Hibiotic® 156 mg 312 mg

amoxicillin + clavulanic acid

Powder for oral Suspension

BROAD SPECTRUM BACTERICIDAL ANTIBIOTIC

Pharmaceutical forms:
Hibiotic® 125/31 Powder for oral suspension.
Hibiotic® 250/62 Powder for oral suspension.
(Dry powder for reconstitution in water, at time of dispensing, to form Oral Suspension).
Qualitative and quantitative composition:
Active ingredients- **Hibiotic®** 125/31 Powder for oral Suspension; after reconstitution, each 5 ml contains Amoxicillin Trihydrate 145.75 mg Eq. to 125 mg Amoxicillin, Potassium Clavulanate 36.5 mg Eq. to 31 mg clavulanic acid.
Inactive ingredients- Diibasic sodium citrate, Tribasic sodium citrate, Carboxy methyl cellulose, Dimethicone, Aromatized apricot powder, Aromatized Mint powder, Aromatized Liquid caramel & Sucrose.
Active ingredients- **Hibiotic®** 250/62 Powder for oral Suspension; after reconstitution each 5 ml contains: Amoxicillin Trihydrate 287.5 mg Eq. to 250 mg Amoxicillin, Potassium clavulanate: Aerosil 1:1 145.6 mg composed from: 72.8 mg potassium clavulanate(eq. to 62 mg Clavulanic acid activity) and 72.8 mg Aerosil.
Inactive ingredients- Citric acid anhydrous Tribasic Sodium citrate,carboxymethyl cellulose sodium, Croscarmellose sodium, Aerosil 200, Lemon flavour powder, Dimethicone 350, Sucrose for antibiotic, Sodium stearyl fumarate.

Clinical particulars
Therapeutic indications
Hibiotic® 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.
Consideration should be given to official guidance on the appropriate use of antibacterial agents.

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 **Hibiotic®** 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 **Hibiotic®** (e.g. those that provide higher doses of amoxicillin and/or different ratios of amoxicillin to clavulanic acid) should be considered as necessary.
for adults and children ≥ 40 kg, this formulation of **Hibiotic®** provides a total daily dose of 1500 mg amoxicillin/375 mg clavulanic acid, when administered as recommended below. For children < 40 kg, this formulation of **Hibiotic®** provides a maximum daily dose of 2400 mg amoxicillin/600 mg clavulanic acid, when administered as recommended below. If it is considered that a higher daily dose of amoxicillin is required, it is recommended that another preparation of **Hibiotic®** is selected in order to avoid administration of unnecessarily high daily doses of clavulanic acid
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/125 mg dose taken three times a day.

Children < 40 kg
30 mg/5 mg/kg/day to 60 mg/15 mg/kg/day given in three divided doses.
No clinical data are available on doses of **Hibiotic®** Amoxicillin/Clavulanic acid 4:1 formulations higher than 40 mg/10 mg/kg per day in children under 2 years.

Elderly
No dose adjustment is considered necessary.

Renal impairment
Dose adjustments are based on the maximum recommended level of amoxicillin. no adjustment in dose is required in patients with creatinine clearance (CrCl) greater than 30 ml/min.

Adults and children ≥ 40 kg

CrCl 30-50 ml/min	500 mg/125 mg twice daily
CrCl ≤ 10 ml/min	500 mg/125 mg once daily
Haemodialysis	500 mg/125 mg every 24 hours; plus 500 mg/125 mg during dialysis, to be repeated at the end of dialysis (as serum concentrations of both amoxicillin and clavulanic acid are decreased)

Children < 40 kg

CrCl 30-50 ml/min	15 mg/3.75 mg/kg twice daily, (maximum 500 mg/125 mg twice daily).
CrCl ≤ 10 ml/min	15 mg/3.75 mg/kg as a single daily dose (maximum 500 mg/125 mg).
Haemodialysis	15 mg/3.75 mg/kg per day once daily. Prior to haemodialysis 15 mg/3.75 mg/kg, in order to restore circulating drug levels, 15 mg/3.75 mg per kg should be administered after haemodialysis.

Hepatic impairment
Dose with caution and monitor hepatic function at regular intervals .
Method of administration
Hibiotic® is for oral use.
Administer at the start of a meal to minimize potential gastrointestinal intolerance and optimise absorption of amoxicillin/clavulanic acid. Therapy can be started parenterally according the SPC of the IV formulation and continued with an oral preparation. Shake to loosen powder, add water as directed, invert and shake. Shake the bottle before each dose.

