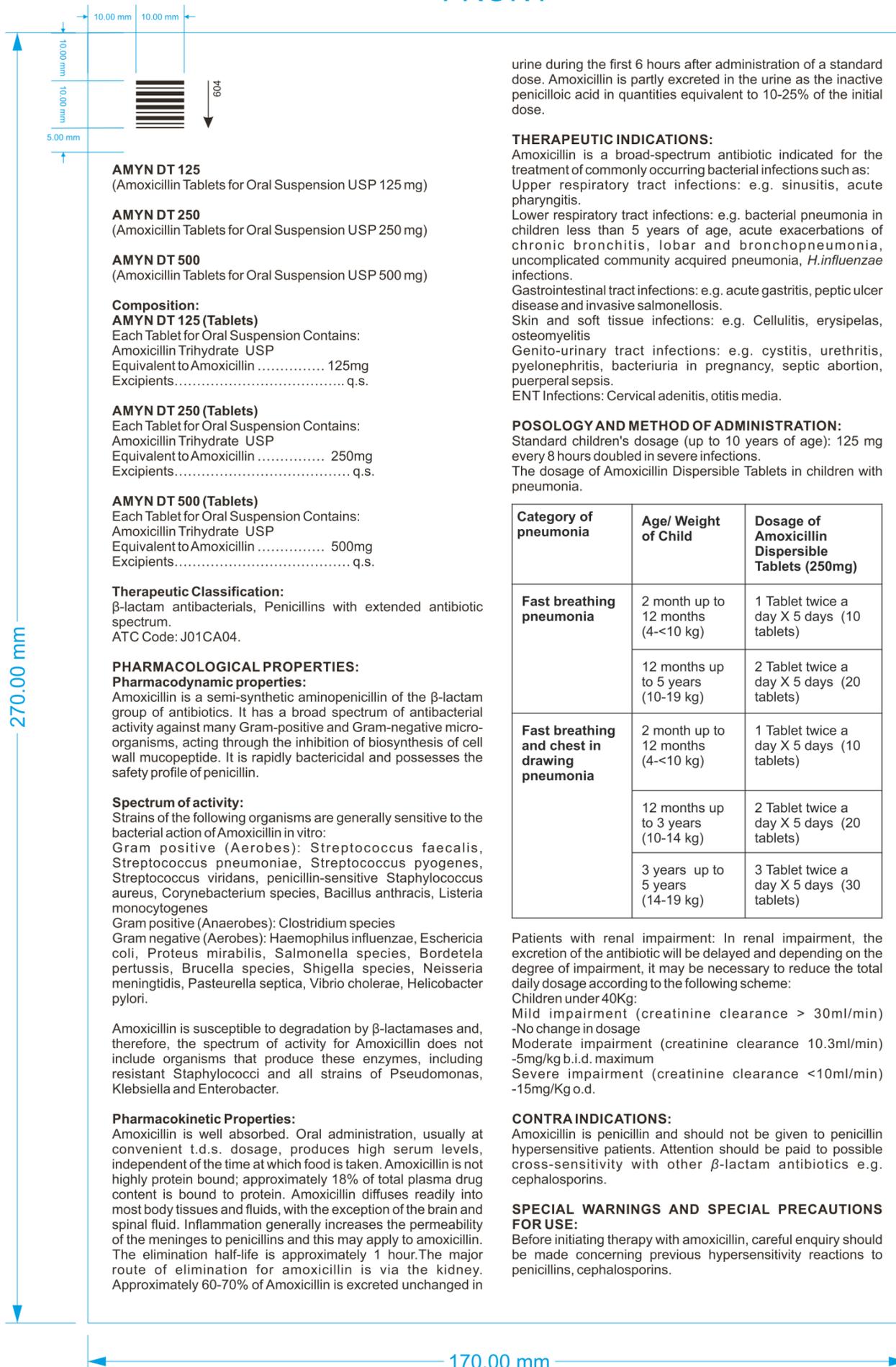


Product Name:	AMYN DT 125 AMYN DT 250 AMYN DT 500	Dept. wise check →	Std. ↓	PDD	PMQC	PROD	QA
Generic Name/ Label Claim:	Amoxicillin Tablets for Oral Suspension USP 125 mg Amoxicillin Tablets for Oral Suspension USP 250 mg Amoxicillin Tablets for Oral Suspension USP 500 mg	PL holder/MA holder/Country:	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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FRONT



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 microorganisms, 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, Escherichia coli, Proteus mirabilis, Salmonella species, Bordetella pertussis, Brucella species, Shigella species, Neisseria meningitidis, 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.

SIGN FOR CHECKING

SIGN FOR APPROVAL

PDD	PMQC	Production

Regulatory Affairs	Marketing	Quality Assurance	PL / MA Holder

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

Annexure- I
CHECK LIST FOR ARTWORK APPROVAL **



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	-		

Cyan
NOT TO BE PRINTED

BACK

270.00 mm

10.00 mm

10.00 mm

10.00 mm

10.00 mm

5.00 mm

170.00 mm

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

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

604

604

ED-3642 P1952899

SIGN FOR CHECKING

SIGN FOR APPROVAL

PDD	PMQC	Production

Regulatory Affairs	Marketing	Quality Assurance	PL / MA Holder

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