Amoxicillin 400 mg. and Clavulanic Acid 57 mg. Powder for Oral Suspension

Ogmatin 457

Eq. to Amoxicillin 400 mg.
Eq. to Clavulanic Acid 57 mg.

Composition :
Each 5 ml of reconstituted suspension contains :

Amoxicillin Trihydrate	B.P.	
Eq. to Amoxicillin		400 mg.
Diluted Potassium Clavulanate	B.P.	
Eq. to Clavulanic Acid		57 mg.
Excipients		q.s.

Flavour : Strawberry

Indications : Ogmatin is indicated for the treatment of the following infections in adults and children :
- Acute bacterial sinusitis (adequately diagnosed)
- Acute otitis media
- Acute exacerbations of chronic bronchitis (adequately diagnosed)
- community acquired pneumonia
- Cystitis
- Pyelonephritis
- Skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis.
- Bone and joint infections, in particular osteomyelitis.

Posology and method of administration : Doses are expressed throughout in terms of amoxicillin / clavulanic acid content except when doses are stated in terms of an individual component.
The dose of **Ogmatin** 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.

The use of alternative presentations of amoxicillin/clavulanic acid (e.g. those that provide higher doses of amoxicillin and/or different ratios of amoxicillin to clavulanic acid) should be considered as necessary.
The duration of therapy should be determined by the response of the patient. Some infections (e.g. osteomyelitis) require longer periods of treatment. Treatment should not be extended beyond 14 days without review.
Adults and children ≥ 40 kg.: One 500 mg. dose taken three times a day.
Children < 40 kg. : 20 mg./5mg./ kg./day to 60 mg./15mg./ kg./day given in three divided doses.
OR as directed by the physician.

Pharmacological properties : Mode of action : Amoxicillin is a semisynthetic penicillin (β-lactam antibiotic) that inhibits one or more enzymes (often referred to as penicillin-binding proteins. PBPs) in the biosynthetic pathway of bacterial peptidoglycan, which is an integral structural component of the bacterial cell wall. Inhibition of peptidoglycan synthesis leads to weakening of the cell wall, which is usually followed by cell lysis and death.
Amoxicillin is susceptible to degradation by β-lactamases produced by resistant bacteria and therefore the spectrum of activity of amoxicillin alone does not include organisms which produce these enzymes.
Clavulanic acid is β-lactam structurally related to penicillins. It inactivates some β-lactamase enzymes thereby preventing inactivation of amoxicillin. Clavulanic acid alone does not exert a clinically useful antibacterial effect.

Contraindications
- Hypersensitivity to the active substances, to any of the penicillins or to any of the excipients.
- History of a severe immediate hypersensitivity reaction (e.g. anaphylaxis) to another β-lactam agent (e.g. cephalosporin, carbapenem or monobactam)
- History of jaundice/hepatic impairment due to amoxicillin / clavulanic acid/.

Special warnings and precautions for use : Before initiating therapy with amoxicillin/clavulanic acid, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other β-lactam agents. 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 penicillin hypersensitivity and in atopic individuals. If an allergic reaction occurs, amoxicillin/clavulanic acid therapy must be discontinued and appropriate alternative therapy instituted.
In the case that an infection is proven to be due to an amoxicillin-susceptible organism(s) then consideration should be given to switching from amoxicillin/clavulanic acid to amoxicillin in accordance with official guidance.
Prolonged use may occasionally result in overgrowth of non-susceptible organisms.
Amoxicillin/clavulanic acid should be used with caution in patients with evidence of hepatic impairment.

Storage : Store at a temperature not exceeding 25°C, protect from light and moisture.
Keep the medicine out of reach of children. SHAKE WELL BEFORE USE.

Dosage : As directed by physician.

Pack Size : 70 ml.

Manufactured for
BETA PHARMA LABORATUVAR ILAÇ SAN .VE TİC .LTD .ŞTİ
MOLLA GURANI MAH. TURGUT OZAL MILLET
CADNO:84/201 FATIH/ ISTANBUL TURKIYE

Amoxicillin 400 mg. and Clavulanic Acid 57 mg. Powder for Oral Suspension

Ogmatin 457

Eq. to Amoxicillin 400 mg.
Eq. to Clavulanic Acid 57 mg.

