MOXICLAV

1. NAME OF THE MEDICINAL PRODUCT
MOXICLAV 625 mg film-coated tablets
MOXICLAV 1g film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet of MOXICLAV 625 mg contains amoxicillin trihydrate equivalent to 500mg amoxicillin base and potassium clavulanate equivalent to 125mg clavulanic acid.
Each tablet of MOXICLAV 1 g contains amoxicillin trihydrate equivalent to 875 mg amoxicillin base and potassium clavulanate equivalent to 125mg clavulanic acid.

Excipient with known effect: propylene glycol.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Film-coated tablet.
White, convex, capsule-shaped, film-coated tablets.

4. CLINICAL PARTICULARS
4.1. Therapeutic indications
The administration of MOXICLAV is indicated in the treatment of infections caused by susceptible microorganisms, such as:
Lower respiratory tract infections caused by β-lactamase producing strains of *Haemophilus influenza* and *Branhamella catarrhalis*
Otitis media caused by β-lactamase producing strains of *Haemophilus influenza* and *Branhamella catarrhalis*
Sinusitis caused by β-lactamase producing strains of *Haemophilus influenza* and *Branhamella catarrhalis*
Urogenitary tract infections caused by, β-lactamase producing strains of *Escherichia coli*, *Klebsiella* spp. And *Enterobacter spp*.
Skin and skin structure infections caused by β-lactamase producing strains of *Staphylococcus aureus*, *Escherichia coli* and *Klebsiella spp*.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2. Posology and method of administration
Posology
The usual administered dose is:
Adults and children over 14 years old: In severe infections, one MOXICLAV tablet (875 + 125) mg every 12 hours or one MOXICLAV tablet (500 + 125) mg every 8 hours. In mild to moderate infections, one MOXICLAV tablet (250 + 125) mg every 8 hours or one MOXICLAV tablet (500 + 125) mg every 12 hours.
For dental infections one MOXICLAV tablet (250 + 125) mg every 8 hours for five days, is recommended.
Children 7 to 14 years old: 5 ml (one teaspoonful) of MOXICLAV oral suspension (250 + 62.5) mg, every 8 hoursChildren 2 to 7 years old: 5 ml (one teaspoonful) of MOXICLAV oral suspension (125 + 31.25) mg, every 8 hoursIn all the above mentioned categories and for more severe infections the administered dose may be doubled.
Children less than 2 years old: 2.5 ml (half teaspoonful) of MOXICLAV oral suspension (125 + 31.25) mg, every 8 hours. In children less than 2 years old the daily administered dose of clavulanic acid should not be greater than 5 mg/kg of body weight. In case of severe infections dosage should not be increased.
Renal Impairment: Mild renal impairment, creatinine clearance greater than 30ml/minute: normal recommended dosage may be used. Moderate renal impairment, creatinine clearance 10ml/minute to 30ml/minute: the normal recommended dosage should be administered, but the dosage interval prolonged to every twelve hours. Severe renal impairment, creatinine clearance less than 10ml/minute: dosage should not exceed 1 x 375mg tablet every twelve hours (adult) or 5ml (125 + 31.25)mg suspension every twelve hours (child).
MOXICLAV tablets (all strengths) are not suitable for children under 14 years.Treatment should not be extended beyond 14 days without review.

Method of administrationOral use.
Administer at the start of a meal to minimize potential gastrointestinal intolerance and optimize absorption of amoxicillin/clavulanic acid.
Therapy can be started parenterally according the SPC of the IV-formulation and continued with an oral preparation.

4.3. Contraindications
Hypersensitivity to the active substances, to any of the penicillins or to any of the excipients listed in section 6.1.
History of a severe immediate hypersensitivity reaction (e.g. anaphylaxis) to another beta-lactam agent (e.g. a cephalosporin, carbapenem or monobactam).
History of jaundice/hepatic impairment due to amoxicillin/clavulanic acid (see section 4.8).

4.4. Special warnings and precautions for use
Before initiating therapy with amoxicillin/clavulanic acid, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other beta-lactam agents (see sections 4.3 and 4.8).

