Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

E-MOXCLAV 228.5 mg/ 5 ml Dry Mix

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Amoxycillin trihydrate 229.55 mg Equivalent to Amoxycillin 200 mg
Potassium clavulanate with syloid (1:1) 67.9 mg Clavulanic acid 28.5 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for oral suspension.

Homogenous powder gives homogenous suspension after reconstitution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

• Ear, nose and throat infections: e.g. otitis media, sinusitis, tonsillitis.

• Lower respiratory tract infections: e.g. acute and chronic bronchitis, pneumonia.

• Genito-urinary tract infections: e.g. cystitis, pyelonephritis, urethritis, gonorrhoea.

• Skin and soft tissue infections: e.g. Boils, abscesses, cellulitis, wound infections.

• Bone and joint infections: e.g. osteomyelitis.

• Gastro-intestinal tract infections: e.g. enteritis, typhoid and paratyphoid fevers.

• Other infections:

- Peritonitis, post-operative infections, endocarditis, septicaemia, biliary tract infections,

and chancroid.

- Septic abortion, pelvic or puerperal sepsis, intra-abdominal sepsis.

- Animal bites, severe dental abscess with spreading cellulitis.

4.2 Posology and method of administration

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

Method of administration

E-MOXCLAV® Tablets and Oral Suspension may be given without regard to meals.

Adults: Usual Dose for Mild – Moderate Infections: One E-MOXCLAV® 375 mg Tablet every 8 hours.

For Severe Infections and For Respiratory Tract Infections: One E-MOXCLAV® 625 mg Tablet every 8 hours or One E-MOXCLAV® 1 gm Tablet every 12 hours.

Renal function impairment: Renal function impairment generally does not require a dose reduction unless impairment is severe. In mild renal impairment (creatinine clearance > 30 ml/minute), no dosage adjustment is necessary. E-MOXCLAV® 1 gm Tablets should only be used in patients with mild impairment without change in dosage. It should not be used in moderate or severe renal impairment.

In moderate renal impairment (creatinine clearance 10 – 30 ml/minute), the adult dose is One E-MOXCLAV® 375 mg Tablet or One E-MOXCLAV® 625 mg Tablet every 12 hours, depending on the severity of infection.

In severe renal impairment (creatinine clearance less than 10 ml /minute), the adult dose is not more than One E-MOXCLAV® 375 mg Tablet or One E-MOXCLAV® 625 mg Tablet every 24 hours, depending on the severity of infection.

In haemodialysis patients: One E-MOXCLAV® 375 mg Tablet or One E-MOXCLAV® 625 mg Tablet every 24 hours, and an additional dose during and at the end of dialysis.

Children: Children 7 – 12 years: 1 teaspoonsful E-MOXCLAV® 312 mg Oral Suspension every 8 hours; or 2 teaspoonfuls E-MOXCLAV® 156 mg Oral Suspension every 8 hours; or 1 teaspoonsful E-MOXCLAV® 457 mg Oral Suspension every 12 hours; or 2 teaspoonfuls E-MOXCLAV® 228.5 mg Oral Suspension every 12 hours.

Children 2 – 7 years: 1 teaspoonful E-MOXCLAV® 156 mg Oral Suspension every 8 hours or 1 teaspoonful E-MOXCLAV® 228.5 mg Oral Suspension every 12 hours.

Children 9 months – 2 years: ½ teaspoonful E-MOXCLAV® 156 mg Oral Suspension every 8 hours or ½ teaspoonful E-MOXCLAV® 228.5 mg Oral Suspension every 12 hours. In severe infections, these dosages may be

doubled.

Another method of calculating children's dose based on amoxycillin content is as follows:

Children < 3 months of age: 30 mg/kg/day divided every 12 hours, based on the amoxycillin content. Use of E-MOXCLAV®156 mg / 5 ml Oral Suspension is recommended.

Children 3 months of age or older: E-MOXCLAV® 156 mg/5 ml or 312 mg/5 ml oral suspension: 20 – 40 mg/kg/day divided every 8 hours. E-MOXCLAV® 228.5 mg/5 ml or 457 mg/5 ml oral suspension: 25-45 mg/kg/day divided every 12 hours.

