Summary of Product Characteristics
CLAMOXIN- 1000 Tablets

1. Name of the medicinal product

1.1 (Invented) name of the medicinal product:

CLAMOXIN-1000 Tablets

2. Qualitative and quantitative composition

Each film coated tablet contains

Amoxicillin Trihydrate BP

Equivalent to Amoxicillin 875 mg

Diluted Potassium Clavulanate BP

Equivalent to Clavulanic Acid 125 mg

Excipients q.s

3. PHARMACEUTICAL FORM

Tablets

White or off white capsule shape film coated tablets scored in the middle on both sides.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

CLAMOXIN 1000 Tablets are indicated for the treatment of bacterial infections caused by organisms sensitive to Amoxicillin:

Infection of the upper and lower respiratory tract

Otitis media (inflammation of middle ear)

Acute sinusitis

Acute exacerbation of chronic bronchitis

Pneumonia

Infections of the kidneys and lower urinary tract

Infections of the skin and soft tissues

4.2 Posology and method of administration

The dose of CLAMOXIN 1000 that is selected to treat an individual infection should take into account:

The expected pathogens and their likely susceptibility to antibacterial agents

The severity and the site of the infection

The age, weight and renal function of the patient as shown below

Adults and Children > 40 Kg: Usual dose:

One CLAMOXIN 1000 tablet two times a day;

For otitis media, sinusitis, lower respiratory tract infections and urinary tract infections:

One CLAMOXIN 1000 tablet three times a day.

Children < 40 Kg:

Children may be treated with formulation found appropriate for the age of the child and severity of the disease.

Usual Dose:

CLAMOXIN 1000 Tablets: 25 mg/3.6 mg/kg/day to 45 mg/6.4 mg/kg/day given as two divided doses;

For Otitis media, sinusitis and lower respiratory tract infections:

CLAMOXIN 1 0 0 0 Tablets: Up to 70 mg/10 mg/kg/day given as two divided doses may be considered.

As the tablets cannot be divided children weighing less than 25 kg must not be treated with Co-amoxiclav tablets BP.

The table below presents the received dose (mg/kg body weight) in children weighing 25 kg to 40 kg upon administering a single 875 mg/125 mg tablet.

Body weight [kg]	40	35	30	25	Single dose recommended [mg/kg body weight] (see above)
Amoxicillin [mg/kg body weight] per single dose (1 film-coated tablet)	21.9	25.0	29.2	35.0	12.5 – 22.5 (up to 35)
Clavulanic acid [mg/kg body weight] per single dose (1 film-coated tablet)	3.1	3.6	4.2	5.0	1.8 – 3.2 (up to 5)

Elderly

No dose adjustment is considered necessary.

Renal impairment

No dose adjustment is required in patients with creatinine clearance (CrCl) greater than 30 ml/min.

In patients with creatinine clearance less than 30 ml/min, the use of amoxicillin to clavulanic acid ratio of 7:1 is not recommended, as no recommendations for dose adjustments are available.

Hepatic impairment
Dose with caution and monitor hepatic function at regular intervals.

Method of administration
CLAMOXIN is for oral use.
Administer at the start of a meal to minimise potential gastrointestinal in al intolerance and optimise absorption of amoxicillin/clavulanic acid.

4.3 Contraindications
CLAMOXIN 1000 Tablets is contraindicated in patients with known hypersensitivity to certain β-lactum antibiotics e.g., penicillins, cephalosporins.

4.4 Special warnings and precautions for use
Caution should be taken in case of hepatic impairment, renal impairment or gastrointestinal disorder with vomiting and diarrhoea, presence of history of manifest allergies or asthma, patients suffering from infections such as mononucleosis or lymphatic leukaemia or has indwelling catheter.
Elderly patients (aged 60 and over) should be treated with caution and should have their liver function monitored. With prolonged therapy, kidney, liver and blood parameters should be regularly monitored.
Patients with existing hepatic impairment should have the liver function closely monitored irrespective of the length of therapy. Should the parameters deteriorate during treatment, termination of therapy should be considered. In rare instances amoxicillin can adversely affect the reliability of contraceptives (hormonal contraceptives, the Pill). It is therefore advisable to take other non-hormonal precautions in addition. The efficacy of CLAMOXIN 1000 tablets can be adversely affected by diarrhoea. Non-enzymatic methods of urine sugardetermination can produce false positive results. The identification of urobilinogen can also be affected.