Serious and occasionally fatal hypersensitivity (including anaphylactoid and severe cutaneous adverse reactions) 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/clavulanic acid therapy must be discontinued and appropriate alternative therapy instituted.

In the case that an infection is proven to be due to an amoxicillin-susceptible organisms(s) then consideration should be given to switching from amoxicillin/clavulanic acid to amoxicillin in accordance with official guidance.

This presentation of MOXICLAV is not suitable for use when there is a high risk that the presumptive pathogens have reduced susceptibility or resistance to beta-lactam agents that is not mediated by beta-lactamases susceptible to inhibition by clavulanic acid. This presentation should not be used to treat penicillin-resistant *S. pneumoniae*.

Convulsions may occur in patients with impaired renal function or in those receiving high doses (see section 4.8).

Amoxicillin/clavulanic acid 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.

Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions.

Prolonged use may occasionally result in overgrowth of non-susceptible organisms.

The occurrence at the treatment initiation of a feverish generalized erythema associated with pustula may be a symptom of acute generalized exanthemous pustulosis (AGEP) (see section 4.8). This reaction requires amoxicillin/clavulanic acid discontinuation and contra-indicates any subsequent administration of amoxicillin.

Amoxicillin/clavulanic acid should be used with caution in patients with evidence of hepatic impairment (see section 4.2).

Hepatic events have been reported predominantly in males and elderly patients and may be associated with prolonged treatment. These events have been very rarely reported in children. In all populations, signs and symptoms usually occur during or shortly after treatment but in some cases may not become apparent until several weeks after treatment has ceased. These are usually reversible. Hepatic events may be severe and, in extremely rare circumstances, deaths have been reported. These have almost always occurred in patients with serious underlying disease or taking concomitant medications known to have the potential for hepatic effects (see section 4.8).

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 diarrhea during or subsequent to the administration of any antibiotics. Should antibiotic-associated colitis occur, amoxicillin/clavulanic acid should immediately be discontinued, a physician be consulted and an appropriate therapy initiated. Anti-peristaltic medicinal products are contra-indicated in this situation.

Periodic assessment of organ system functions, including renal, hepatic and haematopoietic function is advisable during prolonged therapy.

Prolongation of prothrombin time has been reported rarely in patients receiving amoxicillin/clavulanic acid. 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 (see section 4.5 and 4.8).

In patients with renal impairment, the dose should be adjusted according to the degree of impairment (see section 4.2).

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 inorder to reduce the possibility of amoxicillin crystalluria. In patients with bladder catheters, a regular check of patency shouldbe maintained (see section 4.9).

During treatment with amoxicillin, enzymatic glucose oxidase methods should be used whenever testing for the presence of glucose in urine because false positive results may occur with non-enzymatic methods.

The presence of Clavulanic acid in MOXICLAV may cause a non-specific binding of IgG and albumin by red cell membranes leading to a false positive Coombs test.

There have been reports of positive test results using the Bio-Rad Laboratories Platelia *Aspergillus* EIA test in patients receiving amoxicillin/clavulanic acid who were subsequently found to be free of *Aspergillus* infection. Cross-reactions with non-*Aspergillus* polysaccharides and polyfuranoses with Bio-Rad Laboratories Platelia *Aspergillus* EIA test have been reported. Therefore, positive test results in patients receiving amoxicillin/clavulanic acid should be interpreted cautiously and confirmed by other diagnostic methods.

MOXICLAV contains propylene glycol which may cause alcohol-like symptoms.

4.5. Interactions with other medicinal products and other forms of interaction

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 normalized ratio in patients maintained on acenocoumarol or warfarinand prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalized ratio should be carefully monitored with the addition or withdrawal of amoxicillin. Moreover, adjustments in the dose of oral anticoagulants may be necessary (see section 4.4 and 4.8).

Methotrexate

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

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 but not of clavulanic acid.

Mycophenolate mofetil

In patients receiving mycophenolate mofetil, reduction in pre-dose concentration of the active metabolite mycophenolic acid (MPA) of approximately 50% has been reported following commencement of oral amoxicillin plus clavulanic acid. The change in pre-dose level may not accurately represent changes in overall MPA exposure. Therefore, a change in the dose of mycophenolate mofetil should not normally be necessary in the absence of clinical evidence of graft dysfunction. However, close clinical monitoring should be performed during the combination and shortly after antibiotic treatment.

