AMOXICILLIN AND CLAVULANATE POTASSIUM- amoxicillin and clavulanate potassium tablet, film coated
Northwind Pharmaceuticals. LLC

AMOXICILLIN AND CLAVULANATE POTASSIUM tablet

INDICATIONS AND USAGE

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Amoxicillin and Clavulanate Potassium Tablets USP, Amoxicillin and Clavulanate Potassium for Oral Suspension USP, and Amoxicillin and Clavulanate Potassium Tablets USP (Chewable) and other antibacterial drugs, Amoxicillin and Clavulanate Potassium Tablets USP, Amoxicillin and Clavulanate Potassium for Oral Suspension USP, and Amoxicillin and Clavulanate Potassium Tablets USP (Chewable) should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Amoxicillin and Clavulanate Potassium Tablets USP, Amoxicillin and Clavulanate Potassium for Oral Suspension USP, and Amoxicillin and Clavulanate Potassium Tablets USP (Chewable) are combination penicillin-class antibacterials and beta-lactamase inhibitors indicated in the treatment of infections due to susceptible isolates of the designated bacteria in the conditions listed below*:

1.1 Lower Respiratory Tract Infections

– caused by beta-lactamase–producing isolates of Haemophilus influenzae and Moraxella catarrhalis.

1.2 Acute Bacterial Otitis Media

– caused by beta-lactamase–producing isolates of H. influenzae and M. catarrhalis.

1.3 Sinusitis

– caused by beta-lactamase–producing isolates of H. influenzae and M. catarrhalis.

1.4 Skin and Skin Structure Infections

– caused by beta-lactamase–producing isolates of Staphylococcus aureus, Escherichia coli, and Klebsiella species.

1.5 Urinary Tract Infections

– caused by beta-lactamase–producing isolates of E. coli, Klebsiella species, and Enterobacter species.

1.6 Limitations of Use

– When susceptibility test results show susceptibility to amoxicillin, USP, indicating no beta-lactamase production, Amoxicillin and Clavulanate Potassium Tablets USP, Amoxicillin and Clavulanate Potassium for Oral Suspension USP, and Amoxicillin and Clavulanate Potassium Tablets USP (Chewable) should not be used.

DOSAGE AND ADMINISTRATION

VIEW THE MANUFACTURER'S COMPLETE DRUG INFORMATION AT THE FDA SITE:

http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=963e7bea-ff5d-420a-9cb2-e4aefb534b33

DOSAGE AND ADMINISTRATION

Amoxicillin and Clavulanate Potassium Tablets, Amoxicillin and Clavulanate Potassium for Oral

Suspension, and Amoxicillin and Clavulanate Potassium Tablets (Chewable) may be taken without regard to meals; however, absorption of clavulanate potassium is enhanced when Amoxicillin and Clavulanate Potassium Tablets, Amoxicillin and Clavulanate Potassium for Oral Suspension, and Amoxicillin and Clavulanate Potassium Tablets (Chewable) are administered at the start of a meal. To minimize the potential for gastrointestinal intolerance, Amoxicillin and Clavulanate Potassium Tablets, Amoxicillin and Clavulanate Potassium for Oral Suspension, and Amoxicillin and Clavulanate Potassium Tablets (Chewable) should be taken at the start of a meal.

2.1 Adults

The usual adult dose is one 500 mg/125 mg Amoxicillin and Clavulanate Potassium Tablet every 12 hours or one 250 mg/125 mg Amoxicillin and Clavulanate Potassium Tablet every 8 hours. For more severe infections and infections of the respiratory tract, the dose should be one 875 mg/125 mg Amoxicillin and Clavulanate Potassium Tablet every 12 hours or one 500 mg/125 mg Amoxicillin and Clavulanate Potassium Tablet every 8 hours. Adults who have difficulty swallowing may be given the 125 mg/31.25 mg per 5 mL or 250 mg/62.5 mg per 5 mL suspension in place of the 500 mg/125 mg tablet. The 200 mg/28.5 mg per 5 mL suspension or the 400 mg/57 mg per 5 mL suspension may be used in place of the 875 mg/125 mg tablet.

