SUMMARY PRODUCT CHARACTERISTICS (SPC)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

AMYN DT 125 (Amoxicillin Tablets for oral suspension USP 125 mg)

1.1 Strength

Each Tablet for oral suspension contains:

Amoxicillin Trihydrate USP equivalent to Amoxicillin ….. 125 mg,

1.2 Pharmaceutical Form

Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Qualitative declaration:

Each Tablet for oral suspension contains:

Amoxicillin Trihydrate USP equivalent to Amoxicillin ….. 125 mg

2.2 Quantitative declaration:

Qualitative declaration:

Each Tablet for oral suspension contains:

Amoxicillin Trihydrate USP equivalent to Amoxicillin ….. 125 mg

Quantitative declaration:

2.3 Salts and hydrates

Trihydrate.

3. Pharmaceutical form

Description:

White to off-white Round Shaped, flat face beveled edge tablets plain on both sides without any visible defects.

4 Clinical Particulars

4.1 Therapeutic indications

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

Upper respiratory tract infections: e.g. sinusitis, acute pharyngitis.

Lower respiratory tract infections: e.g. acute exacerbations of chronic bronchitis, lobar and bronchopneumonia, uncomplicated community acquired pneumonia, H.influenzae infections.

Gastrointestinal tract infections: e.g. acute gastritis, peptic ulcer disease and invasive salmonellosis.

Skin and soft tissue infections: e.g. Cellulitis, erysipelas, osteomyelitis

Genito-urinary tract infections: e.g. cystitis, urethritis, pyelonephritis, bacteriuria in pregnancy, septic abortion, puerperal sepsis.

ENT Infections: Cervical adenitis, otitis media.

Dental infections: Dental abscess (as an adjunct to surgical management), suppurative odontogenic infections.

Listeria meningitis.

Prophylaxis of endocarditis: Amoxicillin may be used for the prevention of bacteremia associated with procedures such as dental extraction, in patients at risk of developing of endocarditis.

Strains of the following organisms are generally sensitive to the bacterial action of Amoxicillin in vitro:

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

Gram positive (Anaerobes): Clostridium species

Gram negative (Aerobes): Haemophilus influenzae, Eschericia coli, Proteus mirabilis, Salmonella species, Bordetela pertussis, Brucella species, Shigella species, Neisseria meningtidis, Pasteurella septica, Vibrio cholerae, Helicobacter pylori.

Amoxicillin is susceptible to degradation by β-lactamases and, therefore, the spectrum of activity for Amoxicillin does not include organisms that produce these enzymes, including resistant Staphylococci and all strains of Pseudomonas, Klebsiella and Enterobacter.

4.2 Posology and Method of Administration

Posology:

Standard children's dosage (up to 10 years of age)

CHILD up to 10 years: 125 mg every 8 hours doubled in severe infections.

Renal Insufficiency

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:

Children under 40Kg:

Mild impairment (creatinine clearance > 30ml/min)

-No change in dosage

Moderate impairment (creatinine clearance 10.3ml/min)

-5mg/kg b.i.d. maximum

Severe impairment (creatinine clearance <10ml/min)

-15mg/Kg o.d.

Route of administration: Oral

4.3 Method of Administration:

Disperse the tablet in a teaspoonful of water before administration which after complete dispersion Swallow as per dosage.

4.4 Contraindications

Amoxicillin is penicillin and should not be given to penicillin hypersensitive patients. Attention should be paid to possible cross-sensitivity with other β-lactam antibiotics e.g. cephalosporins.

4.5 Special warnings and precautions for use

Before initiating therapy with amoxicillin, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins. 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 β-lactam antibiotics (see contra-indications). 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.

Dosage should be adjusted in patients with renal impairment (see posology and method of administration).

4.6 Interactions with other medicinal products and other forms of interactions

In common with other broad-spectrum antibiotics, Amoxicillin may reduce the efficacy of oral contraceptives and patients should be warned accordingly. Concurrent administration of Allopurinol during treatment with Amoxicillin can increase the likelihood of allergic skin reactions. Prolongation of prothrombin time has been reported rarely in patients receiving Amoxicillin. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently. 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. Probenecid decreases the renal tubular secretion of Amoxicillin. Concurrent use with Amoxicillin may result in increased and prolonged blood levels of Amoxicillin.

4.6 Pregnancy and Lactation

Use in pregnancy:

Animal studies with Amoxicillin have shown no teratogenic effects. However, treatment with Amoxicillin may be considered appropriate when the potential benefits outweigh the potential risks associated with treatment.