4.6. Fertility, pregnancy and lactation

Pregnancy

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development (see section 5.3). Limited data on the use of amoxicillin/clavulanic acid 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 fetal membrane it was reported that prophylactic treatment with amoxicillin/clavulanic acid may be associated with an increased risk of necrotizing enterocolitis in neonates. Use should be avoided during pregnancy, unless considered essential by the physician.

Breast-feeding

Both substances are excreted into breast milk (nothing is known of the effects of clavulanic acid on the breast-fed infant). Consequently, diarrhea and fungus infection of the mucous membranes are possible in the breast-fed infant, so that breast-feeding might have to be discontinued.

Amoxicillin/clavulanic acid should only be used during breast-feeding after benefit/risk assessment by the physician in charge.

4.7. Effects 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 (see section 4.8).

4.8. Undesirable effects

The most commonly reported adverse drug reactions (ADRs) are diarrhea, nausea and vomiting.

The ADRs derived from clinical studies and post-marketing surveillance with amoxicillin/clavulanic acid, sorted by MedDRA System Organ Class are listed below.

Infections and infestations	
Mucocutaneous candidosis	Common
Overgrowth of non-susceptible organisms	Not known
Blood and lymphatic system disorders	
Reversible leucopenia (including neutropenia)	Rare
Thrombocytopenia	Rare
Reversible agranulocytosis	Not known
Hemolytic anemia	Not known
Prolongation of bleeding time and prothrombin time[1]	Not known
Immune system disorders[10]	
Angioneurotic edema	Not known
Anaphylaxis	Not known
Serum sickness-like syndrome	Not known
Hypersensitivity vasculitis	Not known
Nervous system disorders	
Dizziness	Uncommon
Headache	Uncommon
Reversible hyperactivity	Not known
Convulsions[2]	Not known
Aseptic meningitis	Not known
Gastrointestinal disorders	
Diarrhea	Very common
Nausea[3]	Common
Vomiting	Common
Indigestion	Uncommon
Antibiotic-associated colitis[4]	Not known
Black hairy tongue	Not known
Hepatobiliary disorders	
Rises in AST and/or ALT[5]	Uncommon
Hepatitis[6]	Not known
Cholestatic jaundice[6]	Not known
Skin and subcutaneous tissue disorders[7]	
Skin rash	Uncommon
Pruritus	Uncommon
Urticaria	Uncommon
Erythema multiforme	Rare
Stevens-Johnson syndrome	Not known
Toxic epidermal necrolysis	Not known
Bullous exfoliative-dermatitis	Not known
Acute generalized exanthemous pustulosis (AGEP)[9]	Not known
Drug reaction with eosinophilia and systemic symptoms (DRESS)	Very rare
Renal and urinary disorders	
Interstitial nephritis	Not known
Crystalluria[8]	Not known

[1]See section 4.4
[2]See section 4.4.
[3]Nausea is more often associated with higher oral doses. If gastrointestinal reactions are evident, they may be reduced by taking amoxicillin/clavulanic acid at the start of a meal.
[4]Including pseudomembranous colitis and hemorrhagic colitis (see section 4.4)
[5]A moderate rise in AST and/or ALT has been noted in patients treated with beta-lactam class antibiotics, but the significance of these findings is unknown.
[6]These events have been noted with other penicillins and cephalosporins (see section 4.4).
[7]If any hypersensitivity dermatitis reaction occurs, treatment should be discontinued (see section 4.4).
[8]See section 4.9
[9]See section 4.4
[10]See sections 4.3 and 4.4

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 (see section 4.4).

Convulsions may occur in patients with impaired renal function or in those receiving high doses.
Amoxicillin has been reported to precipitate in bladder catheters, predominantly after intravenous administration of large doses. A regular check of patency should be maintained (see section 4.4).