Two 250 mg/125 mg Amoxicillin and Clavulanate Potassium Tablets should not be substituted for one 500 mg/125 mg Amoxicillin and Clavulanate Potassium Tablet. Since both the 250 mg/125 mg and 500 mg/125 mg Amoxicillin and Clavulanate Potassium Tablets contain the same amount of clavulanic acid (125 mg, as the potassium salt), two 250 mg/125 mg tablets are not equivalent to one 500 mg/125 mg Amoxicillin and Clavulanate Potassium Tablet.

The 250 mg/125 mg Amoxicillin and Clavulanate Potassium Tablet and the 250 mg/62.5 mg chewable tablet should not be substituted for each other, as they are not interchangeable. The 250 mg/125 mg Amoxicillin and Clavulanate Potassium Tablet and the 250 mg/62.5 mg chewable tablet do not contain the same amount of clavulanic acid (as the potassium salt). The 250 mg/125 mg Amoxicillin and Clavulanate Potassium Tablet contains 125 mg of clavulanic acid, whereas the 250 mg/62.5 mg chewable tablet contains 62.5 mg of clavulanic acid.

2.2 Pediatric Patients

Based on the amoxicillin component, Amoxicillin and Clavulanate Potassium for Oral Suspension should be dosed as follows:

Neonates and Infants Aged < 12 Weeks (< 3 Months): The recommended dose of Amoxicillin and Clavulanate Potassium for Oral Suspension is 30 mg/kg/day divided every 12 hours, based on the amoxicillin component. Experience with the 200 mg/28.5 mg per 5 mL formulation in this age group is limited, and thus, use of the 125 mg/31.25 mg per 5 mL oral suspension is recommended.

Patients Aged 12 Weeks (3 Months) and Older: See dosing regimens provided in Table 1. The every 12 hour regimen is recommended as it is associated with significantly less diarrhea [see Clinical Studies (14.2)]. However, the every 12 hour suspension (200 mg/5 mL and 400 mg/5 mL) and chewable tablets (200 mg/28.5 mg per 5 mL and 400 mg/57 mg per 5 mL) and chewable tablets (200 mg/28.5 mg and 400 mg/57 mg) contain aspartame and should not be used by phenylketonurics. [see Warnings and Precautions (5.6)]

Patients Weighing 40 kg or More: Pediatric patients weighing 40 kg or more should be dosed according to adult recommendations.

The 250 mg/125 mg Amoxicillin and Clavulanate Potassium Tablets should not be used until the child weighs at least 40 kg, due to the different amoxicillin to clavulanic acid ratios in the 250 mg/125 mg Amoxicillin and Clavulanate Potassium Tablets (250/125) versus the 250 mg/62.5 mg Amoxicillin and Clavulanate Potassium Tablets (Chewable) (250/62.5).

2.3 Patients With Renal Impairment

Patients with impaired renal function do not generally require a reduction in dose unless the impairment is severe. Renal impairment patients with a glomerular filtration rate of < 30 mL/min should not receive the 875 mg/125 mg dose. Patients with a glomerular filtration rate of 10 to 30 mL/min should receive 500 mg/125 mg or 250 mg/125 mg every 12 hours, depending on the severity of the infection. Patients with a glomerular filtration rate less than 10 mL/min should receive 500 mg/125 mg or 250 mg/125 mg every 24 hours, depending on severity of the infection.

Hemodialysis patients should receive 500 mg/125 mg or 250 mg/125 mg every 24 hours, depending on severity of the infection. They should receive an additional dose both during and at the end of dialysis.