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 beta-lactam agent (e.g. a cephalosporin, carbapenem or mono lactam). History of jaundice/hepatic impairment due to amoxicillin/clavulanic acid.

Special warnings and precautions for use
Warning :
Before initiating therapy with amoxicillin/clavulanic acid, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other beta-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 present to be due to an amoxicillin-susceptible organisms (or there consideration should be given to switching from amoxicillin/clavulanic acid to amoxicillin in accordance with official guidance. This presentation of **Hibiotic®** is not suitable for use when there is a high risk that the presumptive pathogens have reduced susceptibility or resistance to beta-lactam agents that is not mediated by beta-lactamases susceptible to inhibition by clavulanic acid. This presentation should not be used to treat penicillin-resistant S. pneumoniae. Convulsions may occur in patients with impaired renal function or in those receiving high doses. Amoxicillin/clavulanic acid should be avoided if infectious mononucleosis is suspected since the occurrence of a morbiliform rash has been associated with this condition following the use of amoxicillin. Concomitant use of allopurinol during treatment with amoxicillin/clavulanic acid may increase the likelihood of allergic skin reactions. Prolonged use may occasionally result in overgrowth of non-susceptible organisms. The occurrence at the treatment initiation of a feverish generalised erythema associated with pustula may be a symptom of acute generalised exanthematous pustulosis (AGEP). This reaction requires **Hibiotic®** discontinuation and contra-indication any subsequent administration of amoxicillin. Amoxicillin/clavulanic acid should be used with caution in patients with evidence of hepatic impairment . Hepatic events have been reported predominantly in males and elderly patients and may be associated with prolonged treatment. These events have been very rarely reported in children. In all populations, signs and symptoms usually occur during or shortly after treatment but in some cases may not become apparent until several weeks after treatment has ceased. These are usually reversible. Hepatic events may be severe and, in extremely rare circumstances, deaths have been reported. These have almost always occurred in patients with serious underlying disease or taking concomitant medications known to have the potential for hepatic effects. Antibiotic-associated colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea during or subsequent to the administration of any antibiotics. Should antibiotic-associated colitis occur, amoxicillin/clavulanic acid should immediately be discontinued, a physician be consulted and an appropriate therapy initiated. Antiperistaltic medicinal products are contra-indicated in this situation. Periodic assessment of organ system functions, including renal, hepatic and haematopoietic function is advisable during prolonged therapy. Prolongation of prothrombin time has been reported rarely in patients receiving amoxicillin/clavulanic acid. Appropriate monitoring should be undertaken when anticoagulants are prescribed concomitantly. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation. In patients with renal impairment, the dose should be adjusted according to the degree of impairment. In patients with reduced urine output, cystitides has been observed very rarely, predominantly with parenteral therapy. During the administration of high doses of amoxicillin, it is advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of amoxicillin crystallizing. In patients with bladder catheters, a regular check of patency should be maintained. During treatment with amoxicillin, enzymatic glucose oxidase methods should be used whenever testing for the presence of glucose in urine because false positive results may occur with non-enzymatic methods. The presence of Clavulanic acid in **Hibiotic®** may cause a non-specific binding of IgG and albumin by red cell membranes leading to a false positive Coombs test. There have been reports of positive test results using the Bio-Rad Laboratories Platelia Aspergillus EIA test in patients receiving amoxicillin/clavulanic acid who were subsequently found to be free of Aspergillus infections. Cross reactions with non-Aspergillus polysaccharides and polyhalomones with Bio-Rad Laboratories Platelia Aspergillus EIA test have been reported. Therefore, positive test results in patients receiving amoxicillin/clavulanic acid should be interpreted cautiously and confirmed by other diagnostic methods. this medicine contains sucrose: not recommended for patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrose-isomathase insufficiency.

Interaction with other medicinal products and other forms of interaction
Oral anticoagulants
Oral anticoagulants and penicillin antibiotics have been widely used in practice without reports of interaction. However, in the literature there are cases of increased international normalized ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalized ratio should be carefully monitored with the addition or withdrawal of amoxicillin. Moreover, adjustments in the dose of oral anticoagulants may be necessary.
Methotrexate
Penicillins may reduce the excretion of methotrexate causing a potential increase in toxicity.
Probenecid
Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin. Concomitant use of probenecid may result in increased and prolonged blood levels of amoxicillin but not of clavulanic acid.
Mycophenolate-mofetil
In patients receiving mycophenolate mofetil, reduction in pre-dose concentration of the active metabolite mycophenolic acid (MPA) of approximately 50% has been reported following commencement of oral amoxicillin plus clavulanic acid. The change in pre-dose level may not accurately represent changes in overall MPA exposure. Therefore, a change in the dose of mycophenolate mofetil should not normally be necessary in the absence of clinical evidence of graft dysfunction. However, close clinical monitoring should be performed during the combination and shortly after antibiotic treatment.