Children 40 kg: Dose according to adult recommendations.

Reconstitution of E-MOXCLAV® Dry Mix: To make up, first shake the bottle to loosen powder, then add water, to the content of bottle and shake well. Fill up to line and allow to stand for 5 minutes to ensure full dispersion. Shake well before use. After reconstitution, E-MOXCLAV® Oral Suspension should be stored in a refrigerator and used only within 10 days.

4.3 Contraindications

E-MOXCLAV is contraindicated in patients with a history of hypersensitivity to beta-lactams, e.g. penicillins and cephalosporins.

E-MOXCLAV is contraindicated in patients with a previous history of *E-MOXCLAV*-associated jaundice/hepatic dysfunction.

4.4 Special warnings and precautions for use

Before initiating therapy with *E-MOXCLAV*, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other allergens.

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 (see *section 4.3*). Hypersensitivity reactions can also progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction. Presenting symptoms of such reactions can include chest pain occurring in association with an allergic reaction to *E-MOXCLAV* (see *section 4.8*). Drug-induced enterocolitis syndrome has been reported mainly in children receiving *E-MOXCLAV* (see *section 4.8*). Drug-induced enterocolitis syndrome is an allergic reaction with the leading symptom of protracted vomiting (1-4 hours after medicinal product administration) in the absence of allergic skin or respiratory symptoms. Further symptoms could comprise abdominal pain, lethargy, diarrhoea, hypotension or leucocytosis with neutrophilia. In severe cases, drug-induced enterocolitis syndrome can progress to shock. If an allergic reaction occurs, *E-MOXCLAV* therapy should be discontinued and appropriate alternative therapy instituted.

Serious anaphylactic reactions require immediate emergency treatment with adrenaline. Oxygen, intravenous (i.v.) steroids and airway management, including intubation may also be required.

Haemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS) has been reported in patients receiving amoxicillin/clavulanate (see *section 4.8*).
HLH/MAS is a syndrome of pathological immune activation, which can be life-threatening. Clinical signs and symptoms of HLH/MAS include fever, rash, neurological symptoms, hepatosplenomegaly, lymphadenopathy, cytopenias, high serum ferritin, hypertriglyceridaemia and abnormalities of liver function and coagulation.

Patients who develop these signs and symptoms should be immediately evaluated and HLH/MAS diagnosis considered. *E-MOXCLAV* therapy should be discontinued unless an alternative aetiology for HLH/MAS can be established.

E-MOXCLAV 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.

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

Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. If prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further.

Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving *E-MOXCLAV* and oral anticoagulants. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation.

Changes in liver function tests have been observed in some patients receiving *E-MOXCLAV*. The clinical significance of these changes is uncertain but *E-MOXCLAV* should be used with caution in patients with evidence of hepatic dysfunction.

Cholestatic jaundice, which may be severe, but is usually reversible, has been reported rarely. Signs and symptoms may not become apparent for up to six weeks after treatment has ceased.

In patients with renal impairment *E-MOXCLAV* dosage should be adjusted as recommended in the *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 in order to reduce the possibility of amoxicillin crystalluria *(*see *section 4.9).*

E-MOXCLAV suspensions contain 12.5 mg aspartame per 5 mL dose, which is a source of phenylalanine and so should be used with caution in patients with phenylketonuria.

4.5 Interaction with other medicinal products and other forms of interactions

Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin. Concomitant use with *E-MOXCLAV* may result in increased and prolonged blood levels of amoxicillin, but not of clavulanic acid.

Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions. There are no data on the concomitant use of *E-MOXCLAV* and allopurinol.

In common with other antibiotics, *E-MOXCLAV* may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.

In the literature, there are rare cases of increased international normalised ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of *E-MOXCLAV*.

In patients receiving mycophenolate mofetil, reduction in pre-dose concentration of the active metabolite mycophenolic acid 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.

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

4.6 Fertility, pregnancy, and lactation

Reproduction studies in animals (mice and rats at doses up to 10 times the human dose) with orally and parenterally administered *E-MOXCLAV* have shown no teratogenic effects. In a single study in women with pre-term, premature rupture of the foetal membrane (pPROM), it was reported that prophylactic treatment with *E-MOXCLAV* may be associated with an increased risk of necrotising enterocolitis in neonates. As with all medicines, use should be avoided in pregnancy, especially during the first trimester, unless considered essential by the physician.