2.4 Directions for Mixing Oral Suspension

Prepare a suspension at time of dispensing as follows: Tap bottle until all the powder flows freely. Add approximately 2/3 of the total amount of water for reconstitution (see Table 2 below) and shake vigorously to suspend powder. Add remainder of the water and again shake vigorously.

Note: Shake oral suspension well before using. Reconstituted suspension must be stored under refrigeration and discarded after 10 days.

CONTRAINDICATIONS

Serious Hypersensitivity Reactions

Amoxicillin/clavulanate potassium is contraindicated in patients with a history of serious hypersensitivity reactions (e.g., anaphylaxis or Stevens-Johnson syndrome) to amoxicillin, clavulanate or to other beta-lactam antibacterial drugs (e.g., penicillins and cephalosporins).

Cholestatic Jaundice/Hepatic Dysfunction

Amoxicillin/clavulanate potassium is contraindicated in patients with a previous history of cholestatic jaundice/hepatic dysfunction associated with amoxicillin/clavulanate potassium.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving beta-lactam antibacterials, including amoxicillin/clavulanate potassium. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/or a history of sensitivity to multiple allergens. Before initiating therapy with amoxicillin and clavulanate potassium tablets, amoxicillin and clavulanate potassium for oral suspension, and amoxicillin and clavulanate potassium tablets (chewable), careful inquiry should be made regarding previous hypersensitivity reactions to penicillins, cephalosporins, or other allergens. If an allergic reaction occurs, amoxicillin and clavulanate potassium tablets, amoxicillin and clavulanate potassium for oral suspension, and amoxicillin and clavulanate potassium tablets (chewable) should be discontinued and appropriate therapy instituted.

Hepatic Dysfunction

Hepatic dysfunction, including hepatitis and cholestatic jaundice has been associated with the use of amoxicillin/clavulanate potassium. Hepatic toxicity is usually reversible; however, deaths have been reported. Hepatic function should be monitored at regular intervals in patients with hepatic impairment.

Clostridium Difficile Associated Diarrhea (CDAD)

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including amoxicillin/clavulanate potassium, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of C. difficile.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin-producing strains of C. difficile cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial use. Careful medical history is necessary since CDAD has been reported to occur over 2 months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibacterial use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

Skin Rash in Patients With Mononucleosis

A high percentage of patients with mononucleosis who receive amoxicillin develop an erythematous skin rash. Thus, amoxicillin and clavulanate potassium tablets, amoxicillin and clavulanate potassium for oral suspension, and amoxicillin and clavulanate potassium tablets (chewable) should not be administered to patients with mononucleosis.

Potential for Microbial Overgrowth

The possibility of superinfections with fungal or bacterial pathogens should be considered during therapy. If superinfection occurs, amoxicillin/clavulanate potassium should be discontinued and appropriate therapy instituted.

Phenylketonurics

Amoxicillin and clavulanate potassium tablets (chewable) and amoxicillin and clavulanate potassium for oral suspension contain aspartame which contains phenylalanine. Each 200 mg/28.5 mg chewable tablet of amoxicillin/clavulanate potassium contains 3.4 mg phenylalanine. Each 400 mg/57 mg chewable tablet contains 6.7 mg phenylalanine. Each 5 mL of the 200 mg/28.5 mg per 5 mL oral suspension contains 0.67 mg phenylalanine. Each 5 mL of the 400 mg/57 mg per 5 mL oral suspension contains 1.12 mg phenylalanine. The other formulations of amoxicillin/clavulanate potassium do not contain phenylalanine.

Development of Drug-Resistant Bacteria

Prescribing amoxicillin and clavulanate potassium tablets, amoxicillin and clavulanate potassium for oral suspension, or amoxicillin and clavulanate potassium tablets (chewable) in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient, and increases the risk of the development of drug-resistant bacteria.