Pregnancy and lactation
Pregnancy
Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development . Limited data on the use of amoxicillin/clavulanic acid during pregnancy in humans do not indicate an increased risk of congenital malformations. In a single study in women with preterm, premature rupture of the fetal membrane it was reported that prophylactic treatment with amoxicillin/clavulanic acid may be associated with an increased risk of necrotising enterocolitis in neonates. Use should be avoided during pregnancy, unless considered essential by the physician.
Lactation
Both substances are excreted into breast milk (nothing is known of the effects of clavulanic acid on the breast-fed infant). Consequently, diarrhea and fungus infection of the mucous membranes are possible in the breast-fed infant, so that breast-feeding might have to be discontinued. Amoxicillin/clavulanic acid should only be used during breast-feeding after benefit/risk assessment by the physician in charge.

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 (e.g. allergic reactions, dizziness, convulsions), which may influence the ability to drive and use machines .

Undesirable effects
The most commonly reported adverse drug reactions (ADRs) are diarrhea, nausea and vomiting.
The ADRs derived from clinical studies and post-marketing surveillance with **Hibiotic®** Amoxicillin/Clavulanic acid preptions, sorted by MedDRA System Organ Class are listed below.
The following terminologies have been used in order to classify the occurrence of undesirable effects.
Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥1/10,000 to <1/1,000)
Very rare (<1/10,000)
Not known (cannot be estimated from the available data)

Infections and infestations	
Mucocutaneous candidiasis	Common
Overgrowth of non-susceptible organisms	Not known
Blood and lymphatic system disorders	
Reversible leucopenia including agranulocytosis	Rare
Thrombocytopenia	Rare
Reversible cases haematopenia	Not known
Haemolytic anaemia	Not known
Prolongation of bleeding time and prothrombin time [1]	Not known
Immune system disorders [2]	
Angioneurotic oedema	Not known
Anaphylaxis	Not known
Serum sickness-like syndrome	Not known
Hypersensitivity vasculitis	Not known
Nervous system disorders	
Dizziness	Uncommon
Headache	Uncommon
Reversible hyperactivity	Not known
Convulsions [3]	Not known
Aseptic meningitis	Not known
Gastrointestinal disorders	
Diarrhea	Common
Nausea [4]	Common
Vomiting	Common
Indigestion	Uncommon
Antibiotic-associated colitis [5]	Not known
Black hairy tongue	Not known
Tooth discoloration [6]	Not known
Hepatobiliary disorders	
Rises in AST and/or ALT [7]	Uncommon
Hepatitis	Not known
Cholestatic jaundice [8]	Not known
Skin and subcutaneous tissue disorders [2]	
Skin rash	Uncommon
Pruritus	Uncommon
Urticaria	Uncommon
Erythema multiforme	Rare
Stevens-Johnson syndrome	Not known
Toxic epidermal necrolysis	Not known
Fixed drug eruption dermatitis	Not known
Acute generalised exanthematous pustulosis (AGEP) [9]	Not known
Renal and urinary disorders	
Interstitial nephritis	Not known
Crystalluria [10]	Not known

[1] In patients treated with oral anticoagulants prudence is because is more often associated with higher risk of bleed. Coagulation disorders associated with antibiotic treatment may be induced by taking **Hibiotic®** at the start of a meal. [2] Cutaneous reactions are extremely rare but may be induced by taking **Hibiotic®** at the start of a meal. [3] Convulsions may occur in patients with impaired renal function or in those receiving high dosages. [4] Nausea is more often associated with higher dosages. [5] Antibiotic-associated colitis includes mild to life-threatening colitis. [6] Tooth discoloration has been reported very rarely in children. Good oral hygiene may help to prevent tooth discoloration as it can usually be removed by brushing. [7] Rises in transaminase levels have been reported in patients treated with beta-lactam and beta-lactamase inhibitor combinations and other penicillins and cephalosporins. Significance of these rises in relation to the administration of these antibiotics is unknown. [8] Cholestasis has been noted with other penicillins. [9] Acute generalised exanthematous pustulosis (AGEP) is a generalised pustular eruption with fever. It is usually first observed in the early days of treatment, it is transient (usually resolves within 5 days) and may be associated with underlying conditions and drug exposures. [10] Crystalluria has been reported in patients treated with beta-lactam and beta-lactamase inhibitor combinations and other penicillins and cephalosporins. Significance of these rises in relation to the administration of these antibiotics is unknown. [11] Tooth discoloration has been reported very rarely in children. Good oral hygiene may help to prevent tooth discoloration as it can usually be removed by brushing.

