FRONT

AMYN

Qualitative and Quantitative Composition (active ingredient only)

AMYN - 250 Capsules contain 250 mg amoxicillin per capsule.
AMYN - 500 Capsules contain 500 mg amoxicillin per capsule.
AMYN SYRUP - 125 contains 125 mg amoxicillin per 5 ml dose.
AMYN SYRUP - 250 contains 250 mg amoxicillin per 5 ml dose.
The Amoxicillin is present as the trihydrate in AMYN oral presentations.

Pharmaceutical form

AMYN capsules : Maroon and beige capsules over printed 'AMOXY 250' or 'AMOXY 500'
AMYN SYRUP : Presented as powder in bottles for preparing 60 ml or 100 ml.

CLINICAL PARTICULARS
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.
Listerial meningitis.
Prophylaxis of endocarditis Amoxicillin may be used for the prevention of bacteraemia 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 influenza, 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 beta-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.*

POSOLOGY AND METHOD OF ADMINISTRATION
Standard adult dosage:
250mg three times daily, increasing to 500mg three times daily for more severe infections.
High dose therapy: Maximum recommended oral dosage 6 gm daily in divided doses;
Short course therapy:
Simple acute urinary tract infection: Two 3g doses with 10-12 hours between the doses.
Dental abscess: Two 3 g doses with 8 hours between the doses
Urinary tract infections : 3 g repeated after 10-12 hrs.
Standard children's dosage (up to 10 years of age):For AMYN syrup
CHILD up to 10 years: 125 mg every 8 hours doubled in severe infections
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 40Kg

Mild impairment (creatinine clearance > 30ml/min)	-No change in dosage
Moderate impairment (creatinine clearance 10-3-ml/min)	-500mg b.i.d. maximum
Severe impairment (creatinine clearance <10ml/min)	-500mg/day maximum

Children under 40Kg

Mild impairment (creatinine clearance > 30ml/min)	-No change in dosage
Moderate impairment (creatinine clearance 10-3-ml/min)	-5mg/kg b.i.d. maximum
Severe impairment (creatinine clearance <10ml/min)	-15mg/Kg o.d.

CONTRA INDICATIONS :
Amoxicillin is a penicillin and should not be given to penicillin hypersensitive patients. Attention should be paid to possible cross-sensitivity with other beta-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.
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 (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).

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

210mm

125mm

BACK

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 sensitisation 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 uticaria 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 haemorrhagic 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 beta-lactam antibiotics, hepatitis and cholesatic jaundice have been reported rarely.
Hematological effects: As with other beta-lactam antibiotics, reversible leucopenia (including severe neutropenia or agranulocytosis), reversible thrombocytopenia and haemolytic anaemia have been reported rarely.
Prolongation of bleeding time and prothrombin time have also been reported rarely.
CNS effects: CNS effects have been reported rarely. They include hyperkinesias, 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 suspension and chewable tablets. It can usually be removed by brushing.

OVERDOSE :
Problems of overdosage with amoxicillin are unlikely to occur. If encountered, gastrointestinal effects such as nausea ,vomiting and diarrhoea 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 haemodialysis.

PHARMACOLOGICAL PROPERTIES
Pharmacodyanamic Properties :
Amoxicillin is a semi-synthetic aminopenicillin of the beta-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 possess the safety profile of a penicillin.
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.

PHARMACEUTICAL PARTICULARS
Special Precautions for Storage
All presentations should be stored in a dry place, below 30°C.
Once dispensed , AMYN Syrup should be stored below 30°C and used within 7 days.

Directions for use for AMYN syrup :
Tap the bottom of the bottle to loosen the powder. Add previously boiled and cooled water up to the circular mark, replace the cap and shake vigorously. Adjust the volume by adding more water if necessary to make up the volume 100 ml and shake again.The syrup is now ready for use.

INSTRUCTIONS TO THE PATIENT
THIS IS A MEDICAMENT
Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
The Doctor and the Pharmacist are experts in medicine, its benefits and risks.
Do not by yourself interrupt the period of treatment prescribed for you.
Do not repeat the same prescription without consulting the doctor

Keep medicament out of reach of children

PRESCRIPTION ONLY MEDICINE

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

E-16780 P1952160

125mm

Check List for Carton / Foil / Leaflet / Label / Shipper				
	Pkgd.	QA	QC	Prod.
E/D. No./Item Code				
Brand Name				
Generic Name				
Pack Size/Strength				
Label Claim				
Colour				
Storage				
Lic. No./Code				
Reg. No.				
Address				
Language				
Barcode				
Pantone Colour				
Dimension(Ht.x Width)				

SIGN. FOR APPROVALS CD No.: Proof No.: Date :

Kopran

ARTWORK APPROVAL

Packaging Development	Quality Assurance (QA)	Quality Control (QC)	Production	Marketing

KOPRAN LIMITED Village Savroli, Taluka Khalapur, Dist. Raigad - 410202

F1/10330/01

SIZE	COLOUR PANTON
210 (L) x 125 mm (W)	Black

	Date
Artwork Generated	16.08.2012
1st Correction	
2nd Correction	
3rd Correction	
4th Correction	
5th Correction	
Final Approval	