Summary of Product Characteristics for Pharmaceutical Products

1. Name of medicinal Product:

SEPTIMOX KID 250mg (Amoxicillin Dispersible Tablets 250mg)

2. Qualitative and quantitative composition

Each uncoated dispersible tablet contains;

Amoxicillin Trihydrate BP

Eq. to

Amoxicillin……250mg.

For full list of excipients, see section 6.1

3. Pharmaceutical form

White to off white coloured, yellow spotted round shaped and flat.one side has a break line and other side plain uncoated tablet. Has a slight pinkish color develop when tablet is dispersed in water.

4. Clinical Particulars

4.1 Therapeutic indications

Indicated for the treatment of bacterial infections caused by susceptible organisms. Examples include:

- Acute bacterial sinusitis
- Acute otitis media
- Acute streptococcal tonsillitis and pharyngitis
- Acute exacerbations of chronic bronchitis
- Community-acquired pneumonia
- Acute cystitis and acute pyelonephritis
- Asymptomatic bacteriuria in pregnancy
- Typhoid and paratyphoid fever
- Dental abscess with spreading cellulitis
- Prophylaxis of endocarditis (in certain procedures)
- Eradication of Helicobacter pylori (in combination therapy)

4.2 Posology and method of administration:

Posology

Doses vary by indication, severity, patient age/weight, renal function. Example from document:

- For adults and children ≥ 40 kg:
    - Acute bacterial sinusitis: 250 mg to 500 mg every 8 hours or 750 mg to 1 g every 12 hours.
    - Community-acquired pneumonia: 500 mg to 1 g every 8 hours.
    - Typhoid/paratyphoid fever: 500 mg to 2 g every 8 hours.
    - Prophylaxis of endocarditis: single dose 2 g orally, 30-60 minutes before procedure.

- For children & infants: Dosing is weight-based; e.g., in community level treatment settings, twice daily for full 5 days (for pneumonia) is recommended.

Method of administration

The dispersible tablet should be dissolved in about 10 mL (about two teaspoonfuls) of water, the entire mixture drank, then the container rinsed with a little more water and that also swallowed. Do *not* chew or swallow the tablet whole.

The duration of therapy should be determined by the type of infection and the response of the patient, and should generally be as short as possible. Some infections require longer periods of treatment (see section 4.4 regarding prolonged therapy).

Oral:

<u>Adults and children ≥40 kg</u>

Indication*	**Dose***
Acute bacterial sinusitis	250 mg to 500 mg every 8 hours or 750 mg to 1 g every 12 hours For severe infections 750 mg to 1 g every 8 hours
Asymptomatic bacteriuria in pregnancy	
Acute pyelonephritis	
Dental abscess with spreading cellulitis	

Acute cystitis	Acute cystitis may be treated with 3 g twice daily for one day
Acute otitis media	500 mg every 8 hours, 750 mg to 1 g every 12 hours For severe infections 750 mg to 1 g every 8 hours for 10 days
Acute streptococcal tonsillitis and pharyngitis	
Acute exacerbations of chronic bronchitis	
Indication*	**Dose***
Community acquired pneumonia	500 mg to 1 g every 8 hours
Typhoid and paratyphoid fever	500 mg to 2 g every 8 hours
Prosthetic joint infections	500 mg to 1 g every 8 hours
Prophylaxis of endocarditis	2 g orally, single dose 30 to 60 minutes before procedure
Helicobacter pylori eradication	750 mg to 1 g twice daily in combination with a proton pump inhibitor (e.g. omeprazole, lansoprazole) and another antibiotic (e.g. clarithromycin, metronidazole) for 7 days
Lyme disease (see section 4.4)	Early stage: 500 mg to 1 g every 8 hours up to a maximum of 4 g/day in divided doses for 14 days (10 to 21 days) Late stage (systemic involvement): 500 mg to 2 g every 8 hours up to a maximum of 6 g/day in divided doses for 10 to 30 days
*Consideration should be given to the official treatment guidelines for each indication	

Children <40 kg

Children may be treated with Amoxil capsules, dispersible tablets suspensions or sachets.

