SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

AMOXSAN® 250 Dispersible Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Amoxicillin Trihydrate equivalent to 250 mg of Amoxicillin
For a full list of excipients, see 6.1.

3. PHARMACEUTICAL FORM

A round, pink biconvex dispersible tablet with white spots and break line on both side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

AMOXSAN® Dispersible Tablet is a broad spectrum antibiotic indicated for the treatment of commonly occurring bacterial infections such as :

- Upper respiratory tract infections e.g., tonsillitis, sinusitis, otitis media.
- Lower respiratory tract infections e.g., acute and chronic bronchitis, lobar and bronchopneumonia
- Genito-urinary tract infections e.g. cystitis, urethritis, pyelonephritis, septic abortion, puerperal sepsis
- Skin and soft tissue infections
- Bone infections
- Gonorrhoea (non-penicillinase producing strains)
- Dental abscess (as an adjunct to surgical management)
- Strains of the following organisms are generally sensitive to the bactericidal action of AMOXSAN *in vitro* :

Gram-positive
Aerobes : *Streptococcus faecalis, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus viridans, penicillin-sensitive Staphylococcus aureus, Corynebacterium species, Bacillus anthracis, Listeria monocytogenes.*

Anaerobes : *Clostridium species.*

Gram-negative
Aerobes : *Haemophilus influenza, Eschericia coli, Proteus mirabilis, Salmonella species, Shigella species, Bordetella pertussis, Brucella species, Neisseria gonorrhoeae, Neisseria meningitides, Pasteurella septica, Vibrio cholera.*

Amoxycillin is susceptible to degradation by beta-lactamase and therefore the spectrum of activity of AMOXSAN does not include organisms which produce these enzymes, including resistant staphylococci and all strains of *Pseudomonas, Klebsiella* and *Enterobacter.*

4.2 Posology and method of administration

AMOXSAN® Dispersible Tablet may be given without regard to meals.
Dissolve one dispersible tablet in approximately one spoonful of drinking water, wait for about 50 seconds until the tablet is completely dispersed into small granules. The suspension may be directly given to patient, followed by drinking water.

Dosages

Usual dosage for the treatment of infection :

- Adults and children over 40 kg : for severe infections, 875 mg every 12 hours or 500 mg three times daily.
- Gonorrhoea : single 3 g dose.
- Children's dosage (Children under 40 kg)
  Standard children's dosage : 125 mg three times daily, increasing to 250 mg three times daily for more severe infections.

Note : Moderate infection are certain infection without complication such as septicemia or bactericemia. Severe infection are certain infection with complication such as septicemia or bactericemia.

Patients with renal impairment.
In renal impairment the excretion of the antibiotic will be delayed and, depending on the degree of impairment, it may be necessary to reduce the total daily dosage according to the following scheme :
Adults and Children over 40 kg

Mild impairment (creatinine clearance > 30 mL/min)	No change in dosage
Moderate impairment (creatinine clearance 10-30 mL/min)	500 mg b.i.d maximum
Severe impairment (creatinine clearance)	500 mg/day maximum
There are currently no dosing recommendations for pediatric patients with impaired renal function	

Patients receiving haemodialysis
Dosing as for patients with severe renal impairment (creatinine clearance < 10 mL/min). They should receive an additional dose both during and at the end of dialysis.
Amoxicillin is removed from the circulation by haemodialysis. Therefore, one additional dose (500 mg for adults or 15 mg/kg for children under 40 kg) may be administered during dialysis and at the end of each dialysis.

It should be recognized that in the treatment of chronic urinary tract infections, frequent bacteriological and clinical appraisals are necessary.
Smaller doses than those recommended above should not be used.
Even higher doses may be needed at the times. 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.
Except for gonorrhea, treatment should be continued for a minimum of 48 to 72 hours beyond the time that the patient becomes symptomatic or evidence of bacterial eradication has been obtained. It is recommended that there be at least 10 days treatment for any infection caused by Streptococcus pyogeness to prevent the occurrence of acute rheumatic fever.
Parenteral therapy is indicated if the oral route is considered impracticable or unsuitable, and particularly for the urgent treatment of severe infection.

4.3 Contraindications

Hypersensitivity to beta lactam antibiotics e.g. penicillins, cephalosporins.

4.4 Special warnings and precautions for use

Before initiating therapy with Amoxicillin, careful inquiry should be made concerning previous hypersensitivity reactions to penicillin.
Periodic assessment of renal, hepatic and hematopoietic functions should be made during prolonged therapy.
Patient with renal disorder must be monitored for its plasma and urine level.
Patient with renal disorder must be necessary to reduce the total daily unit amoxicillin dosage.
As with other antibiotics, Amoxicillin administration may cause superinfection (the common causes are Pseudomonas, Enterobacterium, S. aureus and Candida). If it occurs, treatment should be discontinued and appropriate therapy should be instituted.
Not for meningitis or body j0oint treatment (since oral Amoxicillin does not penetrate the cerebrospinal or synovial liquid).
Caution should be taken when this drug is administered to patients with lymphatic leukemia due to Amoxicillin-induced skin rash susceptibility.
It may be necessary to reduce the total daily unit amoxicillin dosage accordingly for patients with renal disorder.
This product contains mannitol; it may cause osmotic diarrhea in some patients.
Patients with infections mononucleosis (glandular fever), lymphatic leukaemia and possibly with HIV infection are particularly prone to developing erythematous rashes with amoxicillin. Amoxicillin should be discontinued if a skin rash occurs.

