DYNA AMOXYCILLIN

	DESCRIPTION	CONTENT
Dyna Amoxycillin 125mg/5ml MAL19985981AZ	Dry Syrup Colour: White (Pink on adding water) Flavour: Strawberry	Each 5 ml of the reconstituted suspension contains: Amoxycillin Trihydrate equivalent to Amoxycillin ..... 125 mg Preservative: Sodium Benzoate ..... 0.1% w/v
Dyna Amoxycillin 250mg/5ml MAL19985982AZ	Dry Syrup Colour: White (Pink on adding water) Flavour: Strawberry	Each 5 ml of the reconstituted suspension contains: Amoxycillin Trihydrate equivalent to Amoxycillin ..... 250 mg Preservative: Sodium Benzoate ..... 0.1% w/v

PHARMACODYNAMICS:
Amoxycillin is a bactericidal antibiotic which inhibits bacterial cell wall synthesis, probably by acylation of membrane-bound transpeptidease enzymes. This prevents cross-linkage of peptidoglycan chains which is necessary for bacterial cell wall strength and rigidity. Also, cell division and growth are inhibited and lysis of susceptible bacteria frequently occurs. Rapidly dividing bacteria are most susceptible to penicillin group of antibiotics including Amoxycillin.

PHARMACOKINETICS:
Amoxycillin is stable to gastric acid and 50 to 90% of a dose is absorbed after oral administration; absorption is more complete than that of Ampicillin and it is not greatly influenced by the presence of food. After an oral dose of 500 mg, peak serum concentrations of 3 to 20 mcg/ml are attained in 1 to 2 hours; detectable concentrations are present after 8 hours; peak concentrations occur earlier in children and infants but later in neonates. Serum half-life is 1 hour which may be increased to 15 hours in renal failure. After absorption, Amoxycillin enters most tissues and fluids but it is not detectable in the cerebrospinal fluid even when the meninges are inflamed; crosses the placenta and small amounts are secreted in the milk; volume of distribution at steady-state serum concentrations, about 0.3 litres/kilogram body-weight; protein binding, 15 to 25% bound to plasma proteins. Amoxycillin is metabolised to inactive metabolites and 10 to 25% appears to be converted to penicilloic acid. 35 to 45% is excreted in the urine after an oral dose and about 75% after intramuscular or intravenous doses; urinary excretion is delayed by probenecid and it also occurs more slowly in the newborn; small amounts are excreted in the bile.

INDICATIONS:
Infections e.g. otitis media, sinusitis, pharyngitis, pneumonia, bronchitis caused by sensitive gram-positive organisms, including Streptococcus pneumoniae, and other streptococci and Listeria monocytogenes. Gram-negative microorganism including some of strains of Bordetella pertussis, Haemophilus influenzae and some Enterobacteriaceae such as Escherichia coli, Proteus mirabilis, Salmonella and Shigella spp..
ENT infections: otitis media, sinusitis, tonsillitis, pharyngitis, laryngitis, epiglottis.
Lower respiratory tract infections: acute and chronic bronchitis, pneumonia, pleuritis.
Urinary tract infections: acute and recurrent cystitis, acute and chronic pyelonephritis, asymptomatic bacteriuria, prostatitis.
Skin and soft tissue infections: erysipelas, impetigo.

RECOMMENDED DOSE:

Dyna Amoxycillin 125mg/5ml	Adults : 10 ml (2 teaspoonfuls) 3 times daily. Children : 5 ml (1 teaspoonful) 3 times daily, increasing to 10 ml (2 teaspoonfuls) 3 times daily for more severe infections.
Dyna Amoxycillin 250mg/5ml	Adults : 5 ml (1 teaspoonful) 3 times daily. Children : 2.5 ml (½ teaspoonful) 3 times daily, increasing to 5 ml (1 teaspoonful) 3 times daily for more severe infections.

Gonorrhoea : A single dose of 3 g plus 1 g of probenecid where infection is caused by penicillin-sensitive organisms.

Note:
- Patients should continue medicine for full course of treatment.
- Take medicine on empty stomach.
- Reduce dosage is required in patients with impaired renal function.

DIRECTION FOR MIXING:
Shake to loosen powder. Add approximately half the final volume (30 ml or 50 ml) of freshly boiled and cooled water and **shake gently**.
Add more water until the final volume (60 ml or 100 ml) mark is reached and **shake well**.
Keep **refrigerated** (2-8^{o}C) after reconstitution. To be used within **7 days** of mixing.
Complete the prescribed course.

ROUTE OF ADMINISTRATION:
FOR ORAL USE ONLY

CONTRAINDICATIONS:
Not to be used in patients with known hypersensitivity to penicillin.

WARNINGS AND PRECAUTIONS:
Patients hypersensitive to other penicillins or cephalosporins or penicillamine may be hypersensitive to Amoxycillin.
Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients on penicillin therapy with beta-lactams. Before initiating therapy with Dyna Amoxycillin, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, carbapenems or other beta-lactam agents. If an allergic reaction occurs, Dyna Amoxycillin must be discontinued immediately and appropriate alternative therapy instituted.

DRUG INTERACTIONS:
Probenecid prolongs blood levels of Amoxycillin. Antacids and other alkanising agents can impair absorption of Amoxycillin. May reduce effectiveness of oral contraceptives. Concurrent administration of Amoxycillin and Allopurinol increases incidence of rashes.

PREGNANCY AND LACTATION:
Risk-benefit must be considered when given to pregnant women and during breast-feeding.

SIDE EFFECTS:
Side effects are usually mild and transitory e.g. nausea, vomiting, diarrhoea, indigestion. Amoxycillin may give rise to a rash which may be of toxic origin. Rashes almost invariably result when Amoxycillin is given to patients with glandular fever. Small amounts of Amoxycillin excreted in the milk may provoke allergic reactions in breast-fed infants.
Pseudomembranous colitis e.g. severe abdominal or stomach cramps and pain; abdominal tenderness; watery and severe diarrhoea, which may be bloody; fever.
Skin and subcutaneous tissue disorders:
Frequency 'very rare': Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

SYMPTOMS AND TREATMENT OF OVERDOSE:
Problems of overdosage are unlikely to occur. Gross overdosage will produce very high urinary concentration, more so after parenteral administration. Problems are unlikely if adequate fluid intake and urinary output are maintained; however crystalluria is a possibility. More specific measures may be necessary in patients with impaired renal function; the antibiotic is removed by haemodialysis.

PACKING/PACK SIZE(S):
Plastic bottles of 60 ml and 100 ml.

KEEP OUT OF REACH OF CHILDREN
Keep Container Tightly Closed
Do Not Store Above 30^{0}C
Protect From Light
SHAKE WELL BEFORE USE
Keep Refrigerated (2-8°C) After Reconstitution
To Be Used Within 7 Days of Mixing

MANUFACTURER/PRODUCT REGISTRATION HOLDER:
DYNAPHARM (M) SDN. BHD. 198001011897 (65683-V)
2497, Mk. 1, Lorong Perusahaan Baru 5,
Kawasan Perusahaan Perai 3,
13600 Perai, Pulau Pinang, MALAYSIA

PI1PL A003-06
Latest Revision: Nov 2023