Composition :
Each 5 ml of reconstituted suspension contains :

Amoxicillin Trihydrate	B.P.	
Eq. to Amoxicillin		400 mg.
Diluted Potassium Clavulanate	B.P.	
Eq. to Clavulanic Acid		57 mg.
Excipients		q.s.

Flavour : Strawberry

Indications : Ogmatin is indicated for the treatment of the following infections in adults and children :
- Acute bacterial sinusitis (adequately diagnosed)
- Acute otitis media
- Acute exacerbations of chronic bronchitis (adequately diagnosed)
- community acquired pneumonia
- Cystitis
- Pyelonephritis
- Skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis.
- Bone and joint infections, in particular osteomyelitis.

Posology and method of administration : Doses are expressed throughout in terms of amoxicillin / clavulanic acid content except when doses are stated in terms of an individual component.
The dose of **Ogmatin** 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.

The use of alternative presentations of amoxicillin/clavulanic acid (e.g. those that provide higher doses of amoxicillin and/or different ratios of amoxicillin to clavulanic acid) should be considered as necessary.
The duration of therapy should be determined by the response of the patient. Some infections (e.g. osteomyelitis) require longer periods of treatment. Treatment should not be extended beyond 14 days without review.
Adults and children ≥ 40 kg.: One 500 mg. dose taken three times a day.
Children < 40 kg. : 20 mg./5mg./ kg./day to 60 mg./15mg./ kg./day given in three divided doses.
OR as directed by the physician.

Pharmacological properties : Mode of action : Amoxicillin is a semisynthetic penicillin (β-lactam antibiotic) that inhibits one or more enzymes (often referred to as penicillin-binding proteins. PBPs) in the biosynthetic pathway of bacterial peptidoglycan, which is an integral structural component of the bacterial cell wall. Inhibition of peptidoglycan synthesis leads to weakening of the cell wall, which is usually followed by cell lysis and death.
Amoxicillin is susceptible to degradation by β-lactamases produced by resistant bacteria and therefore the spectrum of activity of amoxicillin alone does not include organisms which produce these enzymes.
Clavulanic acid is β-lactam structurally related to penicillins. It inactivates some β-lactamase enzymes thereby preventing inactivation of amoxicillin. Clavulanic acid alone does not exert a clinically useful antibacterial effect.

Contraindications
- Hypersensitivity to the active substances, to any of the penicillins or to any of the excipients.
- History of a severe immediate hypersensitivity reaction (e.g. anaphylaxis) to another β-lactam agent (e.g. cephalosporin, carbapenem or monobactam)
- History of jaundice/hepatic impairment due to amoxicillin / clavulanic acid/.

Special warnings and precautions for use : Before initiating therapy with amoxicillin/clavulanic acid, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other β-lactam agents. 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 penicillin hypersensitivity and in atopic individuals. If an allergic reaction occurs, amoxicillin/clavulanic acid therapy must be discontinued and appropriate alternative therapy instituted.
In the case that an infection is proven to be due to an amoxicillin-susceptible organism(s) then consideration should be given to switching from amoxicillin/clavulanic acid to amoxicillin in accordance with official guidance.
Prolonged use may occasionally result in overgrowth of non-susceptible organisms.
Amoxicillin/clavulanic acid should be used with caution in patients with evidence of hepatic impairment.

Storage : Store at a temperature not exceeding 25°C, protect from light and moisture.
Keep the medicine out of reach of children. SHAKE WELL BEFORE USE.

Dosage : As directed by physician.

Pack Size : 70 ml.

Manufactured for
BETA PHARMA LABORATUVAR ILAÇ SAN .VE TİC .LTD .ŞTİ
MOLLA GURANI MAH. TURGUT OZAL MILLET
CADNO:84/201 FATIH/ ISTANBUL TURKIYE