Summary of Product Characteristics

1. Name of the Drug

Amoxicillin Oral Suspension BP 125 mg/5 ml **(MONX)**

2. Qualitative and quantitative composition

Each 5 ml of reconstituted suspension contains:

Amoxicillin Trihydrate BP

Eq. to Amoxicillin 125 mg

Excipients QS

Color: Sunset Yellow FCF

Composition of the Product:

SR. NO.	Name of Raw Materials	Spec	Quantity / bottle in mg	Overages %	Actual qty. per bottle (mgs)	Quantity per Batch size (kg)	Function
1.	Amoxicillin Trihydrate Eq. to Amoxicillin	BP	2500.000	-	2500.000*	12.500*	Active
2.	Sucrose (Pharma Grade)	BP	8672.400	-	8672.400#	43.362#	Sweetening Agent
3.	Citric Acid (Anhydrous)	BP	20.000	-	20.000	0.100	buffering agent
4.	Sodium Methyl Paraben	BP	40.000	-	40.000	0.200	Preservative
5.	Sodium Propyl Paraben	BP	20.000	-	20.000	0.100	Preservative
6.	Colloidal Silicon Dioxide (Aerosil)	USP	260.000	-	260.000	1.300	Suspending agent
7.	Carboxy Methyl Cellulose Sodium	BP	70.000	-	70.000	0.350	Stabilizer
8.	Dry Essence Orange	IH	200.000	-	200.000	1.000	Flavoring agent
9.	Neotame	NF	12.000	-	12.000	0.060	Sweetenig agent
10.	Colour sunset yellow FCF	IH	1.600	-	1.600	0.008	Colour
11.	Propyl gallate	BP	4.000	-	4.000	0.020	Antioxidant
12.	MCCP PH-112	BP	200.000	-	200.000	1.000	Suspending Agent
		Total	**12000.00**		**12000.00**	**60.00 kg**	

Note:(*)-The Calculation of Amoxicillin Trihydrate as per Assay & Moisture basis.
#Compansated with sucrose

3. The Pharmaceutical form

Dry Powder for Oral suspension

4. Clinical particulars

4.1 Therapeutic indications

Treatment of infection: Amoxicillin is a broad-spectrum antibiotic indicated for the treatment of commonly occurring bacterial infections such as:

- Upper respiratory tract infection Otitis media
- Acute and chronic bronchitis Chronic bronchial sepsis Lobar and bronchopneumonia Cystitis, urethritis, pyelonephritis Bacteriuria in pregnancy
- Gynaecological infections including puerperal sepsis and septic abortion
- Gonorrhoea
- Peritonitis
- Intra-abdominal sepsis Septicaemia Bacterial endocarditis
- Typhoid and paratyphoid fever Skin and soft tissue infections Osteomyelitis
- Dental abscess (as an adjunct to surgical management)
- Helicobacter pylori eradication in peptic (duodenal and gastric) ulcer disease In children with urinary tract infection the need for investigation should be considered.

Prophylaxis of endocarditis:

Amoxicillin may be used for the prevention of bacteraemia, associated with procedures such as dental extraction, in patients at risk of developing bacterial endocarditis. Consideration should be given to official local guidance (e.g. national requirements) on the appropriate use of antibacterial agents. Susceptibility of the causative organisms to the treatment should be tested (if possible), although the therapy may be initiated before the results are available.

4.2 Dosage and method of administration

Treatment of infection

Adult dosage (including elderly patients):

Standard dosage: For less severe infections the usual adult dose is 250 mg three times daily. In more severe conditions the dosage may be doubled.

High-dosage therapy:

(Maximum recommended oral dosage 6 g daily in divided doses): A dosage of 3 g twice daily is recommended in appropriate cases for the treatment of severe or recurrent purulent infection of the respiratory tract.

Short-course therapy: In simple, acute urinary tract infection in adults: two 3 g doses with 10 - 12 hours between the doses. A single dose of 3g is recommended for the treatment of gonorrhoea.

