SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

CLAV 1 GM

2. Qualitative and quantitative composition

Each Film Coated Tablet Contains:

Amoxicillin Trihydrate BP

Eq. to Amoxicillin.....875 Mg.

Clavulanate Potassium BP (As diluted potassium Clavulanate)

Eq. to Clavulanic Acid..... 125 Mg.

For Full list of Excipients, See Section 6.1.

3. Pharmaceutical form

A white colored, capsule shaped, film coated tablets having one side break line and other sides plain.

4. Clinical particulars

4.1 Therapeutic indications

Amoxicillin and Clavulanate Potassium Tablets 875 mg/125 mg is a broad-spectrum antibacterial combination consisting of the semi-synthetic penicillin amoxicillin and the beta-lactamase inhibitor clavulanic acid. It exhibits bactericidal activity against a wide range of Gram-positive and Gram-negative microorganisms, including beta-lactamase producing strains.

It is indicated for the treatment of the following infections when caused by susceptible organisms: Upper Respiratory Tract Infections (URTI): e.g. sinusitis, tonsillitis, pharyngitis, otitis media.
Lower Respiratory Tract Infections: e.g. acute exacerbations of chronic bronchitis, community-acquired pneumonia.
Urinary Tract Infections: e.g. cystitis, pyelonephritis.

Skin and Soft Tissue Infections: e.g. cellulitis, wound infections, animal bites. Dental Infections: e.g. severe dental abscess with spreading cellulitis.

Bone and Joint Infections: e.g. osteomyelitis.

Clinical efficacy has been demonstrated in infections caused by commonly occurring pathogens including Streptococcus pneumoniae, Streptococcus pyogenes, Staphylococcus aureus (methicillin-sensitive strains), Haemophilus influenzae, Moraxella catarrhalis, Escherichia coli, Klebsiella species, Proteus mirabilis, and anaerobic organisms

susceptible to the combination.

The clavulanic acid component protects amoxicillin from degradation by many beta-lactamase enzymes and extends the antibacterial spectrum.

Methicillin-resistant Staphylococcus aureus (MRSA), Pseudomonas aeruginosa, Enterobacter species producing inducible beta-lactamases, and atypical pathogens are generally resistant.

4.2 Posology & Method of Administration

Posology

Doses are expressed throughout in terms of amoxicillin/clavulanic acid content except when doses are stated in terms of an individual component.

The dose of Co-amoxiclav that is selected to treat an individual infection should take into account:

The expected pathogens and their likely susceptibility to antibacterial agents (see section 4.4)

The severity and the site of the infection

The age, weight and renal function of the patient as shown below.

The use of alternative presentations of amoxicillin/clavulanic acid (e.g. those that provide higher doses of amoxicillin and/or different ratios of amoxicillin to clavulanic acid) should be considered as necessary (see sections 4.4 and 5.1).

For adults and children ≥ 40 kg, this formulation of Co-amoxiclav provides a total daily dose of 1750 mg amoxicillin/250 mg clavulanic acid with twice daily dosing and 2625 mg amoxicillin/375 mg clavulanic acid with three times daily dosing, when administered as recommended below. For children < 40 kg, this formulation of Co-amoxiclav provides a maximum daily dose of 1000-2800 mg amoxicillin/143-400 mg clavulanic acid, when administered as recommended below. If it is considered that a higher daily dose of amoxicillin is required, it is recommended that another preparation of amoxicillin/clavulanic acid is selected in order to avoid administration of unnecessarily high daily doses of clavulanic acid (see sections 4.4 and 5.1).

The duration of therapy should be determined by the response of the patient. Some infections (e.g. osteomyelitis) require longer periods of treatment. Treatment should not be extended beyond 14 days without review (see section 4.4 regarding prolonged therapy).

Adults and children ≥ 40 kg

Recommended doses:

• standard dose: (for all indications) 875 mg/125 mg two times a day;

• higher dose - (particularly for infections such as otitis media, sinusitis, lower respiratory tract infections and urinary tract infections): 875 mg/125 mg three times a day.

Children < 40 kg

Children may be treated with Co-Amoxiclav tablets, suspensions or paediatric sachets.