Amoxil Paediatric Suspension is recommended for children under six months of age.

Children weighing 40 kg or more should be prescribed the adult dosage.

Recommended doses:

Indication[+]	**Dose**[+]
Acute bacterial sinusitis	20 to 90 mg/kg/day in divided doses*
Acute otitis media	
Community acquired pneumonia	
Acute cystitis	
Acute pyelonephritis	
Dental abscess with spreading cellulitis	
Acute streptococcal tonsillitis and pharyngitis	40 to 90 mg/kg/day in divided doses*
Typhoid and paratyphoid fever	100 mg/kg/day in three divided doses
Prophylaxis of endocarditis	50 mg/kg orally, single dose 30 to 60 minutes before procedure
Lyme disease (see section 4.4)	Early stage: 25 to 50 mg/kg/day in three divided doses for 10 to 21 days Late stage (systemic involvement): 100 mg/kg/day in three divided doses for 10 to 30 days
+ Consideration should be given to the official treatment guidelines for each indication. *Twice daily dosing regimens should only be considered when the dose is in the upper range.	

Elderly

No dose adjustment is considered necessary.

Renal impairment

GFR (ml/min)	**Adults and children ≥ 40 kg**	**Children < 40 kg**[#]
greater than 30	no adjustment necessary	no adjustment necessary
10 to 30	maximum 500 mg twice daily	15 mg/kg given twice daily (maximum 500 mg twice daily)

less than 10	maximum 500 mg/day.	15 mg/kg given as a single daily dose (maximum 500 mg)
[#] In the majority of cases, parenteral therapy is preferred.		

In patients receiving haemodialysis

Amoxicillin may be removed from the circulation by haemodialysis.

	Haemodialysis
Adults and children ≥ 40 kg	15 mg/kg/day given as a single daily dose. Prior to haemodialysis one additional dose of 15 mg/kg should be administered. In order to restore circulating drug levels, another dose of 15 mg/kg should be administered after haemodialysis.

In patients receiving peritoneal dialysis

Amoxicillin maximum 500 mg/day.

Hepatic impairment

Dose with caution and monitor hepatic function at regular intervals (see sections 4.4 and 4.8).

In patients receiving haemodialysis and peritoneal dialysis

Amoxicillin may be removed from the circulation by haemodialysis.

	Haemodialysis		**Peritoneal dialysis**	
	Intravenous	**Intramuscular**	**Intravenous**	**Intramuscular**
Adults and children ≥ 40 Kg	1 g at the end of dialysis, then 500 mg every 24 hours	500 mg during dialysis, 500 mg at the end, then 500 mg every 24 hours	1 g stat, then 500 mg/day	500 mg/day given as a single dose
Children < 40 kg	25 mg/kg stat and 12.5 mg/kg at the end of th dialysis, then 25 mg/kg/day	15 mg/kg during and at the end of dialysis, then 15 mg/kg ever 24 hours	25 mg/kg/day given as a single dose	15 mg/kg/day given as a single dose

4.3 Contraindications:

Known hypersensitivity to amoxicillin, any penicillin antibiotic, or any excipients.

History of a severe allergic reaction (e.g., anaphylaxis, Stevens-Johnson syndrome) to any β-lactam antibiotic.).

4.4 Special warnings and precautions for use:

Before initiating therapy with amoxicillin, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins and cephalosporins. The possibility of cross-hypersensitivity (10%-15%) with cephalosporins should be taken into account.

Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy. These reactions are

more likely to occur in individuals with a history of hypersensitivity to beta-lactam antibiotics.

Patients suffering from severe gastrointestinal disturbances with diarrhoea and vomiting should not be treated with Amoxicilline Sandoz disper, due to the risk of reduced absorption. In these cases a parenteral treatment with amoxicillin is advisable.

Tablet should be used with caution in patients with allergic diathesis and asthma.