ADVERSE REACTIONS

The following are discussed in more detail in other sections of the labeling:

Anaphylactic reactions [see Warnings and Precautions (5.1)]
Hepatic Dysfunction [see Warnings and Precautions (5.2)]
CDAD [see Warnings and Precautions (5.3)]

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The most frequently reported adverse reactions were diarrhea/loose stools (9%), nausea (3%), skin rashes and urticaria (3%), vomiting (1%) and vaginitis (1%). Less than 3% of patients discontinued therapy because of drug-related adverse reactions. The overall incidence of adverse reactions, and in particular diarrhea, increased with the higher recommended dose. Other less frequently reported adverse reactions (< 1%) include: Abdominal discomfort, flatulence, and headache.

In pediatric patients (aged 2 months to 12 years), 1 U.S./Canadian clinical trial was conducted which

compared 45/6.4 mg/kg/day (divided every 12 hours) of amoxicillin/clavulanate potassium for 10 days versus 40/10 mg/kg/day (divided every 8 hours) of amoxicillin/clavulanate potassium for 10 days in the treatment of acute otitis media. A total of 575 patients were enrolled, and only the suspension formulations were used in this trial. Overall, the adverse reactions seen were comparable to that noted above; however, there were differences in the rates of diarrhea, skin rashes/urticaria, and diaper area rashes. [See Clinical Studies (14.2)]

Postmarketing Experience

In addition to adverse reactions reported from clinical trials, the following have been identified during postmarketing use of amoxicillin/clavulanate potassium. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. These events have been chosen for inclusion due to a combination of their seriousness, frequency of reporting, or potential causal connection to amoxicillin/clavulanate potassium.

Gastrointestinal: Indigestion, gastritis, stomatitis, glossitis, black “hairy” tongue, mucocutaneous candidiasis, enterocolitis, and hemorrhagic/pseudomembranous colitis. Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment. [see Warnings and Precautions (5.3)]

Hypersensitivity Reactions: Pruritus, angioedema, serum sickness–like reactions (urticaria or skin rash accompanied by arthritis, arthralgia, myalgia, and frequently fever), erythema multiforme, Stevens-Johnson syndrome, acute generalized exanthematous pustulosis, hypersensitivity vasculitis, and cases of exfoliative dermatitis (including toxic epidermal necrolysis) have been reported. [see Warnings and Precautions (5.1)]

Liver: Hepatic dysfunction, including hepatitis and cholestatic jaundice, increases in serum transaminases (AST and/or ALT), serum bilirubin, and/or alkaline phosphatase, has been reported with amoxicillin/clavulanate potassium. It has been reported more commonly in the elderly, in males, or in patients on prolonged treatment. The histologic findings on liver biopsy have consisted of predominantly cholestatic, hepatocellular, or mixed cholestatic-hepatocellular changes. The onset of signs/symptoms of hepatic dysfunction may occur during or several weeks after therapy has been discontinued. The hepatic dysfunction, which may be severe, is usually reversible. Deaths have been reported. [see Contraindications (4.2), Warnings and Precautions (5.2)]

Renal: Interstitial nephritis, hematuria, and crystalluria have been reported. [see Overdosage (10)]

Hemic and Lymphatic Systems: Anemia, including hemolytic anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, and agranulocytosis have been reported. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena. Thrombocytosis was noted in less than 1% of the patients treated with amoxicillin/clavulanate potassium. There have been reports of increased prothrombin time in patients receiving amoxicillin/clavulanate potassium and anticoagulant therapy concomitantly. [see Drug Interactions (7.2)]

Central Nervous System: Agitation, anxiety, behavioral changes, confusion, convulsions, dizziness, insomnia, and reversible hyperactivity have been reported.

Miscellaneous: Tooth discoloration (brown, yellow, or gray staining) has been reported. Most reports occurred in pediatric patients. Discoloration was reduced or eliminated with brushing or dental cleaning in most cases.

DRUG INTERACTIONS

Probenecid

Probenecid decreases the renal tubular secretion of amoxicillin but does not delay renal excretion of clavulanic acid. Concurrent use with amoxicillin/clavulanate potassium may result in increased and prolonged blood concentrations of amoxicillin. Coadministration of probenecid is not recommended.