Recommended doses:

• 25 mg/3.6 mg/kg/day to 45 mg/6.4 mg/kg/day given as two divided doses.

• up to 70 mg/10 mg/kg/day given as two divided doses may be considered for some infections (such as otitis media, sinusitis and lower respiratory tract infections).

As the tablets cannot be divided children weighing less than 25 kg must not be treated with Co-Amoxiclav tablets.

The table below presents the received dose (mg/kg body weight) in children weighing 25 kg to 40 kg upon administering a single 875 mg/125 mg tablet.

Body weight [kg]	40	35	30	25	Single dose recommended [mg/kg body weight] (see above)
Amoxicillin [mg/kg body weight] per single dose (1 film-coated tablet)	21.9	25.0	29.2	35.0	12.5 – 22.5 (up to 35)
Clavulanic acid [mg/kg body weight] per single dose (1 filmcoated tablet)	3.1	3.6	4.2	5.0	1.8 – 3.2 (up to 5)

Children weighing less than 25 kg should preferably be treated with Co-Amoxiclav suspension or paediatric sachets.

No clinical data are available on doses of amoxicillin/clavulanic acid 7:1 formulations regarding doses higher than 45 mg/6.4 mg/kg per day in children under 2 years.

There are no clinical data for amoxicillin/clavulanic acid 7:1 formulations for patients under 2 months of age. Dosing recommendations in this population therefore cannot be made.

Elderly

No dose adjustment is considered necessary.

Renal impairment

No adjustment in dose is required in patients with creatinine clearance (CrCl) greater than 30 ml/min.

In patients with creatinine clearance less than 30 ml/min, the use of Co-Amoxiclav presentations with an amoxicillin to clavulanic acid ratio of 7:1 is not recommended, as no recommendations for dose adjustments are available.

Hepatic impairment

Dose with caution and monitor hepatic function at regular intervals (see sections 4.3 and 4.4).

Method of administration
Oral use
Film-coated tablets should be swallowed whole with water.

To minimize potential gastrointestinal intolerance, administer at the start of a meal.

Frequency of administration

To maintain effective antibacterial concentrations:

administer twice daily at approximately 12-hour intervals

doses should be taken regularly throughout the prescribed treatment course

4.3 Contraindications

Hypersensitivity to amoxicillin, clavulanic acid, penicillins, cephalosporins or to any of the excipients listed in section 6.1.

History of severe immediate hypersensitivity reaction (e.g. anaphylaxis) to another beta-lactam antibacterial agent.

History of amoxicillin/clavulanic acid-associated jaundice or hepatic dysfunction.

The product should not be administered to patients with suspected infectious mononucleosis because of the increased risk of morbilliform rash.

4.4 Special warnings and precautions for use

Serious and occasionally fatal hypersensitivity reactions (including anaphylaxis) have been reported in patients receiving penicillins.
Before initiating therapy, careful inquiry should be made concerning previous hypersensitivity reactions to beta-lactams.
Severe cutaneous adverse reactions including: • Stevens–Johnson syndrome • toxic epidermal necrolysis

• acute generalized exanthematous pustulosis (AGEP) • drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported.
If allergic reactions occur, treatment must be discontinued immediately.

Hepatic reactions

Hepatic events have been reported predominantly in males and elderly patients and may be associated with prolonged treatment.
Signs and symptoms may occur during or shortly after treatment but in some cases may not become apparent until several weeks after therapy has ceased.

Gastrointestinal reactions

Antibiotic-associated colitis, including Clostridioides difficile-associated diarrhoea, has been reported and may range from mild to life-threatening.
Use with caution in patients with: • gastrointestinal disease
• history of colitis Persistent severe diarrhoea should be investigated promptly.

Precautions for use

Use with caution in patients with: • renal impairment • hepatic dysfunction • history of seizures • impaired urinary output
Prolonged use may occasionally result in overgrowth of non-susceptible organisms including fungi. Crystalluria has been reported rarely, predominantly with parenteral therapy. Adequate fluid intake and urinary output should be maintained.

