

## Composition

**Onclav 625 Tablet:** Each film coated tablet contains Amoxicillin 500 mg as Amoxicillin Trihydrate BP and Clavulanic Acid 125 mg as diluted Potassium Clavulanate BP.

**Onclav PFS 100 ml:** After reconstitution each 5 ml suspension contains Amoxicillin 125 mg as Amoxicillin Trihydrate BP and Clavulanic Acid 31.25 mg as diluted Potassium Clavulanate BP.

## Pharmacology

An antibacterial combination consisting of the antibiotic Amoxicillin and the beta-lactamase inhibitor Clavulanic Acid, Amoxicillin has a broad spectrum of bactericidal activity against many Gram-positive & Gram-negative microorganisms but it is susceptible to degradation by beta-lactamases and therefore the spectrum of activity does not include microorganisms, which produce these enzymes. Clavulanic acid possesses the ability to inactivate a wide range of beta-lactamase enzymes commonly found in microorganisms resistant to penicillin's and cephalosporins. Thus, Clavulanic acid in combination of Amoxicillin and Clavulanic acid protects Amoxicillin from degradation by beta-lactamase enzymes and effectively extends the antibiotic spectrum to embrace a wide range of microorganisms.

## Indication

Indicated for short-term treatment of bacterial infections at the following sites:

1. Upper respiratory tract infections (including ENT) e.g., tonsillitis, sinusitis, otitis media.
2. Lower respiratory tract infections e.g. acute and chronic bronchitis, lobar and bronchopneumonia.
3. Genito-urinary tract infections e.g. cystitis, urethritis, pyelonephritis.
4. Skin and soft tissue infections.
5. Bone and joint infections e.g. osteomyelitis.
6. Other infections e.g. septic abortion, puerperal sepsis, intra-abdominal sepsis, etc.

## Dose & Administration

a) *Route of administration:* Oral

**Tablet:** Adults and children over 12 years:

The usual adult dose is one Amoxicillin & Clavulanic Acid Tablet every 12 hours. For more severe infections and infections of the respiratory tract, the dose should be one Onclav 625 mg Tablet every 8 hours.

**Suspension:** Children 6 - 12 years: 2 teaspoonful every 8 hours.

Children 1 - 6 years: 1 teaspoonful every 8 hours.

Children below 1 year: 25 mg/kg/day in divided doses every 8 hours, for example a 7.5 kg child would require 2 ml Amoxicillin & Clavulanic Acid suspension. Treatment should not be extended beyond 14 days without review.

## Contra-indication

History of Penicillin hypersensitivity. Attention should be paid to possible cross sensitivity with other beta-lactam antibiotics e.g. cephalosporins. Also contraindicated for patients with previous history of Amoxicillin & Clavulanic Acid or penicillin associated cholestatic jaundice.

## Warning & Precaution

Onclav should be used with care in patients on anti-coagulation therapy or with severe hepatic dysfunction. In patients with moderate or severe renal impairment, dosage should be adjusted. During the administration of high dose of Onclav adequate fluid intake and urinary output should be maintained to minimize the possibility of crystalluria.

## Side-effects

a) *Common:* Amoxicillin, are uncommon and mainly of a mild and transitory nature. Diarrhea, pseudomembranous colitis, indigestion, nausea, vomiting and candidiasis.

b) *Rare:* Erythema multiforme, Stevens-Johnson Syndrome and exfoliative dermatitis

## Use in Pregnancy and Lactation

Amoxicillin and Clavulanic acid have been used orally in human pregnancy in a limited number of cases with no untoward effect; however, use of Amoxicillin in pregnancy is not recommended unless considered essential by the physician. During lactation, trace quantities of Amoxicillin can be detected in breast milk.

## Use In children & adolescent

For use in children & adolescent, please see the 'dose and administration' section of this leaflet.

## Drug Interaction

a) *With Medicine:* Allopurinol: Coadministration with allopurinol increases the risk of rash.

b) *With food & Others:* Amoxicillin + Clavulanic acid is usually taken with or without food.

## Direction for reconstitution of suspension

First Shake the bottle to loosen the powder. Add 60 ml of boiled and cooled water to the dry powder of the bottle. For ease of preparation, add water to the bottle in two proportions. Shake the bottle well after each addition until all the powder is in suspension.

## Overdose

Problems of overdose with Co-amoxiclav are unlikely to occur if encountered gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. Co-amoxiclav may be removed from the circulation by haemodialysis.

## Storage

Store below 30°C. Protected from light & moisture. Keep all medicines out of reach of children.

## Packing

**Onclav 625 Tablet:** Each box contains 20 (5x4's) tablets in Alu-Alu blisters pack.

**Onclav PFS 100 ml:** Each bottle contains 100 ml of Powder for Suspension & a measuring cup.

Manufactured by

**Apex Pharma Ltd.**

Shafipur, Kaliakair, Gazipur, Bangladesh

for

**ONE PHARMA LTD.**

C-23-24, BSCIC I/A

Bogura, Bangladesh