Overdose
Symptoms and signs of overdose
Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. Amoxicillin crystalluria, in some cases leading to renal failure, has been observed . Convulsions may occur in patients with impaired renal function or in those receiving high doses. Amoxicillin has been reported to precipitate in bladder catheters, predominantly after intravenous administration of large doses. A regular check of patency should be maintained .
Treatment of intoxication
Gastrointestinal symptoms may be treated symptomatically, with attention to the water/electrolyte balance. Amoxicillin/clavulanic acid can be removed from the circulation by hemodialysis.

Pharmacological properties
Pharmacodynamic properties
Pharmacotherapeutic group: Combinations of penicillins, incl. beta-lactamase inhibitors;
Mode of action
Amoxicillin is a semisynthetic penicillin (beta-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 beta-lactamases, and therefore spectrum of activity of amoxicillin alone does not include organisms which produce these enzymes. Clavulanic acid is a beta-lactam structurally related to penicillins. It inactivates some beta-lactamase enzymes thereby preventing inactivation of amoxicillin. Clavulanic acid alone does not exert a clinically useful antibacterial effect.
PK/PD relationship
The time above the minimum inhibitory concentration (T>MIC) is considered to be the major determinant of efficacy for amoxicillin.
Mechanisms of resistance
The two main mechanisms of resistance to amoxicillin/clavulanic acid are:
• Inactivation by those bacterial beta-lactamases that are not themselves inhibited by clavulanic acid, including class B, C and D.
• Alteration of PBPs, which reduce the affinity of the antibacterial agent for the target.
Impermeability of bacteria or efflux pump mechanisms may cause or contribute to bacterial resistance, particularly in Gram-negative bacteria.
The prevalence of resistance may vary geographically and with time for selected species, and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infections is questionable.

Commonly susceptible species
Aerobic Gram-positive micro-organisms
Enterococcus faecalis. Gardnerella vaginalis. Staphylococcus aureus* (methicillin-susceptible). Coagulase-negative staphylococci (methicillin-susceptible). Streptococcus agalactiae. Streptococcus pneumoniae[1]. Streptococcus pyogenes and other beta-haemolytic streptococci. Streptococcus viridans group
Aerobic Gram-negative micro-organisms
Capnocytophaga spp. Eikenella corrodens. Haemophilus influenzae[2]. Moraxella catarrhalis. Pasteurella multocida.
Anaerobic micro-organisms
Bacteroides fragilis. Fusobacterium nucleatum. Prevotella spp.
Species for which acquired resistance may be a problem
Aerobic Gram-positive micro-organisms
Enterococcus faecium*
Aerobic Gram-negative micro-organisms
Escherichia coli. Klebsiella oxytoca. Klebsiella pneumoniae. Proteus mirabilis. Proteus vulgaris.
Inherently resistant organisms
Aerobic Gram-negative micro-organisms
Acinetobacter sp. Citrobacter freundii. Enterobacter sp. Legionella pneumophila. Morganella morganii. Providencia spp. Pseudomonas sp. Serratia sp. Stenotrophomonas maltophilia
Other micro-organisms
Chlamydophila pneumoniae. Chlamydophila psittaci. Coxiella burnetii. Mycoplasma pneumoniae.

* = Natural intermediate susceptibility in the absence of acquired mechanism of resistance.
[1] = All methicillin-resistant staphylococci are resistant to amoxicillin/clavulanic acid
[2] Streptococcus pneumoniae that are resistant to penicillin should not be treated with this presentation of amoxicillin/clavulanic acid .
[2] Strains with decreased susceptibility have been reported in some countries in the EU with a frequency higher than 10%

