HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use MOXATAG safely and effectively. See full prescribing information for MOXATAG.

MOXATAG® (amoxicillin extended-release tablets)
Initial U.S. Approval: 1974

----------RECENT MAJOR CHANGES----------

Warnings and Precautions (5) 5/2022

----------INDICATIONS AND USAGE----------

MOXATAG is a penicillin-class antibacterial indicated for the treatment of tonsillitis and/or pharyngitis secondary to *Streptococcus pyogenes* in adults and pediatric patients 12 years and older. (1)

To reduce the development of drug-resistant bacteria and maintain the effectiveness of MOXATAG and other antibacterial drugs, MOXATAG should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria. (1)

----------DOSAGE AND ADMINISTRATION----------

Tonsillitis and/or Pharyngitis: 775 mg once daily for 10 days with a meal. Do not chew or crush tablet. (2)

----------DOSAGE FORMS AND STRENGTHS----------

Tablets: 775 mg (3)

----------CONTRAINDICATIONS----------

Patients with known serious hypersensitivity to amoxicillin or to other drugs in the same class or patients who have demonstrated anaphylactic reactions to beta-lactams (4)

----------WARNINGS AND PRECAUTIONS----------

- Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy. (5.1)
- Serious anaphylactic reactions require immediate emergency treatment with epinephrine. Oxygen, intravenous steroids, and airway management, including intubation, should also be administered as indicated. (5.1)
- Severe cutaneous adverse reactions (SCAR): Monitor closely. Discontinue if rash progresses. (5.2)
- *Clostridioides difficile*-Associated Diarrhea (ranging from mild diarrhea to fatal colitis): Evaluate if diarrhea occurs. (5.3)

----------ADVERSE REACTIONS----------

The most common drug-related adverse reactions (incidence ≥1.0 %) are vulvovaginal mycotic infection, diarrhea, nausea, vomiting and headache. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Pragma Pharmaceuticals, LLC at 414-434-6604 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

----------DRUG INTERACTIONS----------

Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use of amoxicillin and probenecid may result in increased and prolonged blood levels of amoxicillin. (7.1)

----------USE IN SPECIFIC POPULATIONS----------

- Pediatrics: The safety and effectiveness of MOXATAG in pediatric patients younger than 12 years has not been established. (8.4)
- Renal Impairment: MOXATAG has not been studied in patients with renal impairment; however a reduction of amoxicillin dose is generally recommended for patients with severe renal impairment. Therefore, MOXATAG is not recommended for use in patients with severe renal impairment (CrCl < 30 mL/ min) or patients on hemodialysis. (8.6)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 5/2022

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed

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FULL PERSCRIBING INFORMATION

1. INDICATIONS AND USAGE

Tonsillitis and/or Pharyngitis

MOXATAG is indicated for the treatment of tonsillitis and/or pharyngitis secondary to *Streptococcus pyogenes (S. pyogenes)* in adults and pediatric patients 12 years and older.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of MOXATAG and other antibacterial drugs, MOXATAG should be used only to treat or prevent 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.

2. DOSAGE AND ADMINISTRATION

Tonsillitis and/or Pharyngitis

The recommended dose of MOXATAG is 775 mg once daily taken within 1 hour of finishing a meal for 10 days. The full 10-day course of therapy should be completed for effective treatment of tonsillitis and/or pharyngitis secondary to *S. pyogenes*.

Do not chew or crush tablet.

3. DOSAGE FORMS AND STRENGTHS

775 mg blue film-coated, oval-shaped tablets printed with “MB-111” on one side in black edible ink.

4. CONTRAINDICATIONS

MOXATAG is contraindicated in patients with known serious hypersensitivity to amoxicillin or to other drugs in the same class or patients who have demonstrated anaphylactic reactions to beta-lactams.

5. WARNINGS AND PRECAUTIONS

5.1 Anaphylaxis and Hypersensitivity Reactions

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/or a history of sensitivity to multiple allergens. There have been reports of individuals with a history of penicillin hypersensitivity who have experienced severe reactions when treated with cephalosporins. Before initiating therapy with MOXATAG, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, or other allergens. If an allergic reaction occurs, MOXATAG should be discontinued and appropriate therapy instituted.