Dental abscess: two 3 g doses with 8 hours between the doses. Children's dosage (weighing < 40 kg).

The daily dosage for children is 40 - 90 mg/kg/day in two to three divided doses[1] (not exceeding 3 g/day) depending on the indication, severity of the disease and the susceptibility of the pathogen.

Children weighing more than 40 kg 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. In severe or recurrent acute otitis media, especially where compliance may be a problem, 750mg twice a day for two days may be used as an alternative course of treatment in children ages 3 to 10 years.

Early Lyme disease (isolates erythema migrans):

50mg/kg/day in three divided doses, over 14-21 days.

Dosage in impaired renal function:

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

Adults (including elderly patients).

Glomerular filtration rate >30ml/min: No adjustment necessary Glomerular filtration rate 10-30ml/min: Amoxicillin max. 500mg BID Glomerular filtration rate <10ml/min: Amoxicillin max. 500mg/day In case of hemodialysis: 500mg should be administered at the end of the procedure.

Renal impairment in children under 40 kg

Creatinine clearance ml/min	Dose	Interval between administration
> 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)

Helicobacter eradication in peptic (duodenal and gastric) ulcer disease:

Amoxicillin is recommended twice daily in association with a proton pump inhibitor and antimicrobial agents as detailed below:

(Omeprazole 40mg daily, Amoxicillin 1g BID, Clarithromycin 500mg BID) x 7 days Or

(Omeprazole 40mg daily, Amoxicillin 750mg-1g BID, Metronidazole 400mg TID) x 7days Treatment should be continued for 2-3 days following the disappearance of symptoms. It is recommended that at least 10 days

treatment be given for any infection caused by betahemolytic streptococci in order to achieve eradication of the organism.

Method of administration
Oral Route

4.3 Contraindications

Hypersensitivity to the active substance, other penicillin's or to any of the excipients. Attention should be paid to possible cross-sensitivity with other beta-lactam e.g. semisynthetic penicillin's, ampicillin or cephalosporins.

4.4 Special warnings and precautions for use

Before initiating therapy with any penicillin careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other allergens.

In patients with renal impairment, the rate of excretion of amoxicillin will be reduced depending on the degree of impairment and it may be necessary to reduce the total daily unit amoxicillin dosage accordingly.

Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in persons with a history of hypersensitivity to beta-lactam antiobiotics and/ or a history of sensitivity to multiple allergens

Erythematous (morbilliform) rashes have been associated with glandular fever in patients receiving amoxicillin.

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

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 renal impairment, the rate of excretion of amoxicillin will be reduced depending on the degree of impairment and it may be necessary to reduce the total daily unit amoxicillin dosage accordingly.

Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving amoxicillin and oral anticoagulants. 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. This medicinal product contains sucrose and sodium benzoate. Sucrose is broken down in the digestive system, by substances called enzymes, into glucose and fructose and thus is unsuitable for patients who suffer from fructose intolerance, glucose-galactose malabsorption syndrome (faulty absorption from the digestive tract) or a deficiency in the enzyme which breaks down sucrose.

Paediatric population: Precaution should be taken in premature children and during the neonatal period: renal, hepatic and haematological functions should be monitored.

4.5 Drug interactions and other forms of interactions

When administered concurrently, the following drugs may interact with amoxicillin: Oral contraceptives

In common with other broad spectrum antibiotics, amoxicillin may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.

Bacteriostatic antibiotics: Chloramphenicol, erythromycins, sulfonamides or tetracyclines may interfere with the bactericidal effects of penicillins. This has been demonstrated in vitro; however, the clinical significance of this interaction is not well documented.

Probenecid: Probenecid may decrease the renal tubular secretion of amoxicillin resulting in increased blood levels and/or amoxicillin toxicity.

Allopurinol: Concurrent administration of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions.

Methotrexate: Excretion of methotrexate is reduced by penicillins; increased risk of toxicity.