Pharmacokinetic properties
Absorption
Amoxicillin and clavulanic acid, are fully dissociated in aqueous solution at physiological pH. Both components are rapidly and well absorbed by the oral route of administration. Absorption of amoxicillin/clavulanic acid is optimized when taken at the start of a meal. Following oral administration, amoxicillin and clavulanic acid are approximately 70% bioavailable. The plasma profiles of both components are similar and the time to peak plasma concentration (T_{max}) in each case is approximately one hour.
Amoxicillin and clavulanic acid serum concentrations achieved with amoxicillin/clavulanic acid are similar to those produced by the oral administration of equivalent doses of amoxicillin or clavulanic acid alone.
Distributing: About 25% of total plasma clavulanic acid and 18% of total plasma amoxicillin is bound to protein. The apparent volume of distribution is around 0.3-0.4 L/kg for amoxicillin and around 0.2 L/kg for clavulanic acid. Following intravenous administration, both amoxicillin and clavulanic acid have been found in gall bladder, abdominal tissue, skin, fat, muscle tissues, synovial and peritoneal fluids, bile and pus. Amoxicillin does not adequately distribute into the cerebrospinal fluid. From animal studies there is no evidence for significant tissue retention of drug-derived material for either component. Amoxicillin, like most penicillins, can be detected in breast milk. Trace quantities of clavulanic acid can also be detected in breast milk . Both amoxicillin and clavulanic acid have been shown to cross the placental barrier .
Biotransformation: Amoxicillin is partly excreted in the urine as the inactive penicilloic acid in quantities equivalent to up to 10 to 25% of the initial dose. Clavulanic acid is extensively metabolized in man and eliminated in urine and faeces and as carbon dioxide in expired air.
Elimination: The major route of elimination for amoxicillin is via the kidney, whereas for clavulanic acid it is by both renal and non-renal mechanisms. Amoxicillin/clavulanic acid has a mean elimination half-life of approximately one hour and a mean total clearance of approximately 25 L/h in healthy subjects. Approximately 60 to 70% of the amoxicillin and approximately 40 to 65% of the clavulanic acid are excreted unchanged in urine during the first 6 h after administration of single **Hibiotic®** 250 mg/125 mg or 500 mg/125 mg tablets. Various studies have found the urinary excretion to be 50-85% for amoxicillin and between 27-60% for clavulanic acid over a 24 hour period. In the case of clavulanic acid, the largest amount of drug is excreted during the first 2 hours after administration. Concomitant use of probenecid delays amoxicillin excretion but does not delay renal excretion of clavulanic acid .
Age: The elimination half-life of amoxicillin is similar for children aged around 3 months to 2 years and older children and adults. For very young children (including preterm newborns) in the first week of life the interval of administration should not exceed twice daily administration due to immaturity of the renal pathway of elimination. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.
Gender: Following oral administration of amoxicillin/clavulanic acid to healthy males and female subjects, gender has no significant impact on the pharmacokinetics of either amoxicillin or clavulanic acid.
Renal impairment
The total serum clearance of amoxicillin/clavulanic acid decreases proportionately with decreasing renal function. The reduction in drug clearance is more pronounced for amoxicillin than for clavulanic acid, as a higher proportion of amoxicillin is excreted via the renal route. Doses in renal impairment must therefore prevent undue accumulation of amoxicillin while maintaining adequate levels of clavulanic acid .
Hepatic impairment
Hepatically impaired patients should be dosed with caution and hepatic function monitored at regular intervals.
Package :
Hibiotic® 125/31 or 250/62 Powder for Oral Suspension: Carton Box containing amber glass (Type **III**) bottle of 40 gm powder with insert leaflet.
Special precautions for storage
Hibiotic® 125/31 or 250/62 Suspension: Before Reconstitution: Store at temperature not exceeding 25° C. After reconstitution: Keep in refrigerator (but not frozen) for only 7 days.
Special precautions for disposal and other handling
Check cap seal is intact before using. Shake bottle to loosen powder. Add volume of water (as indicated below) invert and shake well. Alternatively fill the bottle with water to just below the mark on bottle label, invert and shake well. Then top up with water exactly to the mark, invert and again shake well.

Strength	Volume of water to be added at reconstitution (ml)	Final volume of reconstituted oral suspension (ml)
125 mg/31 mg/5 ml or 250mg / 62mg	Make up to mark	60

Shake the bottle well before each dose.

Keep all medicaments out of reach of children

Product of:
AMOUN PHARMACEUTICAL CO. S.A.E.
El-Obour City, Al Qalyubia, Egypt.