Oral Anticoagulants

Abnormal prolongation of prothrombin time (increased international normalized ratio [INR]) has been reported in patients receiving amoxicillin and oral anticoagulants. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently with amoxicillin/clavulanate potassium. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation.

Allopurinol

The concurrent administration of allopurinol and amoxicillin increases the incidence of rashes in patients receiving both drugs as compared to patients receiving amoxicillin alone. It is not known whether this potentiation of amoxicillin rashes is due to allopurinol or the hyperuricemia present in these patients.

Oral Contraceptives

Amoxicillin/clavulanate potassium may affect intestinal flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral estrogen/progesterone contraceptives.

Effects on Laboratory Tests

High urine concentrations of amoxicillin may result in false-positive reactions when testing for the presence of glucose in urine using CLINITEST®, Benedict's Solution, or Fehling's Solution. Since this effect may also occur with amoxicillin/clavulanate potassium, it is recommended that glucose tests based on enzymatic glucose oxidase reactions be used.

Following administration of amoxicillin to pregnant women, a transient decrease in plasma concentration of total conjugated estriol, estriol-glucuronide, conjugated estrone, and estradiol has been noted.

USE IN SPECIFIC POPULATIONS

Pregnancy

Teratogenic Effects

Pregnancy Category B

Reproduction studies performed in pregnant rats and mice given amoxicillin/clavulanate potassium (2:1 ratio formulation of amoxicillin:clavulanate) at oral doses up to 1200 mg/kg/day revealed no evidence of harm to the fetus due to amoxicillin/clavulanate potassium. The amoxicillin doses in rats and mice (based on body surface area) were approximately 4 and 2 times the maximum recommended adult human oral dose (875 mg/125 mg every 12 hours). For clavulanate, these dose multiples were approximately 9 and 4 times the maximum recommended adult human oral dose (125 mg every 8 hours). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery

Oral ampicillin-class antibiotics are poorly absorbed during labor. It is not known whether use of amoxicillin/clavulanate potassium in humans during labor or delivery has immediate or delayed adverse effects on the fetus, prolongs the duration of labor, or increases the likelihood of the necessity for an obstetrical intervention.

Nursing Mothers

Amoxicillin has been shown to be excreted in human milk. Amoxicillin/clavulanate potassium use by nursing mothers may lead to sensitization of infants. Caution should be exercised when amoxicillin/clavulanate potassium is administered to a nursing woman.

Pediatric Use

The safety and effectiveness of amoxicillin and clavulanate potassium for oral suspension and amoxicillin and clavulanate potassium tablets (chewable) have been established in pediatric patients. Use of amoxicillin and clavulanate potassium for oral suspension and amoxicillin and clavulanate potassium tablets (chewable) in pediatric patients is supported by evidence from studies of amoxicillin and clavulanate potassium tablets in adults with additional data from a study of amoxicillin and clavulanate potassium for oral suspension in pediatric patients aged 2 months to 12 years with acute otitis media. [see Clinical Studies (14.2)]

Because of incompletely developed renal function in neonates and young infants, the elimination of amoxicillin may be delayed; clavulanate elimination is unaltered in this age group. Dosing of amoxicillin and clavulanate potassium for oral suspension and amoxicillin and clavulanate potassium tablets (chewable) should be modified in pediatric patients aged < 12 weeks (< 3 months). [see Dosage and Administration (2.2)]

Geriatric Use

Of the 3,119 patients in an analysis of clinical studies of amoxicillin/clavulanate potassium, 32% were ≥ 65 years old, and 14% were ≥ 75 years old. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

This drug is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. 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.

Dosing in Renal Impairment

Amoxicillin is primarily eliminated by the kidney and dosage adjustment is usually required in patients with severe renal impairment (GFR < 30 mL/min). See Patients With Renal Impairment (2.3) for specific recommendations in patients with renal impairment.