In patients with renal impairment the excretion of amoxicillin will be delayed and, depending on the degree of the impairment, it may be necessary to seduce the total daily dosage (see section 4.2)

The prolonged use of amoxicillin may occasionally result in an overgrowth of non-susceptible organisms or yeasts. Patients should therefore carefully be watched for superinfections.

The occurrence of anaphylactic shock and other severe allergic reactions is rare following the oral administration of amoxicillin. However, if such reactions occur, appropriate emergency treatment measures must be taken: I.v. administration of epinephrine, followed by antihistaminic drugs, volume substitution and administration of glucocorticoids. Patients should be kept under close observation, and further therapeutic measures (artificial respiration, oxygen) should be administered as required.

The presence of high urinary concentrations of amoxicillin can cause precipitation of the product in urinary catheters. Therefore, catheters should be visually inspected at intervals.

At high doses, adequate fluid intake and urinary output must be maintained to minimise the possibility of amoxicillin crystalluria.

Tablet should be used with caution in patients with viral infections, acute lymphatic leukaemia, or infectious mononucleosis (due to an increased risk of erythematous skin rashes).

Pseudomembranous colitis should be borne in mind if severe persistent diarrhoea occurs (in most cases caused by Clostridium difficile). In this case Tablets hould be discontinued and an adequate therapy (e.g.: vancomycin 4 x 250 mg p.o.) has to be started.

Tablet contain aspartame (E951) and should be used with care in patients with phenylketonuria. In homozygotic patients with phenylketonuria, the amount of phenylalanine that is supplied by aspartame must be included in the calculation for the dietary regulations.
A dose adjustment of digoxin may be necessary on concurrent administration with amoxicillin. A dose adjustment of anticoagulants may be necessary on concurrent administration with amoxicillin (see section 4.5). Serum methotrexate levels should be carefully monitored on concurrent administration with amoxicillin.

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

Allopurinol
Concomitant administration of allopurinol may promote the occurrence of allergic cutaneous reactions and is therefore not advised.

Digoxin
An increase in the absorption of digoxin is possible on concurrent administration with amoxicillin. A dose adjustment of digoxin may be necessary.

Disulfiram
Simultaneous administration of disulfiram is contraindicated.

Anticoagulants
Concomitant administration of amoxicillin and anticoagulants, from the coumarin class, may prolong the bleeding time. A dose adjustment of anticoagulants may be necessary. (see section 4.4)

Probenicid
By inhibiting the renal elimination of amoxicillin the concomitant administration of probenecid leads to an increase in the concentrations of amoxicillin in serum and bile.

Other antibiotics
In general amoxicillin should not be combined with bacteriostatic chemotherapeutics/antibiotics (like tetracyclines, macrolids, sulfonamids or chloramphenicol), because in vitro antagonism is observed. When used simultaneously with aminoglycosides a synergistic effect may occur.

4.6 Pregnancy and lactation:

Amoxicillin passes the placenta and foetal plasma concentrations are approximately 25-30% of the maternal plasma concentrations.
Data on a limited number of exposed pregnancies indicate no adverse effects of amoxicillin on pregnancy or on the health of the foetus/new-born child. To date, no other relevant epidemiological data are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.

Caution should be exercised when prescribing to pregnant women.

Amoxicillin diffuses into the breast milk (approx. 10% of the corresponding serum concentration) and in rare cases, this can lead to diarrhoea and/or fungal colonisation of the mucosa in the infant. The possibility of sensitisation of the infant to beta-lactam drugs should also be considered.

4.7 Effects on ability to drive and use machines:

No effect on ability to drive and use machines. However, if dizziness or other central nervous side-effects occur, caution is advised.

4.8 Undesirable effects:

In this section undesirable effects are defined as follows: Common: 10%, or less, but greater than 1% Uncommon: 1%, or less, but greater than 0.1% Rare: 0.1% or less, but greater than 0.01% Very rare, including isolated cases: 0.01% or less

Infections and infestations

Uncommon
Prolonged and repeated use of the preparation can result in superinfections and colonization with resistant organisms or yeasts such as oral and vaginal candidiasis.

Blood and the lymphatic system disorders

Rare
Eosinophilia and haemolytic anaemia have been reported rarely.

