Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:
Medicloamp dry syrup

2. Qualitative and quantitative composition
Each 5 ml syrup contains:
Ampicillin trihydrate
equivalent to.....125 mg ampicillin
Cloxacillin sodium
equivalent to.....125mg cloxacillin.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form
Dry syrup (Powder for oral suspension)
Whitish-orange coloured, mixed granular powder, free from any visible impurities and which on reconstitution gives a coloured viscous suspension with a sweet taste and fruity flavour.

4. Clinical particulars
4.1 Therapeutic indications
Medicloamp is indicated for the treatment of the following infections in adults and children.
Respiratory Tract Infections caused by Streptococcus pneumoniae. Staphylococcus aureus (penicillinase and non-penicillinase-producing), H. influenzae, and Group A betahemolytic streptococci.

Bacterial Meningitis caused by E. coli, Group B Streptococci, and other Gram-negative bacteria (Listeria monocytogenes, N. meningitidis). The addition of an aminoglycoside with ampicillin may increase its effectiveness against Gram-negative bacteria.

Septicemia and Endocarditis caused by susceptible Gram-positive organisms including Streptococcus spp., penicillin G-susceptible staphylococci, and enterococci. Gram-negative sepsis caused by E. coli, Proteus mirabilis and Salmonella spp. responds to ampicillin. Endocarditis due to enterococcal strains usually respond to intravenous therapy. The addition of an aminoglycoside may enhance the effectiveness of ampicillin when treating streptococcal endocarditis.

Urinary Tract Infections caused by sensitive strains of E. coli and Proteus mirabilis.

Gastrointestinal Infections caused by Salmonella typhi (typhoid fever), other Salmonella spp., and Shigella spp. (dysentery) usually respond to oral or intravenous therapy.
Bacteriology studies to determine the causative organisms and their susceptibility to ampicillin should be performed. Therapy may be

instituted prior to obtaining results of susceptibility testing. It is advisable to reserve the parenteral form of this drug for moderately severe and severe infections and for patients who are unable to take the oral forms. A change to oral ampicillin may be made as soon as appropriate.
To reduce the development of drug-resistant bacteria and maintain the effectiveness of ampicillin for injection and other antibacterial drugs, ampicillin for injection should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.
Indicated surgical procedures should be performed.

4.2 Posology and method of administration

Posology

Infections of the respiratory tract and soft tissues. Patients weighing 40 kg (88 lbs) or more: 250 mg to 500 mg every 6 hours. Patients weighing less than 40 kg (88 lbs): 25 to 50 mg/kg/day in equally divided doses at 6- to 8- hour intervals. Infections of the gastrointestinal and genitourinary tracts (including those caused by Neisseria gonorrhoeae in females). Patients weighing 40 kg (88 lbs) or more: 500 mg every 6 hours. Patients weighing less than 40 kg (88 lbs): 50 mg/kg/day in equally divided doses at 6- to 8- hour intervals. In the treatment of chronic urinary tract and intestinal infections, frequent bacteriological and clinical appraisal is necessary. Smaller doses than those recommended above should not be used. Higher doses should be used for stubborn or severe infections. In stubborn infections, therapy may be required for several weeks. It may be necessary to continue clinical and/or bacteriological follow-up for several months after cessation of therapy. Urethritis in males due to N. gonorrhoeae.

Adults – Two doses of 500 mg each at an interval of 8 to 12 hours. Treatment may be repeated if necessary or extended if required. In the treatment of complications of gonorrheal urethritis, such as prostatitis and epididymitis, prolonged and intensive therapy is recommended. Cases of gonorrhea with a suspected primary lesion of syphilis should have darkfield examinations before receiving treatment. In all other cases where concomitant syphilis is suspected, monthly serological tests should be made for a minimum of four months. The doses for the preceding infections may be given by either the intramuscular or intravenous route. A change to oral ampicillin may be made when appropriate.

Bacterial Meningitis

Adults and children – 150 to 200 mg/kg/day in equally divided doses every 3 to 4 hours. (Treatment may be initiated with intravenous drip therapy and continued with intramuscular injections.) The doses for

other infections may be given by either the intravenous or intramuscular route.

Neonates (less than or equal to 28 days of postnatal age) - Dosage should be based on Gestational age and Postnatal age according to Table 1.

Table 1: Dosage in Neonates (less than or equal to 28 days of postnatal age) for Bacterial Meningitis and Septicemia

Gestational age (weeks)	Postnatal age (days)	Dosage
less than or equal to 34	less than or equal to 7	100 mg/kg/day in equally divided doses every 12 hours
less than or equal to 34	greater than or equal to 8 and less than 28	150 mg/kg/day in equally divided doses every 12 hours
greater than 34	less than or equal to 28	150 mg/kg/day in equally divided doses every 8 hours

Septicemia

Adults and children – 150 to 200 mg/kg/day. Start with intravenous administration for at least three days and continue with the intramuscular route every 3 to 4 hours.