OVERDOSAGE

In case of overdosage, discontinue medication, treat symptomatically, and institute supportive measures as required. A prospective study of 51 pediatric patients at a poison-control center suggested that overdosages of less than 250 mg/kg of amoxicillin are not associated with significant clinical symptoms1.

Interstitial nephritis resulting in oliguric renal failure has been reported in patients after overdosage with amoxicillin/clavulanate potassium.

Crystalluria, in some cases leading to renal failure, has also been reported after amoxicillin/clavulanate potassium overdosage in adult and pediatric patients. In case of overdosage, adequate fluid intake and diuresis should be maintained to reduce the risk of amoxicillin/clavulanate potassium crystalluria.

Renal impairment appears to be reversible with cessation of drug administration. High blood levels may occur more readily in patients with impaired renal function because of decreased renal clearance of amoxicillin/clavulanate potassium. Amoxicillin/clavulanate potassium may be removed from circulation by hemodialysis. [see Dosage and Administration (2.3)]

DESCRIPTION

Amoxicillin and Clavulanate Potassium Tablets, Amoxicillin and Clavulanate Potassium for Oral Suspension, and Amoxicillin and Clavulanate Potassium Tablets (Chewable) are oral antibacterial combinations consisting of the semisynthetic antibiotic amoxicillin, USP and the beta-lactamase

inhibitor, clavulanate potassium, USP (the potassium salt of clavulanic acid). Amoxicillin, USP is an analog of ampicillin, derived from the basic penicillin nucleus, 6-aminopenicillanic acid. Chemically, amoxicillin, USP is (2S,5R,6R)-6-[(R)-(-)-2-Amino-2-(p-hydroxyphenyl)acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate.

Clavulanic acid is produced by the fermentation of Streptomyces clavuligerus. It is a beta-lactam structurally related to the penicillins and possesses the ability to inactivate some beta-lactamases by blocking the active sites of these enzymes. Chemically, clavulanate potassium, USP is potassium (Z)-(2R,5R)-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]-heptane-2-carboxylate

VIEW THE MANUFACTURER'S COMPLETE DRUG INFORMATION AT THE FDA SITE:

http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=963e7bea-ff5d-420a-9cb2-e4aefb534b33

PATIENT COUNSELING INFORMATION

Information for Patients

Patients should be informed that amoxicillin and clavulanate potassium tablets, amoxicillin and clavulanate potassium for oral suspension, and amoxicillin and clavulanate potassium tablets (chewable) may be taken every 8 hours or every 12 hours, depending on the dose prescribed. Each dose should be taken with a meal or snack to reduce the possibility of gastrointestinal upset.

Patients should be counseled that antibacterial drugs, including amoxicillin and clavulanate potassium tablets, amoxicillin and clavulanate potassium for oral suspension, and amoxicillin and clavulanate potassium tablets (chewable), should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When amoxicillin and clavulanate potassium tablets, amoxicillin and clavulanate potassium for oral suspension, and amoxicillin and clavulanate potassium tablets (chewable) are prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may: (1) decrease the effectiveness of the immediate treatment, and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by amoxicillin and clavulanate potassium tablets, amoxicillin and clavulanate potassium for oral suspension, and amoxicillin and clavulanate potassium tablets (chewable) or other antibacterial drugs in the future.

Counsel patients that diarrhea is a common problem caused by antibacterials, and it usually ends when the antibacterial is discontinued. Sometimes after starting treatment with antibacterials, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as 2 or more months after having taken their last dose of the antibacterial. If diarrhea is severe or lasts more than 2 or 3 days, patients should contact their physician.

