH: +9144-30149992/30149955

Fax: 260211286283

**Manufacturing Site address:**

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.: MEDOP/IND/010 Certificate No.: N353/08

Renewal registration - 05262/07406/REN/2020

**9. Date of first authorization/renewal of the authorization**

First authorization – 15/06/2016

Renewal authorization - 10.08.2020

**10. Date of revision of the text**

12.07.2023