Treatment of intoxication
Gastrointestinal symptoms may be treated symptomatically, with attention to the water/electrolyte balance. Amoxicillin/clavulanic acid can be removed from the circulation by hemodialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Combinations of 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.
Clavulanic acid is a beta-lactam structurally related to penicillins. It inactivates some beta-lactamase enzymes thereby preventing inactivation of amoxicillin. Clavulanic acid alone does not exert a clinically useful antibacterial effect.

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/clavulanic acid are:

- Inactivation by those bacterial beta-lactamases that are not themselves inhibited by clavulanic acid, 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
MIC breakpoints for amoxicillin/clavulanic acid are those of the European Committee on Antimicrobial Susceptibility Testing (EUCAST)

Organism	**Susceptibility Breakpoints (µg/ml)**		
	Susceptible	**Intermediate**	**Resistant**
Haemophilus influenzae[1]	≤1	-	>1
Moraxella catarrhalis[1]	≤1	-	>1
Staphylococcus aureus[2]	≤2	-	>2
Coagulase-negative staphylococci[2]	≤0.25		>0.25
Enterococcus[1]	≤4	8	>8
Streptococcus A, B, C, G[5]	≤0.25	-	>0.25
Streptococcus pneumoniae[3]	≤0.5	1-2	>2
Enterobacteriaceae[1,4]	-	-	>8
Gram-negative Anaerobes[1]	≤4	8	>8
Gram-positive Anaerobes[1]	≤4	8	>8
Non-species related breakpoints[1]	≤2	4-8	>8

[1]The reported values are for Amoxicillin concentrations. For susceptibility testing purposes, the concentration of Clavulanic acid is fixed at 2 mg/l.
[2]The reported values are Oxacillin concentrations.
[3]Breakpoint values in the table are based on Ampicillin breakpoints.
[4]The resistant breakpoint of R>8 mg/l ensures that all isolates with resistance mechanisms are reported resistant.
[5]Breakpoint values in the table are based on Benzylpenicillin breakpoints.

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 vaginalis* *Staphylococcus aureus* (methicillin-susceptible)[£] Coagulase-negative staphylococci (methicillin-susceptible) *Streptococcus agalactiae* *Streptococcus pneumoniae*[1] *Streptococcus pyogenes* and other beta-hemolytic streptococci *Streptococcus viridans* group Aerobic Gram-negative micro-organisms *Capnocytophaga* spp. *Eikenella corrodens* *Haemophilus influenzae*[2] *Moraxella catarrhalis* *Pasteurella multocida* Anaerobic micro-organisms *Bacteroides fragilis* *Fusobacterium nucleatum* *Prevotella* spp.
Species for which acquired resistance may be a problem
Aerobic Gram-positive micro-organisms *Enterococcus faecium*[$] Aerobic Gram-negative micro-organisms *Escherichia coli* *Klebsiella oxytoca* *Klebsiella pneumoniae* *Proteus mirabilis* *Proteus vulgaris*
Inherently resistant organisms
Aerobic Gram-negative micro-organisms *Acinetobacter* sp. *Citrobacter freundii* *Enterobacter* sp. *Legionella pneumophila* *Morganella morganii* *Providencia* spp. *Pseudomonas* sp. *Serratia* sp. *Stenotrophomonas maltophilia* Other micro-organisms *Chlamydophila pneumoniae* *Chlamydophila psittaci* *Coxiella burnetti* *Mycoplasma pneumoniae*
[$]Natural intermediate susceptibility in the absence of acquired mechanism of resistance. [£]All methicillin-resistant staphylococci are resistant to amoxicillin/clavulanic acid. [1]*Streptococcus pneumoniae* that are resistant to penicillin should not be treated with this presentation of amoxicillin/clavulanic acid (see sections 4.2 and 4.4). [2]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. Absorption of amoxicillin/clavulanic acid is optimized when taken at the start of a meal. 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 (Tmax) in each case is approximately one hour.

The pharmacokinetic results for a study, in which amoxicillin/clavulanic acid (500 mg/125 mg tablets three times daily or 875 mg/125 mg tablets given twice daily) was administered in the fasting state to groups of healthy volunteers are presented below.