Concomitant medicinal products

Caution is advised when administered with: • oral anticoagulants – monitor INR/prothrombin time • methotrexate – possible increased toxicity • allopurinol – increased risk of allergic skin reactions • probenecid – decreases renal tubular secretion of amoxicillin

Warnings related to excipients

Microcrystalline cellulose and crospovidone may rarely cause gastrointestinal

discomfort in sensitive individuals.

Magnesium stearate and silicon dioxide are generally well tolerated but may rarely cause hypersensitivity reactions.

Residual processing solvents such as isopropyl alcohol and methylene dichloride are controlled within acceptable pharmaceutical limits during manufacture.

4.5 Interaction with other medicinal products and other forms of interaction Anticoagulants / Antithrombotic agents

1. Warfarin and other oral anticoagulants • Prolongation of prothrombin time and INR has been reported. • Monitor coagulation parameters during co-administration.

Drugs affecting renal elimination

2. Probenecid • Reduces renal tubular secretion of amoxicillin. • Concurrent use is not recommended.
3. Methotrexate • Penicillins may reduce methotrexate excretion and increase toxicity.

Drugs associated with hypersensitivity reactions

4. Allopurinol • Concurrent administration may increase likelihood of allergic skin reactions.

Other interactions

5. Oral contraceptives • Broad-spectrum antibiotics may reduce efficacy of combined oral contraceptives. • Additional contraceptive precautions may be considered.

4.6 Fertility, pregnancy and lactation

Pregnancy

Limited data on the use of amoxicillin/clavulanic acid during pregnancy do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development.

Use during pregnancy should be avoided unless considered essential by the physician.

Use in premature rupture of fetal membranes may be associated with an increased risk of neonatal necrotizing enterocolitis.

Breastfeeding

Amoxicillin and clavulanic acid are excreted into breast milk in small quantities.

Possible effects in the breastfed infant include diarrhoea, candidiasis and hypersensitivity reactions.

Amoxicillin/clavulanate may be used during breastfeeding after assessment of benefit and risk.

Fertility

Animal studies do not indicate harmful effects with respect to fertility. No human data are available regarding effects on fertility.

4.7 Effects on ability to drive and use machines

Undesirable effects such as dizziness, allergic reactions or convulsions may occur and may influence the ability to drive or operate machines.

Patients should avoid driving or operating hazardous machinery if affected.

4.8 Undesirable effects

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 (≥ 10,000 to <1/1,000) Very rare (<1/10,000) Not known (cannot be estimated from the available data) **Infections and infestations**

• Common: mucocutaneous candidiasis • Uncommon: overgrowth of non-susceptible organisms

Blood and lymphatic system disorders

• Rare: reversible leukopenia, thrombocytopenia • Very rare: haemolytic anaemia, prolonged bleeding time

Immune system disorders

• Rare: angioedema, serum sickness-like reactions • Very rare: anaphylaxis, severe hypersensitivity reactions

Nervous system disorders

• Uncommon: dizziness, headache • Very rare: convulsions, hyperactivity

Gastrointestinal disorders

• Very common: diarrhoea • Common: nausea, vomiting • Uncommon: dyspepsia • Very rare: antibiotic-associated colitis including pseudomembranous colitis

Hepatobiliary disorders

• Uncommon: moderate rise in AST and/or ALT • Rare: hepatitis, cholestatic jaundice

Skin and subcutaneous tissue disorders

• Common: skin rash, pruritus, urticaria • Rare: erythema multiforme • Very rare: Stevens–Johnson syndrome, toxic epidermal necrolysis, AGEP

Renal and urinary disorders

• Rare: interstitial nephritis • Very rare: crystalluria

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 pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose Symptoms

Overdose may lead to: • gastrointestinal symptoms including nausea, vomiting and diarrhoea • fluid and electrolyte imbalance • crystalluria which may progress to renal failure • CNS effects including convulsions in predisposed patients

Management

There is no specific antidote.