Neonates (less than or equal to 28 days of postnatal age) - Dosage should be based on Gestational age and Postnatal age according to Table 1 (above). Treatment of all infections should be continued for a minimum of 48 to 72 hours beyond the time that the patient becomes asymptomatic, or evidence of bacterial eradication has been obtained. A minimum of 10 days treatment is recommended for any infection caused by Group A beta-hemolytic streptococci to help prevent the occurrence of acute rheumatic fever or acute glomerulonephritis.

4.3 Contraindications

Hypersensitivity to the active substance, to any of the penicillins or to any of the excipients listed in section 6.1. of the SPC. History of a severe immediate hypersensitivity reaction (e.g., anaphylaxis) to another betalactam 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 (see sections 4.3 and 4.8). 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 (see section 5.1). 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 (see section 4.8).

Renal impairment

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

Skin reactions

The occurrence at the treatment initiation of a feverish generalised erythema associated with pustula may be a symptom of acute generalised exanthemous pustulosis (AGEP, see section 4.8). 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 (see section 4.8). 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 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 (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 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 (see section 4.8).

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 (see section 4.5 and 4.8).

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 (see section 4.8 and 4.9).

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 aspartame, a source of phenylalanine. This medicine should be used with caution in patients with phenylketonuria.

This medicinal product contains maltodextrin (glucose). Patients with rare glucosegalactose malabsorption 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 new born babies.

4.5 Interaction with other medicinal products and other forms of interaction

The concurrent administration of allopurinol and ampicillin increases substantially the incidence of skin rashes in patients receiving both drugs as compared to patients receiving ampicillin alone. It is not known whether this potentiation of ampicillin rashes is due to allopurinol or the hyperuricemia present in these patients.

Drug/Laboratory Test Interactions With high urine concentrations of ampicillin, false-positive glucose reactions may occur if Clinitest, Benedict's Solution, or Fehling's Solution are used. Therefore, it is recommended that glucose tests based on enzymatic glucose oxidase reactions (such as Clinistix or Tes-Tape) be used. Carcinogenesis, Mutagenesis, and Impairment of Fertility No long-term animal studies have been conducted with this drug.

4.6 Pregnancy and Lactation

Reproduction studies have been performed in laboratory animals at doses several times the human dose and have revealed no evidence of adverse effects due to ampicillin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery

Oral ampicillin-class antibiotics are poorly absorbed during labor. Studies in guinea pig showed that intravenous administration of ampicillin slightly decreased the uterine tone and frequency of contractions, but moderately increased the height and duration of contractions. However, it is not known whether use of these drugs in humans during labor or delivery has immediate or delayed adverse effects on the foetus, prolongs the duration of labor, or increases the likelihood that forceps delivery or other obstetrical intervention or resuscitation of the new-born will be necessary.

Nursing Mothers

Ampicillin is excreted in trace amounts in human milk. Therefore, caution should be exercised when ampicillin-class antibiotics are administered to a nursing woman

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 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 (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥1/10,000 to <1/1,000)
Very rare (≥1/10,000)
Not Known (cannot be estimated from the available data

Infections and infestations	
Very rare	Mucocutaneous candidiasis
Blood and lymphatic system disorders	
Very rare	Reversible leucopenia (including severe neutropenia or agranulocytosis), reversible thrombocytopenia and haemolytic anaemia. Prolongation of bleeding time and prothrombin time (see section 4.4).
Immune system disorders	

Very rare	Severe allergic reactions, including angioneurotic oedema, anaphylaxis, serum sickness and hypersensitivity vasculitis (see section 4.4).
Not known	Jarisch-Herxheimer reaction (see section 4.4).
Nervous system disorders	
Very rare	Hyperkinesia, dizziness and convulsions (see section 4.4).

Gastrointestinal disorders	
Clinical Trial Data	
*Common	Diarrhoea and nausea
*Uncommon	Vomiting
Post-marketing Data	
Very rare	Antibiotic associated colitis (including pseudomembraneous colitis and haemorrhagic colitis see section 4.4). Black hairy tongue Superficial tooth discolouration[#]
Hepatobiliary disorders	
Very rare	Hepatitis and cholestatic jaundice. A moderate rise in AST and/or ALT.
Skin and subcutaneous tissue disorders	
Clinical Trial Data	
*Common	Skin rash
*Uncommon	Urticaria and pruritus
Post-marketing Data	
Very rare	Skin reactions such as erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous and exfoliative dermatitis, acute generalised exanthematous pustulosis (AGEP) (see section 4.4), and drug reaction with eosinophilia and systemic symptoms (DRESS).
Renal and urinary tract disorders	

Very rare:	Interstitial nephritis Crystalluria (see sections 4.4 and 4.9 Overdose)
* The incidence of these AEs was derived from clinical studies involving a total of approximately 6,000 adult and paediatric patients taking amoxicillin. # 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.	

Reporting of suspected adverse reactions
Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS)
https://pv.pharmacyboardkenya.org

4.9 Overdose

In cases of overdose, discontinue medication, treat symptomatically, and institute supportive measures as required. In patients with renal function impairment, ampicillinclass antibiotics can be removed by hemodialysis but not peritoneal dialysis.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: penicillins with extended spectrum; ATC code: J01CA01.
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 main mechanisms of resistance to amoxicillin are:
• Inactivation by bacterial beta-lactamases.
• 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 are those of the European Committee on Antimicrobial Susceptibility Testing (EUCAST) version 5.0.