هـاى بيـوتك® ١٥٦مجم ٣١٢مجم

أموكسيسيللين + حمض الكلافيولانيك

مسحوق لتحضير معلق للشرب

مضاد حيوى قاتل للبكتيريا واسع المدى

المواد الفعالة بـ هاى بيوتك® ١٥٦ ملجم:
يحتوى كل ٥ مللى من المعلق على ١٤٢,٧٥ مجم اموكسيسيللين تراى هيدرات يكافئ ١٢٥ مجم اموكسيسيللين + كلافيولانات البوتاسيوم ٣٦,٤ مجم يكافئ ٣١ مجم حمض الكلافيولانيك.
المواد الفعالة بـ هاى بيوتك® ٣١٢ ملجم:
يحتوى كل ٥ مللى من المعلق على ٢٨٧,٥ مجم اموكسيسيللين تراى هيدرات يكافئ ٢٥٠ مجم اموكسيسيللين + كلافيولانات البوتاسيوم ١:١ ٦, ١٤٥ مجم مكون من ٧٢,٨ مجم كلافيولانات البوتاسيوم يكافئ ل ٦٢ مجم حمض الكلافيولانيك و ٧٢,٨ مجم ايروسيل.
المواد الغير فعالة بـ هاى بيوتك® ١٢٥ ملجم: سترات الصوديوم ثلاثى القاعدة – سترات الصوديوم ثلاثى القاعدة – كاربوكسى ميثيل سيلليلوز – داى ميثيكون – بودرة بنكهة المشمش – بودرة بنكهة النعناع – نكهة سائل الكرامبل – سكر.
المواد الغير فعالة بـ هاى بيوتك® ٢١٢ ملجم: حمض الستريك – سترات الصوديوم ثلاثى القاعدة – كاربوكسى ميثيل سيلليلوز الصوديوم – كروسكارميلوز الصوديوم – ايروسيل ٢٠٠ – رائحة الليمون – داميثيكون – سكر – سوديوم استيريل فيومارات.
أقرأ هذه النشرة كاملة بعناية قبل البدء بـ إستخدام هذا الدواء. أحتفظ بهذه النشرة: قد تحتاج لقراءتها مرة أخرى. إذا كان لديك أى أسئلة أخرى، أسأل طبيبك أو الصيدلى. عادة مايوصف هذا الدواء لوضع أو طفل. لايجب وصفه للآخرين فقد يضرهم، حتى لو كانت أعراضهم هى نفس أعراض طفلك. إذا لوحظ أى من الآثار الجانبية الخطيرة، أو إذا لاحظت أى آثار جانبية غير المذكورة بـ هذه النشرة، يرجى إخبار الطبيب أو الصيدلى بـ هذه النشرة.

١. ما هو هاى بيوتك® و متى يتم استخدامه
٢. قبل إعطاء هاى بيوتك®
٣. كيفية إعطاء هاى بيوتك®
٤. الآثار الجانبية المحتملة
٥. كيفية تخزين هاى بيوتك®
٦. للمزيد من المعلومات

١. ما هو هاى بيوتك® و فيما يستخدم ؟
هاى بيوتك® مضاد حيوى يعمل عن طريق قتل البكتيريا التى تسبب العدوى. يحتوى **هاى بيوتك®** على اثنين من الأدوية المختلفة هما أموكسيسيللين وحمض الكلافيولانيك. أموكسيسيللين ينتمى إلى مجموعة من الأدوية تسمى البنسيلين التى يمكن بـ بعض الأحيان ان تتوقف عن العمل (يصبح غير نشط). والعنصر الآخر (حمض الكلافيولانيك) هو الذى يحافظ على نشاط الأموكسيسيللين .
يستخدم **هاى بيوتك®** فى الرضع و الأطفال لعلاج العدوى التالية :
عدوى الأذن الوسطى و الجيوب الأنفية
عدوى الجهاز التنفسى
عدوى المسالك البولية
عدوى الجلد و الأنسجة الرخوة بما بـ ذلك عدوى الأسنان
عدوى العظام والمفاصل