Use in 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 ability to drive and use machine

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

4.8 Undesirable effects

Side effects, as with other penicillins, are uncommon and mainly of a mild and transitory nature. Hypersensitivity reactions: If any hypersensitivity occurs, the treatment should be discontinued. Skin rash, pruritis and urticaria have been reported occasionally. Rarely, skin reaction such as erythema multiforme and Steven-Johnson syndrome, toxic epidermal necrolysis and bullous and exfoliative dermatitis have been reported. As with other antibiotics, severe allergic reactions including angioneurotic oedema, anaphylaxis, serum sickness and hypersensitivity vasculitis have been reported rarely.

Gastrointestinal reactions: Effects include nausea, vomiting and diarrhea. Intestinal candidiasis and antibiotic associated colitis (including pseudo-membranous colitis and hemorrhagic colitis) have been reported rarely. Intestinal nephritis can occur rarely.

Hepatic effects: A moderate rise in AST and/or ALT has been occasionally noted but the significance of this is unclear. As with other β-lactam antibiotics, hepatitis and cholestatic jaundice have been reported rarely.

Hematological effects: As with other β-lactam antibiotics, reversible leucopenia (including severe neutropenia or agranulocytosis), reversible thrombocytopenia and hemolytic anemia have been reported rarely. Prolongation of bleeding time and prothrombin time has also been reported rarely.

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

Miscellaneous: Superficial tooth discoloration has been reported rarely and mostly with the dispersible tablets. It can usually be removed by brushing.

4.9 Overdose and antidote

Problems of over dosage with amoxicillin are unlikely to occur. If encountered, gastrointestinal effects such as nausea, vomiting and diarrhea may be evident and should be treated symptomatically with attention to the water/electrolyte balance. During the administration of high doses of amoxicillin, adequate fluid intake and urinary output must be maintained. Amoxicillin can be removed from the circulation by hemodialysis.

5.0 Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: β-lactam antibacterials, Penicillins with extended antibiotic spectrum.

ATC code: J01CA04.

Amoxicillin is a semi-synthetic aminopenicillin of the β-lactam group of antibiotics. It has a broad spectrum of antibacterial activity against many Gram-positive and Gram-negative micro-organisms, acting through the inhibition of biosynthesis of cell wall mucopeptide. It is rapidly bactericidal and possesses the safety profile of penicillin.

5.2 Pharmacokinetic properties

Amoxicillin is well absorbed. Oral administration, usually at convenient t.d.s. dosage, produces high serum levels, independent of the time at which food is taken. 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. The elimination half-life is approximately 1 hour. The major route of elimination for amoxicillin is via the kidney. Approximately 60-70% of Amoxicillin is excreted unchanged in urine during the first 6 hours after administration of a standard dose. Amoxicillin is partly excreted in the urine as the inactive penicilloic acid in quantities equivalent to 10-25% of the initial dose.

5.3 Pre-clinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to those already included in other sections. Non-clinical data reveal no special hazards for humans based on conventional studies of safety, pharmacology, repeat–dose toxicity or genotoxicity.

6.0 Pharmaceutical Particulars

6.1 List of Excipients

Sr No.	Approved Name	Specification
1	Microcrystalline Cellulose	BP
2	Aspartame	EP
3	Crospovidone	BP
4	Ess.Fl.DCTrusil Lemon	IH
5	Flavour Peppermint DC 117 Quest	IH
6	Magnesium stearate	BP
7	Purified Talc	BP
8	Colloidal Anhydrous Silica	BP

EP- European Pharmacopoeia
BP-British Pharmacopoeia
IH-In-House Specification

6.2 Incompatibilities:

None

6.3 Shelf life

Proposed shelf life: 24 Months (2 years)

6.4 Special precautions for storage:

Store below 30°C in a dry place .

6.5 Nature and contents of container

Primary: Alu/Alu Strip

Secondary: Paperboard carton

6.6 Special precautions for disposal and other handling

None.

7. MARKETING AUTHORISATION HOLDER

KOPRAN LIMITED,

Parijat House, 1076,

Dr. E. Moses Road, Worli,

Mumbai: 400 018, India

Manufacturer

Kopran Limited,

Plant-1 (Pen Plant), Village Savroli ,

Taluka Khalapur,

District Raigad – 410202, India

8. Marketing authorization registration number(s).

09343/6129/NMR/2018

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Dec 23, 2023

10. DATE OF REVISION OF THE TEXT

Not applicable