



CODAL-SYNTO



Proven efficacy through the years of experience



Syntoclav[®]

Amoxicillin/Clavulanic acid

SYNTOCLAV[®] 375mg tablets • SYNTOCLAV[®] 625mg tablets • SYNTOCLAV[®] 156,25mg/5ml • SYNTOCLAV FORTE[®] 312,5mg/5ml

Summary of SPC for Syntoclav®

Trade Name of the Medicinal Product:	Syntoclav®
Qualitative and Quantitative Composition:	Each tablet of Syntoclav 375mg contains amoxicillin trihydrate E.P equivalent to 250mg amoxicillin base and potassium clavulanate E.P equivalent to 125mg clavulanic acid. Each tablet of Syntoclav 625mg contains amoxicillin trihydrate E.P equivalent to 500mg amoxicillin base and potassium clavulanate E.P equivalent to 125mg clavulanic acid. After reconstitution each 5ml of Syntoclav contains amoxicillin trihydrate E.P equivalent to 125mg amoxicillin base and potassium clavulanate E.P equivalent to 31.25mg clavulanic acid. After reconstitution each 5ml of Syntoclav Forte contains amoxicillin trihydrate E.P equivalent to 250mg amoxicillin base and potassium clavulanate E.P equivalent to 62.5mg clavulanic acid.
Therapeutic indications:	Infections of the upper respiratory tract, such as otitis media, sinusitis and recurrent tonsillitis; Infections of the lower respiratory tract such as bronchopneumonia and severe acute exacerbation in chronic bronchitis; Infection of skin and soft tissue, such as dental abscess, animal bites and cellulitis; Infections of the abdomen and the genital-urinary tract, such as cystitis, recurrent or complicated cystitis, intra-abdominal sepsis, pelvic sepsis, puerperal sepsis and septic abortion.
Posology and Method of Administration:	Adults and children over twelve years of age: In mild to moderate infections, 1 x 375mg tablet three times a day in equally divided doses. In severe infections, 1 x 625mg tablet three times a day in equally divided doses. For dental infections the recommended dosage is 1 x 375mg tablet three times a day in equally divided doses for five days. Children under twelve years of age: The suspension forms are recommended for use in such patients. Dosage for children aged less than one year should be calculated on bodyweight. Suggested dosages for older children are given as guidance: Aged 1 – 6 years, body weight 10Kg – 18Kg: 5ml Syntoclav suspension (125/31.25), three times a day in equally divided doses. Age 6 – 12 years, body weight 18Kg – 40Kg: 5ml Syntoclav Forte suspension (250/62.5), three times a day in equally divided doses.
Contra-indications:	Penicillin hypersensitivity or a history of related beta lactam sensitivity, such as to cephalosporin antibiotics. A history of penicillin associated jaundice or hepatic dysfunction.
Special Warnings and Precautions for Use:	Renal impairment; Hepatic impairment or evidence of hepatic dysfunction; Patients with reduced urine output; Anaphylactoid reactions; Patients with asthma, infectious mononucleosis or chronic lymphoid leukaemia; Patients on anticoagulant therapy; Prolonged usage of Syntoclav.
Interactions with other Medicaments and other forms of Interaction:	Allopurinol; Anticoagulants; Oral contraceptives; Probenecid; Tetracycline antibiotics; False positive results may be obtained using test methods relying on copper sulphate reagent.
Pregnancy and Lactation:	Use of Syntoclav in pregnancy should be avoided, especially in the first trimester, unless the clinical benefits outweigh the potential unknown risk to the foetus. Caution should be exercised in the administration of Syntoclav during lactation.
Undesirable Effects:	Syntoclav is generally well tolerated and such side effects as occur are usually mild and transitory. The most frequent adverse reactions are: diarrhoea/loose stools (9%), nausea (3%), skin rashes and urticaria (3%), vomiting (1%) and vaginitis (1%). Other, less frequent, adverse reactions are: abdominal discomfort, flatulence and headache.

MAH: Codal Synto Ltd.