Mean (±SD) pharmacokinetic parameters					
Active substance(s) administered	Dose (mg)	Cmax (µg/ml)	Tmax* (h)	AUC(0-24h) (µg.h/ml)	T1/2 (h)
Amoxicillin					
AMX/CA 500mg/125mg	500	7.19±2.26	1.5 (1.0-2.5)	53.5±8.87	1.15±0.20
AMX/CA 875mg/125mg	875	11.64±2.78	1.5 (1.0-2.5)	53.52±12.31	1.19±0.21
Clavulanic acid					
AMX/CA 500mg/125mg	125	2.40±0.83	1.5 (1.0-2.0)	15.72±3.86	0.98±0.12
AMX/CA 875mg/125mg	125	2.18±0.99	1.25 (1.0-2.0)	10.16±3.04	0.96±0.12
AMX – amoxicillin, CA – clavulanic acid *Median (range)					

Amoxicillin and clavulanic acid serum concentrations achieved with amoxicillin/clavulanic acid are similar to those produced by the oral administration of equivalent doses of amoxicillin or clavulanic acid alone.

Distribution

About 25% of total plasma clavulanic acid and 18% of total plasma amoxicillin is bound to protein. The apparent volume of distribution is around 0.3-0.4 l/kg for amoxicillin and around 0.2 l/kg for clavulanic acid.

Following intravenous administration, both amoxicillin and clavulanic acid have 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 for either component. Amoxicillin, like most penicillins, can be detected in breast milk. Trace quantities of clavulanic acid can also be detected in breast milk (see section 4.6).

Both amoxicillin and clavulanic acid have been shown to cross the placental barrier (see section 4.6).

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. Clavulanic acid is extensively metabolized in man and eliminated in urine and feces and as carbon dioxide in expired air.

Elimination

The major route of elimination for amoxicillin is via the kidney, whereas for clavulanic acid it is by both renal and non-renal mechanisms.

Amoxicillin/clavulanic acid has a mean elimination half-life of approximately one hour and a mean total clearance of approximately 25 l/h in healthy subjects. Approximately 60 to 70% of the amoxicillin and approximately 40 to 65% of the clavulanic acid are excreted unchanged in urine during the first 6 h after administration of single amoxicillin/clavulanic acid 250 mg/125 mg or 500 mg/125 mg tablets. Various studies have found the urinary excretion to be 50-85% for amoxicillin and between 27-60% for clavulanic acid over a 24 hour period. In the case of clavulanic acid, the largest amount of drug is excreted during the first 2 hours after administration.

Concomitant use of probenecid delays amoxicillin excretion but does not delay renal excretion of clavulanic acid (see section 4.5).

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 (see section 4.2).

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

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

MOXICLAV 625 mg:
- Magnesium stearate,
- cellulose microcrystalline,
- colloidal anhydrous silica,
- sodium starch glycollate,
- hydroxypropylmethyl cellulose (methocel E15)
- propylene glycol,
- polyethylene glycol,
- talc,
- titanium dioxide (E171).

MOXICLAV 1 g:
- Microcrystalline cellulose,
- sodium starch glycolate,
- colloidal anhydrous silica,
- magnesium stearate,
- Opadry II White 85G18490

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

MOXICLAV 625 mg: 36 months
MOXICLAV 1 g: 24 months

6.4. Special precautions for storage

Store below 30°C in the original package, in order to protect from light and moisture.

6.5. Nature and contents of container

MOXICLAV 625 mg: Tropicalised blisters, of aluminium-polyvinylchloride-aluminium, packs of 16 or 20 tablets with patient information leaflet are available. Available also in hospital packs of 100, 500 and 1000 tablets.

MOXICLAV 1 g: Tropicalised blisters, of aluminium-polyvinylchloride-aluminium, with 4, 7, 8 or 10 tablets. Packs of 10, 14, 16, 18 or 20 tablets with patient information leaflet are available. Available also in hospital packs of 100, 500 and 1000 tablets.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. PRODUCT REGISTRATION HOLDER
Komedic Sdn. Bhd., No. 4 Jalan PJS 11/14, Bandar Sunway, 46150 Petaling Jaya, Selangor, Malaysia

8. MANUFACTURER
Medochemie Ltd (Factory B – Oral Facility) Agios Athanassios Indusrial Area, Iapetou 48, Limassol, 4101, Cyprus

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