Serious anaphylactic reactions require immediate emergency treatment with epinephrine. Oxygen, intravenous steroids, and airway management, including intubation, should also be administered as indicated.

5.2 Severe Cutaneous Adverse Reactions
MOXATAG may cause severe cutaneous adverse reactions (SCAR), such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP). If patients develop a skin rash they should be monitored closely and MOXATAG discontinued if lesions progress.

5.3 *Clostridioides difficile*-Associated Diarrhea (CDAD)
Clostridioides difficile Associated Diarrhea (CDAD) has been reported with nearly all antibacterial agents, including amoxicillin, 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 antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

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

5.4 Mononucleosis Rash
A high percentage of patients with mononucleosis who receive ampicillin develop an erythematous skin rash. Thus, ampicillin-class antibacterial drugs should not be administered to patients with mononucleosis.

5.5 Development of Drug-Resistant Bacteria
Prescribing MOXATAG in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

5.6 False-Positive Urinary Glucose Tests
High urine concentrations of ampicillin may result in false-positive reactions when testing for the presence of glucose in urine using glucose tests based on the Benedict's copper reduction reaction that determines the amount of reducing substances like glucose in the urine. Since this effect may also occur with amoxicillin, it is recommended that glucose tests based on enzymatic glucose oxidase reactions should be used.

6. ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Anaphylaxis and Hypersensitivity Reactions *[see Warnings and Precautions (5.1)]*
- Severe Cutaneous Adverse Reactions *[see Warnings and Precautions (5.2)]*
- *Clostridioides difficile*-Associated Diarrhea (CDAD) *[see Warnings and Precautions (5.3)]*

6.1 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.

Tonsillitis and/or Pharyngitis

In a controlled Phase 3 trial, 302 adult and pediatric patients (≥12 years) were treated with MOXATAG 775 mg once-daily for 10 days and 306 adult and pediatric patients (≥12 years) were treated with penicillin VK 250 mg QID for 10 days.

In this clinical trial, the majority of treatment-emergent adverse reactions were of a mild and transient nature with similar frequency reported in both treatment groups. Discontinuation due to drug-related treatment-emergent adverse reactions occurred in 1.3% of the MOXATAG-treated patients and 3.3% of the penicillin VK-treated patients.

The most frequently reported adverse reactions (≥1%) which were suspected or probably drug-related are shown in Table 1.

Table 1. Drug-Related Treatment-Emergent Adverse Reactions by System Organ Class Experienced by ≥1% of Patients in Either Treatment Group – ITT/Safety Population

	Number (%) of patients	
System Organ Class/Preferred Term*	MOXATAG (N=302)	Penicillin VK (N=306)
Patients with at least one drug-related treatment-emergent adverse event	32 (10.6)	45 (14.7)
Infections and infestations		
Vulvovaginal mycotic infection	6 (2.0)	8 (2.6)
Gastrointestinal disorders		
Diarrhea	5 (1.7)	6 (2.0)
Nausea	4 (1.3)	2 (0.7)
Vomiting	2 (0.7)	5 (1.6)
Abdominal pain	1 (0.3)	3 (1.0)
Nervous system disorders		
Headache	3 (1.0)	3 (1.0)

*Presented in decreasing order of frequency in the MOXATAG column within each system organ class.

6.2 Adverse Reactions for Other Amoxicillin Products

The following adverse reactions have been reported for other products containing amoxicillin:

Infections and Infestations: Mucocutaneous candidiasis.

Gastrointestinal: Nausea, vomiting, diarrhea, and hemorrhagic/pseudomembranous colitis. Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment.

Immune: Hypersensitivity reactions, anaphylactic/anaphylactoid reactions (including shock), angioedema, serum sickness-like reactions (urticaria or skin rash accompanied by arthritis, arthralgia, myalgia, and frequently fever), hypersensitivity vasculitis *[see Warnings and Precautions (5.1)]*.

Skin and Appendages: Rashes, pruritis, urticaria, erythema multiforme, SJS, TEN, DRESS, AGEP, exfoliative dermatitis *[see Warnings and Precautions (5.2)]*.