Patients should be advised to keep suspension refrigerated. Shake well before using. When dosing a child with the suspension (liquid) of amoxicillin/clavulanate potassium, use a dosing spoon or medicine dropper. Be sure to rinse the spoon or dropper after each use. Bottles of suspension of amoxicillin/clavulanate potassium may contain more liquid than required. Follow your doctor’s instructions about the amount to use and the days of treatment your child requires. Discard any unused medicine.

Patients should be aware that amoxicillin and clavulanate potassium tablets, amoxicillin and clavulanate potassium for oral suspension, and amoxicillin and clavulanate potassium tablets (chewable) contain a penicillin class drug product that can cause allergic reactions in some individuals.

LABEL

NDC: 51655-160-02

Amoxicillan & Clav/Potassium

875/125MG

2 Tablets

Lot: Exp: Rx Only

Store at 20C to 25C (68-77F)

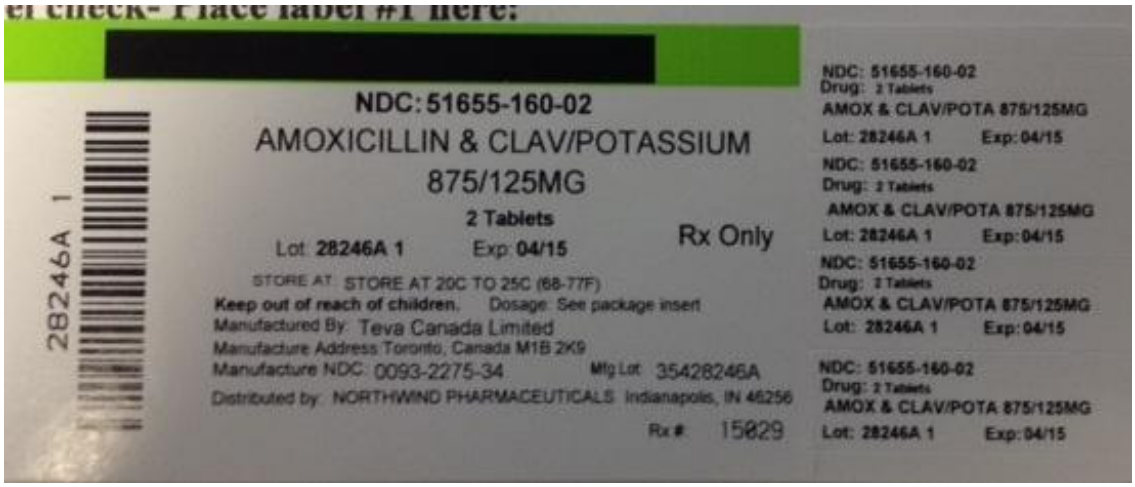
Keep out the reach of children. Dosage: See package insert

Manufactured by: Teva Canada Ltd

Manufacture Address: Toronto, Canada M1B 2K9

Manufacture NDC: 0093-2275-34 Mfg Lot:

Distributed by Northwind Pharmacaeuticals Indianapolis, IN 46256



AMOXICILLIN AND CLAVULANATE POTASSIUM

amoxicillin and clavulanate potassium tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51655-160(NDC:0093-2275)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AMOXICILLIN (UNII: 804826J2HU) (AMOXICILLIN ANHYDROUS - UNII:9EM05410Q9)	AMOXICILLIN ANHYDROUS	875 mg
CLAVULANATE POTASSIUM (UNII: Q42OMW3AT8) (CLAVULANIC ACID - UNII:23521W1S24)	CLAVULANIC ACID	125 mg

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	OVAL	**Size**	22mm
Flavor		**Imprint Code**	93;22;75
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51655-160-02	2 in 1 BOTTLE, DISPENSING		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065096	07/18/2014	

Labeler - Northwind Pharmaceuticals. LLC (036986393)

Registrant - Northwind Pharmaceuticals, LLC (036986393)

Establishment

Name	Address	ID/FEI	Business Operations
EPM Packaging		079124340	repack(51655-160)

Revised: 7/2014 Northwind Pharmaceuticals. LLC