E-MOXCLAV may be administered during the period of lactation. With the exception of the risk of sensitisation, associated with the excretion of trace quantities in breast milk, there are no known detrimental effects for the breast-fed infant.

4.7 Effects on ability to drive and use machines

Adverse effects on the ability to drive or operate machinery have not been observed.

4.8 Undesirable effects

Data from large clinical trials was used to determine the frequency of very common to rare undesirable effects. The frequencies assigned to all other undesirable effects (i.e. those occurring at < 1/10,000) were mainly determined using post-marketing data and refer to a reporting rate rather than a true frequency.

The following convention has been used for the classification of frequency: 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.

Infections and infestations

Common Mucocutaneous candidiasis

Blood and lymphatic system disorders

Rare Reversible leucopenia (including neutropenia) and thrombocytopenia.

Very rare Reversible agranulocytosis and haemolytic anaemia. Prolongation of bleeding time and prothrombin time.

Immune system disorders

Very Rare Haemophagocytic lymphohistiocytosis/macrophage activation syndrome, anaphylaxis, angioneurotic oedema (see *section 4.4*), serum sickness-like syndrome, hypersensitivity vasculitis (see also *Skin and subcutaneous tissue disorders*).

Nervous system disorders

Uncommon Dizziness, headache

Very rare Reversible hyperactivity, aseptic meningitis, convulsions. Convulsions may occur in patients with impaired renal function or in those receiving high doses.

Cardiac disorders

Very rare Kounis syndrome (see *section 4.4*).

Gastrointestinal disorders

Adults

Very common Diarrhoea
Common Nausea, vomiting ***Children***

Common	Diarrhoea, nausea, vomiting

All populations

Nausea is more often associated with higher oral dosages. If gastrointestinal reactions are evident, they may be reduced by taking *E-MOXCLAV* at the start of a meal.

Uncommon	Indigestion
Very rare	Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis), drug-induced enterocolitis syndrome (see *section 4.4*).
	Black hairy tongue
	Superficial tooth discolouration has been reported very rarely in children. Good oral hygiene may help to prevent tooth discolouration as it can usually be removed by brushing**.**

Hepatobiliary disorders

Uncommon	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.
Very rare	Hepatitis and cholestatic jaundice. These events have been noted with other penicillins and cephalosporins.

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.

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.

Skin and subcutaneous tissue disorders	Uncommon Skin rash, pruritus, urticaria Rare Erythema multiforme
Very rare	Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous exfoliative-dermatitis, acute generalised exanthemous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS), and symmetrical drug-related intertriginous and flexural exanthema (SDRIFE) (baboon syndrome) (see also *Immune system disorders*).
	If any hypersensitivity dermatitis reaction occurs, treatment should be discontinued.

Linear IgA disease.

Renal and urinary disorders

Very rare Interstitial nephritis, crystalluria *(*see *section 4.9)*

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

Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. Gastrointestinal symptoms may be treated symptomatically with attention to the water electrolyte balance.

Amoxicillin crystalluria, in some cases leading to renal failure, has been observed *(*see *section 4.4).*

E-MOXCLAV can be removed from the circulation by haemodialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: J01CR02.
Pharmacotherapeutic group: Combinations of penicillins, incl. beta-lactamase inhibitors.

Resistance to many antibiotics is caused by bacterial enzymes which destroy the antibiotic before it can act on the pathogen. The clavulanate in *E-MOXCLAV* anticipates this defence mechanism by blocking the beta-lactamase enzymes, thus rendering the organisms susceptible to amoxicillin's rapid bactericidal effect at concentrations readily attainable in the body.

Clavulanate by itself has little antibacterial activity; however, in association with amoxicillin as *E-MOXCLAV* it produces an antibiotic agent of broad-spectrum with wide application in hospital and general practice.

In the list below, organisms are categorised according to their *in vitro* susceptibility to *E-MOXCLAV*.