٢. قبل إعطاء هاى بيوتك
لا تعطى طفلك **هاى بيوتك®** إذا كانت لديه حساسية لأموكسيسيللين، حمض الكلافيولانيك أو أي من المكونات الأخرى من **هاى بيوتك®** إذا حدث له بـ أي وقت مضى حساسية من أى من المضادات الحيوية الأخرى تشمل اعراضها طفح جلدي أو تورم بـ الوجه أو الرقبة.
إذا حدث له بـ أي وقت مضى مشاكل بـ الكبد أو اليرقان (أصفرار الجلد) عند أستخدام المضادات الحيوية .
لا تعطى **هاى بيوتك®** لطفلك إذا كان أى من الأعراض السابقة تنطبق عليه. إذا كنت غير متأكد ، تحدث إلى الطبيب أو الصيدلى قبل إعطاء **هاى بيوتك®**.
أتخذ عناية خاصة مع **هاى بيوتك®**
تحقق من الطبيب أو الصيدلى قبل إعطاء طفلك هذا الدواء إذا كان:
مصاب بالحمى الغدية. يعالج من مشاكل الكبد أو الكلى
يعانى من عدم اخراج البول بانتظام.
إذا لم تكن متأكدا عما إذا كان أى من الأعراض السابقة تنطبق على طفلك ، تحدث إلى الطبيب أو الصيدلى قبل إعطاء **هاى بيوتك®**.
بـ بعض الحالات، قد يحتاج طبيبك، أن يتحقق من نوع البكتيريا التى تسبب العدوى لطفلك ، اعتمادا على هذه النتائج يمكن إعطاء طفلك تركيبات مختلفة من **هاى بيوتك®** أو دواء مختلف .
قد يسبب **هاى بيوتك®** تفاعلم بعض الحالات التى قد تكون موجودة بالفعل وقد يسبب آثار جانبية خطيرة وتشمل الحساسية أو إلتهاب الأمعاء الغليظة أو تشنجات يجب أن تراقب ظهور أعراض معينة إذا كان طفلك يأخذه **هاى بيوتك®** للحد من خطر حدوث أي مشاكل.
اختبارات الدم أو البول
إذا كان طفلك سوف يقوم بعمل اختبارات الدم(مثل اختبارات كرات الدم الحمراء أوأختبارات وظائف الكبد) أو اختبارات البول، يجب أخبار الطبيب أو الممرضة ان طفلك يأخذ **هاى بيوتك®** وذلك **لأن هاى بيوتك®** يمكن أن يؤثر على نتائج هذه الأنواع من الاختبارات.
إستخدام الأدوية الأخرى
تحذير: تناول أموكسيسيللين مع مضادات التجلط من عائلة الكومارين قد يتسبب فى زيادة زمن النزيف وقد يحتاج الدريض لإعادة ضبط جرعة مضادات التجلط
يرجى اخبار الطبيب أو الصيدلى إذا كان طفلك يأخذ أو أخذ مؤخرا أى أدوية أخرى . وهذا يشمل الأدوية التى بشراءها دون وصفة طبية والأدوية العشبية.
إذا كان طفلك يأخذ أموبيسيزول (التى تستخدم لمرض التفرس) مع **هاى بيوتك®**. فإنه قد يكون من الأرجح أن يكون أكثر عرضه للاصابة بحساسية الجلد .
إذا كان طفلك يأخذ أمبوبيسيد (التى تستخدم لمرض التفرس). قد يشعر طبيبك ضبط جرعة **هاى بيوتك®**
إذا تم إستخدام الأدوية المساعدة فى وقف جلطات الدم (مثل الوارفارين) مع **هاى بيوتك®** قد تكون هناك حاجة إلى اجراء اختبارات إضافية للدم.
يمكن أن يؤثر **هاى بيوتك®** على كيفية عمل البثوتريكسات (دواء يستخدم لعلاج السرطان أو الأمراض الروماتيزمية) .
تناول **هاى بيوتك®** قد يؤثر على كيفية عمل ميكوفينولات موفتيل (دواء يستخدم لمنع رفض الجسم الأعضاء المزروعة) .
يحتوى **هاى بيوتك®** على سكروز : إذا كان طبيبك قد أخبرك من قبل أن لديك عدم تحمل لبعض السكريات (خلل فى قدرة الجسم على إمتصاص بعض أنواع السكريات) يجب ألا تستخدم هذا الدواء
الحمل و الرضاعة الطبيعية
إذا كنت حاملاً أو ترضعين رضاعة طبيعية، يرجى إخبار الطبيب أو الصيدلى.
إسألى طبيبك، أو الصيدلى للحصول على المشورة قبل اتخاذ أى دواء .