Very rare

There have been isolated reports of leucopenia, granulocytopenia, thrombocytopenia, pancytopenia, anaemia, myelosuppression, agranulocytosis, prolongation of bleeding time, and prolongation of prothrombin time. However, these changes were reversible on discontinuation of therapy.

Immune system disorders

Rare
Laryngeal oedema, serum sickness, allergic vasculitis and anaphylactic shock may occur in rare cases.

Nervous system disorders

Rare

CNS effects have been seen rarely. They include hyperkinesia, dizziness and convulsions. Convulsions may occur in patients with impaired renal function or in those receiving high doses.

Gastrointestinal disorders:

Common

Gastric complaints, nausea, loss of appetite, vomiting, flatulence, soft stools, diarrhoea, enanthemas (particularly in the region of the mouth), dry mouth, taste disturbances. These effects on the gastrointestinal system are mostly mild and frequently disappear either during the treatment or very soon after completion of therapy. The occurrence of these side-effects can generally be reduced by taking amoxicillin during meals.

If severe and persistent diarrhoea occurs, the very rare possibility of pseudomembranous colitis should be considered. The administration of anti-peristaltic drug is contraindicated.

Rare

A superficial discoloration of the teeth (especially in case of the suspension) is rare. Usually the discoloration can be removed by teeth brushing.

Very rare

Development of black tongue.

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 Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org/

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 haemodialysis.

5. Pharmacological Properties:

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: Beta-lactam antibacterials, penicillin

ATC code: J01CAO4.

Mechanism of action

Amoxicillin is a broad-spectrum, β-lactam antibiotic belonging to the aminopenicillin subgroup.

It acts by inhibiting bacterial cell wall synthesis. Specifically, it binds to

penicillin-binding proteins (PBPs) located inside the bacterial cell wall and interferes with the final transpeptidation step of peptidoglycan synthesis — a vital structural component of the cell wall.
This inhibition leads to weakening of the cell wall, followed by cell lysis and death due to osmotic instability.
Amoxicillin is bactericidal against susceptible Gram-positive and Gram-negative microorganisms, including Streptococcus spp., Enterococcus faecalis, Haemophilus influenzae, Escherichia coli, and Proteus mirabilis.

5.2 Pharmacokinetic properties:

Absorption:

The absolute bioavailability of amoxicillin depends on the dose and ranges between 75 and 90%. In the dose range between 250 mg and 750 mg the bioavailability (parameters: AUC and/or recovery in urine) is linearly proportional to the dose. At higher doses the extent of absorption decreases. The absorption is not affected by concomitant food intake. Oral administration of a single dose of 500 mg amoxicillin results in plasma concentrations of 6-11 mg/l. After administration of a single dose of 3 g amoxicillin, the plasmaconcentrations reach 27 mg/l. Peak plasma concentrations are present about 1-2 hours after administration.

Distribution:

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 the liquor cerebrospinalis. In inflamed meninges the concentration can reach approximately 20% the concentration in blood. Amoxicillin crosses the placenta and a small percentage is excreted into the breast milk.

Biotransformation and 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 end-stage renal failure the half-life ranges between 5 to 20 hours. The substance is haemodialysable..

5.3 Preclinical safety data:

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction.

6. Pharmaceutical Properties

6.1 List of excipients

Inactive ingredients: Dummy Granules, Kyron T-314, Aerosil, Ess. Mix Fruit Dry Powder, Magnesium Stearate, Color Erythrosine Supra and Aspartame.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store at controlled room temperature.

6.5 Nature and contents of container

10 Tablets in one Alu-Alu Pack.

6.6 Special precautions for disposal and other handling

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

7. Marketing Authorisation Holder

Marketing Authorisation Holder:
NATIONAL PHARMACY LTD,
Colchester Park,

P.O Box 17843 - 00500

Nairobi, Kenya.

8. Marketing Authorisation Number(s):

H1994/9617/R1

9. Date of First Authorisation/Renewal of the Authorisation

25/3/2025

10. Date of Revision of the Text:

25/3/2025