Oral typhoid vaccine: The oral typhoid vaccine is inactivated by antibacterials Sulfinpyrazone. Excretion of penicillins is reduced by sulfinpyrazone.

Anticoagulants: 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 amoxicillin.

Muscle relaxants: Piperacillin (and possibly other penicillins) enhance the effects of nondepolarising muscle relaxants and suxamethonium.

Antibacterials: Absorption of phenoxymethylpenicillin (and possibly other penicillins) reduced by neomycin.

Drug/laboratory test interactions: 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.

4.6 Effects on fertility, pregnancy and lactation

There have been no teratogenic effects with amoxicillin in animal studies. The suitability of amoxicillin for use in human pregnancy has been well documented in clinical studies since 1972. When antibiotic therapy is required during human pregnancy, amoxicillin may be considered appropriate when the potential benefits outweigh the potential risks associated with treatment.

Lactation: Amoxicillin may be given during lactation. With the exception of the risk of sensitization associated with the excretion of trace quantities of amoxicillin in breast milk, there are no known detrimental effects for the breast-fed infant.

4.7 Effects on the ability to drive and use machinery

Amoxicillin has no or negligible influence on the ability to drive and use machines.

4.8 Adverse effects

Side effects, as with other penicillins, are uncommon and mainly of a mild and transitory nature.

The following convention has been utilised for the classification 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).The majority of adverse events listed below are not unique to amoxicillin and may occur when using other penicillins.

Unless otherwise stated, the frequency of adverse events has been derived from more than 30 years of post-marketing reports.

Infections and infestations

Very rare: Mucocutaneous candidiasis

Blood and lymphatic system disorders:

Very rare: Reversible leucopenia (including severe neutropenia and agranulocytosis), reversible thrombocytopenia and haemolytic anaemia have been reported.

Prolongation of bleeding time and prothrombin time

Immune system disorders

Very rare: Hypersensitivity reactions:

Severe allergic reactions including angioneurotic oedema, anaphylaxis, serum sickness and hypersensitivity vasculitis

If a hypersensitivity reaction occurs, the treatment must be discontinued.

Nervous system disorders

Very rare: Hyperkinesia, dizziness and convulsions. Convulsions may occur in patients with impaired renal function or in those receiving high doses.

Hepatobiliary disorders:

Very rare: Hepatitis and cholestatic jaundice.

Moderate rise in AST and/or ALT, but the significance of this is unclear.

Skin and subcutaneous tissue disorders

*Common: Skin rash,

*Uncommon: Pruritus and urticaria.

Very rare: Skin reactions such as erythema multiforme and Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous and exfoliative dermatitis and acute generalised exanthematous pustulosis (AGEP)

Renal and urinary tract disorders

Very rare: Interstitial nephritis

Crystalluria can occur

*The incidence of these AEs was derived from clinical studies involving a total of approximately 6,000 adult and paediatric patients taking amoxicillin.

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 the national reporting system listed in Appendix V.

4.9 Overdose and treatment of intoxication

Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be treated symptomatically with attention to the water/electrolyte balance. Amoxicillin crystalluria, in some cases leading to renal failure has been observed.

Gross overdosage will produce high urinary concentrations. Problems are unlikely if adequate fluid intake and urinary output are maintained. More specific measures may be necessary in patients with impaired renal function: the antibiotic is removed by haemodialysis.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Beta-lactam antibacterials, penicillins with extended spectrum; **ATC code:** J01CA04.

Mechanism of action -

Amoxicillin is a broad spectrum semi-synthetic penicillin, which is acid-resistant and has a similar antibacterial spectrum to ampicillin.

PK/PD relationship

For amoxicillin, time above MIC (T>MIC) is the key pharmacodynamics parameter in predicting a successful clinical and bacteriological outcome. Mechanism of resistance: Amoxicillin is better absorbed after oral administration, yielding blood levels approximately twice as high as those obtained with similar doses of ampicillin.