Management includes: • symptomatic and supportive treatment • maintenance of adequate hydration • monitoring of renal function and electrolyte balance • haemodialysis may assist in removal of amoxicillin/clavulanic acid

Patients should remain under clinical observation until recovery.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Penicillins in combination with beta-lactamase inhibitors ATC code: J01CR02

Amoxicillin/Clavulanic acid is a combination antibacterial product consisting of amoxicillin, a broad-spectrum semisynthetic penicillin, and clavulanic acid, a beta-lactamase inhibitor. Amoxicillin exerts bactericidal activity by inhibiting bacterial cell wall synthesis through binding to penicillin-binding proteins (PBPs), leading to bacterial cell lysis and death.

Clavulanic acid possesses only weak intrinsic antibacterial activity but irreversibly inhibits a wide range of clinically important beta-lactamases, thereby protecting amoxicillin from enzymatic degradation and extending its antibacterial spectrum.

The combination is active against a wide range of Gram-positive and Gram-negative organisms, including Streptococcus pneumoniae, Streptococcus pyogenes, Staphylococcus aureus (methicillin-sensitive strains), Haemophilus influenzae, Moraxella catarrhalis, Escherichia coli, Klebsiella species, Proteus mirabilis, and Enterococcus faecalis.

Resistance may occur through production of beta-lactamases not inhibited by clavulanic acid, alteration of PBPs, reduced permeability to antibacterial agents, or active efflux mechanisms. Methicillin-resistant staphylococci and most strains of Pseudomonas aeruginosa are resistant to the combination.

5.2 Pharmacokinetic properties

Absorption

Amoxicillin and clavulanic acid are rapidly and well absorbed following oral administration. Peak plasma concentrations are generally achieved within

1–2 hours after dosing. Oral bioavailability of both components is approximately 60–70%.
Administration at the start of a meal enhances clavulanic acid absorption and improves gastrointestinal tolerability.

Distribution

Both amoxicillin and clavulanic acid are widely distributed throughout body tissues and fluids, including lung tissue, middle ear fluid, pleural fluid, bile, and urine.
Plasma protein binding is approximately 18% for amoxicillin and 25% for clavulanic acid. Both components cross the placenta and are excreted in breast milk in small amounts.

Metabolism

Amoxicillin is partially metabolised to inactive penicilloic acid derivatives, while clavulanic acid undergoes extensive hepatic metabolism to inactive metabolites. The metabolites are eliminated via renal, biliary, and pulmonary routes.

Elimination

Amoxicillin and clavulanic acid are eliminated primarily by renal excretion. Approximately 60–70% of amoxicillin and 40–65% of clavulanic acid are excreted unchanged in the urine within the first 6 hours after administration. The elimination half-life of both components is approximately 1 hour in healthy adults and may be prolonged in patients with renal impairment.

5.3 Preclinical safety data

Preclinical studies with amoxicillin and clavulanic acid revealed no special hazards for humans based on conventional studies of safety pharmacology, repeated-dose toxicity, genotoxicity, and reproductive toxicity.

Animal studies demonstrated that high doses may produce gastrointestinal disturbances and reversible renal effects consistent with the pharmacological properties of beta-lactam antibiotics. Reproductive studies showed no evidence of teratogenicity or impairment of fertility.

Clavulanic acid has shown no significant mutagenic or carcinogenic potential in standard preclinical studies. As with other beta-lactam antibacterial agents, hypersensitivity reactions may occur in susceptible individuals.

6 Pharmaceutical particulars

6.1 List of excipients

MCCP, Colloidal Silicon dioxide, Cross Povidone XL, Magnesium Stearate, Silicon dioxide, Seal Coat White, Film

Coat White, IPA, Methylene dichloride

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C and protect from light.

6.5 Nature and contents of container

10 tablets packed in a blister. Such 10 blisters packed in a carton with package insert.Special precautions for disposal and other handling

No special requirements.

7. Marketing Authorization Holder

LEXINE TECHNOCHEM
PVT. LTD.
Opp Ramakaka
Deri, Chhani,
Vadodara- 391 740,
Gujarat, India.

8. Marketing authorisation number(s)

H 2016/ CTD 2159/ 061

9. Date of first authorisation/renewal of the authorisation

N/A

10. Date of revision of the text

05/08/2026