In vitro* susceptibility of micro-organisms to *E-MOXCLAV
Where clinical efficacy of *E-MOXCLAV* has been demonstrated in clinical trials this is indicated with an asterisk (*). Organisms that do not produce beta-lactamase are identified (with †). If an isolate is susceptible to amoxicillin, it can be considered susceptible to *E-MOXCLAV.*
C**ommonly susceptible species**

Gram-positive aerobes:
Bacillius anthracis
Enterococcus faecalis

Listeria monocytogenes *Nocardia asteroides* *Streptococcus pyogenes**† *Streptococcus agalactiae**† *Streptococcus* spp. (other beta-hemolytic)*† *Staphylococcus aureus* (methicillin susceptible)* *Staphylococcus saprophyticus* (methicillin susceptible) Coagulase negative staphylococcus (methicillin susceptible)
Gram-negative aerobes: *Bordetella pertussis Haemophilus influenzae** *Haemophilus parainfluenzae* *Helicobacter pylori* *Moraxella catarrhalis** *Neisseria gonorrhoeae* *Pasteurella multocida* *Vibrio cholerae*
Other: *Borrelia burgdorferi* *Leptospira ictterohaemorrhagiae* *Treponema pallidum*
Gram positive anaerobes: *Clostridium* spp. *Peptococcus niger* *Peptostreptococcus magnus* *Peptostreptococcus micros* *Peptostreptococcus* spp.
Gram-negative anaerobes: *Bacteroides fragilis Bacteroides* spp. *Capnocytophaga* spp. *Eikenella corrodens*

Fusobacterium nucleatum *Fusobacterium* spp. *Porphyromonas* spp. *Prevotella* spp.
Species for which acquired resistance may be a problem
Gram-negative aerobes: *Escherichia coli* Klebsiella oxytoca* *Klebsiella pneumoniae** *Klebsiella* spp. *Proteus mirabilis* *Proteus vulgaris* *Proteus* spp. *Salmonella* spp. Shigella spp.
Gram-positive aerobes: *Corynebacterium* spp. *Enterococcus faecium* *Streptococcus pneumoniae*†* Viridans group streptococcus
Inherently resistant organisms
Gram-negative aerobes: *Acinetobacter* spp. *Citrobacter freundii* *Enterobacter* spp. *Hafnia alvei* *Legionella pneumophila* *Morganella morganii* *Providencia* spp. *Pseudomonas* spp. *Serratia* spp. *Stenotrophomas maltophilia Yersinia enterolitica*

Others:
Chlamydia pneumoniae *Chlamydia psittaci* *Chlamydia* spp. *Coxiella* *burnetti* *Mycoplasma* spp.

5.2 Pharmacokinetic properties

The pharmacokinetics of the two components of *E-MOXCLAV* are closely matched. Peak serum levels of both occur about 1 hour after oral administration. Absorption of *E-MOXCLAV* is optimised at the start of a meal.

Doubling the dosage of *E-MOXCLAV* approximately doubles the serum levels achieved.

Both clavulanate and amoxicillin have low levels of serum binding; about 70% remains free in the serum.

5.3 Preclinical safety data

No further information of relevance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Syloid, colloidal silicon dioxide, xanthan gum, succinic acid, sucralose, orange flavour powder, sodium citrate anhydrous, sunset yellow, avicel.

6.2 Incompatibilities

None known.

6.3 Shelf life

2 Years.

6.4 Special precautions for storage

Store at temperature not exceeding 25° C, and protect from light and moisture.

The reconstituted suspension is stable for 7 days when kept under refrigeration.

6.5 Nature and contents of the container

E-MOXCLAV® 228.5 mg/5 ml Oral Suspension: A bottle of 75 ml after reconstitution.

6.6 Special precautions for disposal and other handling

Not Applicable.

7. MARKETING AUTHORIZATION HOLDER

Egyptian International
Pharmaceutical
Industries Company
(EIPICO), P. O. Box 149,
Egypt.

8. MARKETING AUTHORIZATION NUMBER(S)

H2025/CTD11088/22367

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORIZATION

14 July 2025

10. DATE OF REVISION OF THE TEXT

24/08/2026