Amoxicillin is used for the same purposes as ampicillin and is especially suitable for the treatment of infections of the urinary and respiratory tracts by ampicillinsensitive organisms. It is rapidly bactericidal and possesses the safety profile of a penicillin. 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.

Breakpoints (EUCAST)

Organism	Susceptibility Breakpoints (pg/ml)		
	Susceptible	Intermediate	Resistant
Haemophilus influenzae	< 1	-	> 1
Moraxella catharrhalis	< 1	-	> 1
Enterococcus	< 4	8	> 8
Streptococcus A, B, C, **G**[1]	< 0.25	-	> 0.25

Streptococcus pneumoniae[2]	< 0.5	1-2	> 2
Enterobacteriaceae[3]	-	-	> 8
Gram-negative anaerobes	< 0.5	-	> 2
Gram-positive Anaerobes	< 4	8	> 8
Non-species related breakpoints	< 2	4-8	> 8
[1] Breakpoint values in the table are based on Benzylpenicillin breakpoints.			

[2] Breakpoint values in the table are based on ampicillin breakpoints.	
[3] 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

Corynebactierum diphteriae Enterococcus faecalis $

Listeria monocytogenes Streptococcus agalactiae Streptococcus bovis Streptococcus pyogenes *

Aerobic Gram-negative

Helicobacter pylori

Anaerobes

Peptostreptococci

Others

Borrelia

Species for which acquired resistance may be a problem

Aerobic Gram-positive

Corynebacterium spp Enterococcus faecium $

Streptococcus pneumoniae * +

Streptococcus viridans Aerobic Gram-negative Escherichia coli +

Haemophilus influenzae *

Haemophilus para-influenzae *

Moraxella catarrhalis +

Proteus mirabilis Anaerobes Prevotella 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

5.2 Pharmacokinetic properties

Absorption -

Amoxicillin trihydrate is resistant to inactivation by the acid of gastric secretions and is rapidly absorbed when given by mouth. It is more completely absorbed than ampicillin and is reported to produce peak antibiotic plasma concentrations that are up to 2% times as high as from the same dose of ampicillin.

Peak plasma amoxicillin concentrations of about 5pg per ml have been observed 1 to 2 hours after a dose of 250mg with detectable amounts present for up to 8 hours. Doubling the dose can produce double the concentrations. The presence of food in the stomach does not appear to diminish absorption significantly.

Distribution -
Amoxicillin gives good penetration into bronchial secretions and high urinary concentrations of unchanged antiobiotic. 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 cerebrospinalis. Amoxicillin crosses the placenta and a small percentage is excreted into the breast milk.

Biotransformation & Elimination:
The main route of excretion of amoxicillin is the kidney. About 60-80% of an oral dose of amoxicillin are 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 metabolised to inactive penicilloic acid. The serum half-life in patients with normal renal function is approximately 1 - 1.5 hour. In patients with endstage renal failure the half-life ranges between 5 to 20 hours. The substance is haemodialysable.

5.3 Preclinical safety data

data Not Applicable.

6. Pharmaceutical data

6.1 List of excipients

Sucrose
Citric Acid (Anhydrous)
Sodium Methyl Paraben
Sodium Propyl Paraben
Colloidal Silicon Dioxide (Aerosil)
Carboxy Methyl Cellulose Sodium
Dry Essence Orange
Neotame
Colour sunset yellow FCF
Propyl gallate
MCCP PH-112

6.2 Incompatibilities

Not applicable.

6.3 Storage period

36 Months

6.4 Special preservation precautions

Store below 25°C, Protected from light and moisture.

6.5 Nature and contents of the outer packaging

An orange coloured flavored suspension, after reconstitution, sSuch 100ml HDPE bottle is packed in a printed carton along with insert.

6.6 Special precautions for disposal

Not applicable.

7. Marketing Authorization Holder

Company name: ZIKE CORPORATION LTD.

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8. Marketing Authorization Number

H97/014

9. Date of first authorization/renewal of the Authorization

31/07/2026

10. Date of text update

31/07/2026