٣. كيفية إعطاء هاى بيوتك
دائما إستخدم **هاى بيوتك®** تماما كما يصف طبيبك. يجب عليك التحقق مع طبيبك أو الصيدلى إذا كنت غير متأكد .
البالغين والأطفال الذين يبلغ وزنهم ٤٠ كجم أو أكثر
لا ينصح باستخدام هذا الدواء عادة للبالغين والأطفال الذي يبلغ وزنهم ٤٠ كجم أو اكثر أو أسأل طبيبك أو الصيدلى للحصول على المشورة.
الأطفال الذين يقل وزنهم عن ٤٠ كجم
يعتمد حساب الجرعات على وزن جسم الطفل بالكيلوجرام.
طبيبك سوف ينصح بكمية **هاى بيوتك®** التى يجب أن تعطى لطفلك.
يجب عليك استخدام ملعقة القياس البلاستيك لاعطاء الجرعة الصحيحة لطفلك.
الجرعة المعتادة هى ٢٠ مجم / ٥ مجم (٥ مل) إلى ٦٠ مجم / ١٥ مجم لكل كيلوجرام من وزن الجسم يوميا، تعطى على ثلاث جرعات مقسمة .
المرضى الذين يعانون من مشاكل بـ الكلى و الكبد
إذا كان طفلك يعانى من مشاكل فى الكلى يمكن خفض الجرعة. أو إعطاء تركيز مختلف أو دواء مختلف يمكن اختياره من قبل الطبيب.
إذا كان طفلك لديه مشاكل فى الكبد يجب اجراء إختبارات الدم بصورة أكثر تكرارا لمتابعة حالة الكبد.
كيفية إعطاء هاى بيوتك®
تروح الرجاءة جيدا قبل كل جرعة
تعطى قبل بداية الوجبة أو فيلها بوقت قصير
تعطى الجرعات بالتساوى خلال اليوم . الايجب أن يقل الوقت بين كل جرعتين عن ٤ ساعات. لاتأخذ جرعتين فى نفس الساعة .
لا تعطى طفلك **هاى بيوتك®** لأكثر من أسبوعين . إذا كنت لا تراك تشعر بتحوله طفلك يجب أن تعود لاستشارة الطبيب .
إذا اعطيت هاى بيوتك® بجرعة أعلى مما يجب
قد تحدث بعض الأعراض مثل اضطراب بـ المعدة (الشعور بالغثيان ، القئ أوالإسهال) أو التشنجات يجب التحدث الى الطبيب بـ أقرب وقت ممكن. اصطحب معك زجاجة الدواء لعرضها على الطبيب.
إذا نسيت أن تعطى جرعة هاى بيوتك
إذا كنت قد نسيت أن تعطى طفلك جرعة **هاى بيوتك®** ، يجب إعطائها فى اسرع وقت، و يجب أن لا تعطى طفلك الجرعة التالية الا بعد حوالى ٤ ساعات.
إذا توقف طفلك عن أخذ هاى بيوتك®
يجب إعطاء طفلك **هاى بيوتك®** حتى يتم الانتهاء من العلاج. حتى لو كان يشعر بتحسن. يحتاج طفلك كل جرعة للمساعدة بـ مكافحة العدوى. إذ لم يتم القضاء على البكتيريا بشكل كامل قد تظهر العدوى مرة أخرى.
إذا كان لديك أى أسئلة أخرى عن استخدام هذا المنتج، إسأل طبيبك أو الصيدلى.

٤. الآثار الجانبية المحتملة
مثل جميع الأدوية **هاى بيوتك®** يمكن أن يتسبب بـ آثار جانبية . على الرغم من ان هذا لا يحدث للجميع. الآثار الجانبية المذكورة أدناه قد تحدث مع هذا الدواء.
الاعراض التى تحتاج الى مراقبة طبورها
اعراض الحساسية :
• الطفح الجلدي • التهاب الأوعية الدموية والتى قد تكون مرتبة على شكل بقع حمراء أو ارجوانية مرتفعة عن سطح الجلد. ولكن يمكن أن تؤثر على أجزاء أخرى من الجسم.
• الحمى (إرتفاع الحرارة) . و آلام المفاصل. و تورم الغدد بـ الرقبة. الإبط أو الفخذ. • تورم. وأحيانا بـ الوجه أو الفم (وذمة وعائية) . مما تسبب صعوبة بـ التنفس. • الهبوط الحاد.
اتصل بالطبيب فورا إذا حصل لطفلك أي من هذه الأعراض .
ويجب التوقف عن تناول **هاى بيوتك®**
• التهاب الأمعاء الغليظة: • التهاب الأمعاء الغليظة. مما يسبب الإسهال المائى عادة مع ظهور الدم والمخاط فى البراز وألام بـ المعدة و / أو حمى .
اتصل بطبيبك بـ أقرب وقت ممكن للحصول على المشورة إذا حدث لطفلك هذه الأعراض.
الآثار الجانبية الشائعة جدا
قد تصيب أكثر من ١ بـ كل ١٠ أ