4.5 Interaction with other medicinal products and other forms of interaction
Caution should be taken while administering Amoxicillin concomitantly with tetracylines, macrolides, sulphonamides or chloramphenicol antibiotics, probenecid, allopurinol, diuretics, hormonal contraceptives, digoxin, disulfiram and coumarin.

4.6 Pregnancy and lactation
CLAMOXIN 1000 tablets should be used during pregnancy only if potential benefits outweigh the risk. Since Amoxicillin is eliminated in breast milk, breast fed babies may therefore have diarrhoea and colonization of the mucous membranes by yeast, possibly resulting in a need to discontinue breast feeding. The possibility of sensitization should also be taken into consideration.

4.7 Effects on ability to drive and use machines
No studies on the effects on the ability to drive and use machines have been performed. However, undesirable effects may occur such as dizziness and convulsions, which may influence the ability to drive and use machines.

4.8 Undesirable effects

Commonly reported adverse drug reactions are diarrhoea, nausea and vomiting, also uncommon reactions such as mucocutaneous candidosis, dizziness, headache, indigestion, rise in AST/ALT, skin rash, pruritis and urticarial.

Rarely reactions such as overgrowth of non-susceptible organisms, reversible leucopenia, thrombocytopenia, reversible agranulocytosis, haemolytic anemia, prolongation of bleeding time and prothrombin time, angioneurotic oedema, anaphylaxis, serum sickness like syndrome, reversible hyperactivity, convulsions, antibiotic associated colitis, hepatitis, chloestatic jaundice, erythema multiforme, stevens Johnson syndrome, toxic epidermal necrolysis, bullous exfoliative dermatitis, insterstitial nephritis and crystalluria.

4.9 Overdose

Symptoms such as gastrointestinal disturbance of fluid, electrolyte balances, renal failure and convulsions may occur in patients those receiving high doses. Gastrointestinal symptoms may be treated symptomatically, with attention to the water/electrolyte balance. Amoxicillin/clavulanic acid can be removed from the circulation by haemodialysis.

5. Pharmacological properties:

5.1 Pharmacodynamic properties

The efficacy of amoxicillin and clavulanic acid is the result of bacterial activ ity of amoxicillin combined with the inhibitory activity of clavulanic acid on β-lactamases produced by different bacterial strains. Like other β-lactums, clavulanic acid penetrates through the bacterial cell wall but it generally possesses poor instrinsic antimicrobial activity and is generally a more potent inhibitor of cell free β-lactamases. The binding of β-lactamases with clavulanic acid is a complex physiochemical process, which rapidly leads to lysis of the cell.

5.2 Pharmacokinetic properties

Amoxicillin and clavulanate potassium are well absorbed from gastrointestinal tract after oral administration of Amoxicillin Clavulanate potassium. The safety and efficacy of Amoxicillin, clavulanate potassium have been established in clinical trials where Amoxicillin, Clavulanate Potassium was taken without regard to meals. Amoxicillin diffuses readily into most body tissues and fluids with the exception of the brain and spinal fluid. The results of experiments involving the administration of clavulanic acid to animals suggest that this compound, like amoxicillin is well distributed in body tissues. Approximately 50 % to 70 % of amoxicillin and approximately 25 % to 40 % of clavulanic acid are excreted unchanged in urine during the first 6 hours after oral administration.

5.3 Preclinical safety data

Nonclinical data reveal no special hazard for humans based on studies of safety pharmacology, genotoxicity and toxicity to reproduction. Repeat dose toxicity studies performed in dogs with amoxicillin/clavulanic acid demonstrate gastric irritancy and vomiting, and discoloured tongue. Carcinogenicity studies have not been conducted with Co-amoxiclav tablets or its components.

6. Pharmaceutical particulars

6.1 List of excipient(s)

Microcrystalline Cellulose, Magnesium Stearate, Colloidal anhydrous silica, Sodium Starch Glycolate, Hydroxypropyl Methyl Cellulose E-5 (HPMC E5), Hydroxypropyl Methyl Cellulose E15 (HPMC E15), Titanium Dioxide, Polyethylene Glycol 6000, Simeticone and Purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store in cool and dry place, below 25°C.

6.5 Nature and contents of container

Each carton contains tropical blister pack containing 1x7, 2x7 & 2x10 tablets along with leaflet.

6.6 Special precautions for disposal

No special requirements

7. Marketing authorization holder

BLISS GVS PHARMA LTD.

102, Hyde Park, Saki Vihar Road,

Andheri (East).

Mumbai - 400 072, INDIA.