Organism	**MIC breakpoint (mg/L)**	
	Susceptible ≤	**Resistant >**
Enterobacteriaceae	81	8
Staphylococcus spp.	Note[2]	Note [2]
Enterococcus spp.[3]	4	8
Streptococcus groups A, B, C and G	Note [4]	Note [4]
Streptococcus pneumoniae	Note [5]	Note [5]
Viridans group steprococci	0.5	2
Haemophilus influenzae	26	26
Moraxella catarrhalis	Note [7]	Note [7]
Neisseria meningitidis	0.125	1
Gram positive anaerobes except *Clostridium difficile*[8]	4	8
Gram negative anaerobes[8]	0.5	2
Helicobacter pylori	0.125[9]	0.125[9]
Pasteurella multocida	1	1
Non- species related breakpoints[10]	2	8

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 ≤ 0.5 mg/L 2 Most staphylococci are penicillinase producers, which are resistant to amoxicillin. Methicillin resistant isolates are, with few exceptions, resistant to all beta-lactam agents. 3 Susceptibility to amoxicillin can be inferred from ampicillin. 4 The susceptibility of streptococcus groups A, B, C and G to penicillins is inferred from the benzylpenicillin susceptibility. 5 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. 6 Breakpoints are based on intravenous administration. Beta-lactamase positive isolates should be reported resistant. 7 Beta lactamase producers should be reported resistant. 8 Susceptibility to amoxicillin can be inferred from benzylpenicillin. 9 The breakpoints are based on epidemiological cut-off values (ECOFFs), which distinguish wild-type isolates from those with reduced susceptibility. 10The non-species related breakpoints are based on doses of at least 0.5 g x 3or 4 doses daily (1.5 to 2 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.

In vitro susceptibility of micro-organisms to Amoxicillin
Commonly Susceptible Species
Gram-positive aerobes:
Enterococcus faecalis Beta-hemolytic streptococci (Groups A, B, C and G)
Listeria monocytogenes
Species for which acquired resistance may be a problem
Gram-negative aerobes:
Escherichia coli
Haemophilus influenzae
Helicobacter pylori
Proteus mirabilis
Salmonella typhi
Salmonella paratyphi
Pasteurella multocida
Gram-positive aerobes:
Coagulase negative staphylococcus
Staphylococcus aureus£
Streptococcus pneumoniae
Viridans group streptococcus
Gram-positive anaerobes:
Clostridium spp.
Gram-negative anaerobes:
Fusobacterium spp.
Other:
Borrelia burgdorferi
Inherently resistant organisms
Gram-positive aerobes:
Enterococcus faecium†
Gram-negative aerobes:
Acinetobacter spp.
Enterobacter spp.
Klebsiella spp.
Pseudomonas spp.
Gram-negative anaerobes:
Bacteroides spp. (many strains of Bacteroides fragilis are resistant).
Others:
Chlamydia spp.
Mycoplasma spp.
Legionella spp.
Natural intermediate susceptibility in the absence of acquired mechanism of resistance.
Almost all S.aureus are resistant to amoxilcillin due to production of penicillinase. In addition, all methicillin-resistant strains are resistant to amoxicillin.

5.2 Pharmacokinetic properties

Ampicillin for injection diffuses readily into most body tissues and fluids. However, penetration into the cerebrospinal fluid and brain occurs only when the meninges are inflamed. Ampicillin is excreted largely unchanged in the urine and its excretion can be delayed by concurrent administration of probenecid. Due to maturational changes in renal function, ampicillin half-life decreases as postmenstrual age (a sum of gestational age and postnatal age) increases for infants with postnatal age of less than 28 days. The active form appears in the bile in higher concentrations than those found in serum. Ampicillin is the least serum-bound of all the penicillins, averaging about 20% compared to approximately 60 to 90% for other penicillins. Ampicillin for injection is well-tolerated by most patients and has been given in doses of 2 grams daily for many weeks without adverse reactions.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction and development. Carcinogenicity studies have not been conducted with amoxicillin.

6 Pharmaceutical Particulars

6.1 List of Excipients

Sucrose
Sucrose
(Crushed –Fine)
Sodium benzoate
Sodium Saccharin
Disodium Edetate (EDTA)
Sodium citrate
Vanilla Flavour Dry
Sunset Yellow FD & C Yellow 6 Colour (E110)
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf-Life

Dry powder: 24 months
Reconstituted suspension: 7 days
Reconstituted suspensions: Refrigerator

6.4 Special Precautions for storage

Store below 30°C, in a dry place. Protect from light.

6.5 Nature and Content of container

Glass bottles 100ml Amber
ROPP CAPS 25 mm
Plastic Measuring Cup 10ml (25mm)

6.6 Special precautions for disposal and other handling

Read package insert before use.

7 Marketing Authorization Holder

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8 Marketing Authorization Number

H88324

9 Date of first authorization/renewal of the authorization

February 2026

10 Date of revision of the text

01/02/2026