Annexure- I

CHECK LIST FOR ARTWORK APPROVAL **

Kopran

Product Name:	AMYN DT 125 AMYN DT 250 AMYN DT 500			**Dept. wise check →**	**Std. ↓**	**PDD**	**PMQC**	**PROD**	**QA**
Generic Name/ Label Claim:	Amoxicillin Tablets for Oral Suspension USP 125 mg Amoxicillin Tablets for Oral Suspension USP 250 mg Amoxicillin Tablets for Oral Suspension USP 500 mg			**PL holder/MA holder/Country:**	Common English				
Item Description:	Leaflet	**Pack Size**	AMYN DT 125: Strip of 10's, 20's, 30's and 100's Tablets. AMYN DT 250: Strip of 10's, 20's, 30's and 100's Tablets. AMYN DT 500: Strip of 10's, 20's, 30's and 100's Tablets.	**Storage:**	Store below 30 °C in a dry place.				
Artwork Code/Item code	ED-3642 P1952899	**Supersedes**	NA	**Pharma code (Numerical Value)**	604				
Specification:	60 gsm Maplitho	**Layout No.**	NA	**Bar code (Numerical Value)**	NA				
Varnish :	NA	**Design**	NA	**Minimum Font Size**	6 Pt.				
Dimension :	170mm(L) x 270mm(W)	**Grain Direction**	Perpendicular to machine	**Lic. No. /Code No.**	NA				
Folding Size :	Final Fold 85MM X 33.75MM	**Print Size**	NA	**Regn. No.**	NA				
Language :	English	**Print Repeat**	NA	**Artist name**	Shantanu Shahane				
Colour/Pantone :	PANTONE Black C			**Artwork preparation date**	24/10/2019				
Reason For Revision	NEW ARTWORK			**Artwork correction date**	-				
				CD release Date	-				

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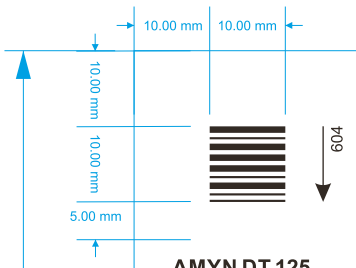
NOT TO BE PRINTED

FRONT



270.00 mm

AMYN DT 125
(Amoxicillin Tablets for Oral Suspension USP 125 mg)

AMYN DT 250
(Amoxicillin Tablets for Oral Suspension USP 250 mg)

AMYN DT 500
(Amoxicillin Tablets for Oral Suspension USP 500 mg)

Composition:
AMYN DT 125 (Tablets)
Each Tablet for Oral Suspension Contains:
Amoxicillin Trihydrate USP
Equivalent to Amoxicillin 125mg
Excipients..... q.s.

AMYN DT 250 (Tablets)
Each Tablet for Oral Suspension Contains:
Amoxicillin Trihydrate USP
Equivalent to Amoxicillin 250mg
Excipients..... q.s.

AMYN DT 500 (Tablets)
Each Tablet for Oral Suspension Contains:
Amoxicillin Trihydrate USP
Equivalent to Amoxicillin 500mg
Excipients..... q.s.

Therapeutic Classification:
β-lactam antibacterials, Penicillins with extended antibiotic spectrum.
ATC Code: J01CA04.

PHARMACOLOGICAL PROPERTIES:
Pharmacodynamic properties:
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.

Spectrum of activity:
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.

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.

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. bacterial pneumonia in children less than 5 years of age, 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.

POSOLOGY AND METHOD OF ADMINISTRATION:
Standard children's dosage (up to 10 years of age): 125 mg every 8 hours doubled in severe infections.
The dosage of Amoxicillin Dispersible Tablets in children with pneumonia.

Category of pneumonia	Age/ Weight of Child	Dosage of Amoxicillin Dispersible Tablets (250mg)
Fast breathing pneumonia	2 month up to 12 months (4-<10 kg)	1 Tablet twice a day X 5 days (10 tablets)
	12 months up to 5 years (10-19 kg)	2 Tablet twice a day X 5 days (20 tablets)
Fast breathing and chest in drawing pneumonia	2 month up to 12 months (4-<10 kg)	1 Tablet twice a day X 5 days (10 tablets)
	12 months up to 3 years (10-14 kg)	2 Tablet twice a day X 5 days (20 tablets)
	3 years up to 5 years (14-19 kg)	3 Tablet twice a day X 5 days (30 tablets)

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.

CONTRA INDICATIONS:
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.

SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE:
Before initiating therapy with amoxicillin, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins.

170.00 mm

SIGN FOR CHECKING

PDD	PMQC	Production

SIGN FOR APPROVAL

Regulatory Affairs	Marketing	Quality Assurance	PL / MA Holder

** All concern should be sign /mail with verified artwork as per check list.

Annexure- I

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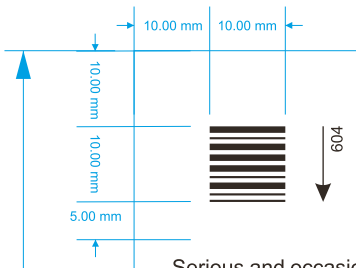
BACK



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).
This medicinal product contains aspartame, a source of phenylalanine, may be harmful for people with phenylketonuria.

INTERACTION WITH OTHER MEDICAMENTS AND OTHER FORM OF MEDICAMENTS:
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.

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.

EFFECTS ON THE ABILITY TO DRIVE OR OPERATE MACHINERY:
Adverse effects on the ability to drive or operate machinery have not been observed.

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.

OVERDOSE:
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.

PHARMACEUTICAL PARTICULARS

Special Precautions for Storage:
Store below 30 °C in a dry place.
Tablets must be used immediately after removal from packaging.

Directions for use for AMYN DT Tablets:
Disperse the tablets in teaspoonful of clean water or milk before administration. Softly stir the dispersion before swallowing. Rinse with small amount of clean water or milk and swallow again. Use clean and appropriate container to disperse the tablets.

PRESENTATION:
AMYN DT 125: Strip of 10's, 20's, 30's and 100's Tablets.
AMYN DT 250: Strip of 10's, 20's, 30's and 100's Tablets.
AMYN DT 500: Strip of 10's, 20's, 30's and 100's Tablets.

Keep medicine out of reach of children.
Read package insert carefully before use.

PRESCRIPTION ONLY MEDICINE

Kopran

Manufactured in India:
KOPRAN LIMITED
Village Savroli, Tal. Khalapur,
Dist.Raigad-410 202.

ED-3642 P1952899

270.00 mm

170.00 mm

SIGN FOR CHECKING

PDD	PMQC	Production

SIGN FOR APPROVAL

Regulatory Affairs	Marketing	Quality Assurance	PL / MA Holder

** All concern should be sign /mail with verified artwork as per check list.