4.5 Interaction with other medicinal products and other forms of infection

Probenecid may increase and prolong blood level of Amoxicillin.

Concomitant use with allopurinol may result in increased skin reactions.

4.6 Pregnancy and lactation

Teratogenic effects

Pregnancy Category B. Reproduction studies have been performed in moce and rats at doses up to 10 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to amoxicillin. 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.

Nursing mothers

Penicillins have been shown to be excreted in human milk. Amoxicillin use by nursing mothers may lead to sensitization of infants. Caution should be exercised when amoxicillin is 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 Undersirable effects

Hypersensitivity reactions such as erythematous maculopapular rashes, urticarial, skin rashes, serum sickness.

Serious and fatal hypersensitivity reaction is anaphylaxis, especially in patient with hypersensitivity condition to penicillin.

Gastrointestinal disturbances, such as nausea, vomiting and diarrhea.

Haematological reactions (usually reversible).

4.9 Overdose

In case of overdosage, discontinue medication, treat symptomatically, and institute supportive measures as required. If the overdosage is very recent and there is no contraindication, an attempt at emesis or other means of removal of drug from the stomach may be performed. A prospective study of 51 pediatric patients at a poison – control center suggested that overdosages of less than 250 mg/kg of amoxicillin are not associated with significant clinical symptoms and do not require gastric emptying.

Interstitial nephritis resulting in oliguric renal failure has also been reported in a small number of patients after overdosage with amoxicillin.

Crystalluria, in some cases leading to renal failure, has also been reported after amoxicillin overdosage in adult and pediatric patients. In case of overdosage,

adequate fluid intake and diuresis should be maintained to reduce the risk of amoxicillin crystalluria.
Renal impairment appears to be reversible with cessation of drug administration. High blood levels may occur more readily in patients with impaired renal function because of decreased renal clearance of amoxicillin. Amoxicillin may be removed from circulation by hemodialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Amoxicillin is a derivative of semisynthetic penicillin which is acid stable. Its bactericidal activity is similar to that of ampicillin.
Amoxicillin is effective against Gram – positive and Gram – negative organisms.
Among those bacteria which are sensitive to Amoxicillin are:
Staphylococcus
Streptococcus
Diplococcus pneumoniae
Bacillus anthracis
Enterococcus
Corynebacterium diphtheria
Salmonella sp
Shigella sp
H. influenza
Proteus mirabilis
E. coli
N. gonorrhoeae
N. meningitides

5.2 Pharmacokinetic properties

Amoxicillin is rapidly and well absorbed from the gastrointestinal tract, irrespective of the presence of food, giving a high blood level after one hour. Its absorption is better than that of ampicillin.
Amoxicillin is not highly protein bound, approximately 18% of total plasma drug content is bound to protein. Amoxicillin diffuses readily into most body tissues and fluids, with the exception of the brain and spinal fluid. Inflammation generally increases the permeability of the meninges to penicillins and this may apply to amoxicillin.
Amoxicillin is mainly excreted through the kidneys, in the urine Amoxicillin is recovered in active form
The elimination half life is approximately 1 hour. Tha major route of elimination for amoxicillin is via the kidney. Approximately 60-70% of AMOXSAN® 250 Dispersible Tablet is excreted unchanged in urine during the first 6 hours after administration equivalent to 10-25% of the initial dose..

Concurrent administration of probenecid delays amoxicillin excretion**.**

5.3 Preclinical safety data
Not Applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Mannitol DC
Crospovidone
Aspartame
Silicon Dioxide Colloidal
Strawberry Dry Flavor
Talc
Pigment Red No. 3 FDC E 127
Magnesium Stearate

6.2 Incompatibilities
Not Applicable

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store at room temperature below 30°C, away from light.

6.5 Nature and contents of container
Box of 10 Strips @ 10 Tablets

6.6 Special precautions for disposal
Not Applicable

7. MARKETING AUTHORISATION HOLDER
PT CAPRIFARMINDO LABS.
Jl. Purnawarman No. 47
Bandung – Indonesia
Phone : + 62 22 686 7967
Fax : 62 22 686 7969

8. MANUFACTURER

PT. SANBE FARMA UNIT II
Jl. Mahar Martanegara No. 162 (Jl. Leuwigajah No. 162)
RT. 01 RW. 12
Kelurahan Baros Kecamatan Cimahi Tengah
Kota Cimahi – Indonesia
Phone : +62 22 6613311
Fax : +62 22 6613297

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

October 6, 2015

10. DATE OF REVISION OF THE TEXT

August 2, 2017