Liver: A moderate rise in AST (SGOT) and/or ALT (SGPT) has been noted, but the significance of this finding is unknown. Hepatic dysfunction including cholestatic jaundice, hepatic cholestasis and acute cytolytic hepatitis have been reported.

Hemic and Lymphatic Systems: Anemia, including hemolytic anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, and agranulocytosis have been reported during therapy with penicillins. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena.

Central Nervous System: Reversible hyperactivity, agitation, anxiety, insomnia, confusion, convulsions, behavioral changes, aseptic meningitis, and/or dizziness have been reported rarely.

Renal: Crystalluria has also been reported.

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

7. DRUG INTERACTIONS

7.1 Probenecid

Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use of MOXATAG and probenecid may result in increased and prolonged blood levels of amoxicillin. The clinical relevance of this finding has not been evaluated.

7.2 Other Antibacterial Drugs

Chloramphenicol, macrolides, sulfonamides, and tetracyclines may interfere with the bactericidal effects of penicillin. This has been demonstrated *in vitro*; however, the clinical significance of this interaction is not well documented.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Available data from published epidemiologic studies and pharmacovigilance case reports over several decades with amoxicillin use have not established drug-associated risks of major birth defects, miscarriage, or adverse maternal or fetal outcomes *(see Data)*. No adverse developmental effects were observed in animal reproduction studies with administration of amoxicillin to pregnant mice and rats at doses up to 12.5 and 25 times the recommended human dose *(see Data)*.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data

Human Data

While available studies cannot definitively establish the absence of risk, published epidemiological data and post-marketing case reports have not reported a consistent association with amoxicillin and major birth defects, miscarriage, or adverse maternal or fetal outcomes when amoxicillin was used during pregnancy. Available studies have methodologic limitations, including small sample size, retrospective data collection, under-capture of non-live births, exposure misclassification and inconsistent comparator groups.

Animal Data

Reproduction studies have been performed in mice and rats at doses up to 2,000 mg/kg (12.5 and 25 times the human dose based on body surface area comparison) and have revealed no evidence of harm to the fetus due to amoxicillin.

8.2 Lactation

Risk Summary

Data from a published clinical lactation study reports that amoxicillin is present in human milk. Published adverse effects with amoxicillin exposure in the breastfed infant include diarrhea. There are no data on the effects of amoxicillin on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for MOXATAG and any potential adverse effects on the breast-fed child from MOXATAG or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness of MOXATAG in pediatric patients 12 years of age and older have been established based on results of a clinical trial that included adults and pediatric patients (12 years and older) *[see Clinical Studies (14)]*. Sixty-three (21%) of the study participants were pediatric patients 12 years of age and older. There were no significant differences in treatment response or adverse reactions from adults.

The safety and effectiveness of MOXATAG in pediatric patients younger than 12 years has not been established.

8.5 Geriatric Use

Clinical studies with MOXATAG did not include a sufficient number of patients aged 65 years and over to determine whether they respond differently from younger patients. Other reported clinical experiences with amoxicillin have not yet identified differences in responses between the elderly and younger patients, but a greater sensitivity of some older individuals cannot be ruled out.

This drug is known to be substantially excreted by the kidneys, 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.

8.6 Renal Impairment

MOXATAG has not been studied in patients with renal impairment; however, a reduction of amoxicillin dose is generally recommended for patients with severe renal impairment. Therefore, MOXATAG is not recommended for use in patients with severe renal impairment (CrCl <30 mL/min) or patients on hemodialysis.

10. OVERDOSAGE

In case of overdose, discontinue medication, treat symptomatically, and institute supportive measures as required. If the overdose is very recent and there is no contraindication, an attempt at emesis or other means of removal of drug from the stomach may be performed. A prospective study of 51 pediatric patients at a poison-control center suggested that over dosages of less than 250 mg/kg of amoxicillin are not associated with significant clinical symptoms and do not require gastric emptying.

Interstitial nephritis resulting in oliguric renal failure has been reported in a small number of patients after overdosage with amoxicillin. Crystalluria, in some cases leading to renal failure, has also been reported after amoxicillin overdosage in adult and pediatric patients. In case of overdosage, adequate fluid intake and diuresis should be maintained to reduce the risk of amoxicillin 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. Amoxicillin may be removed from circulation by hemodialysis.

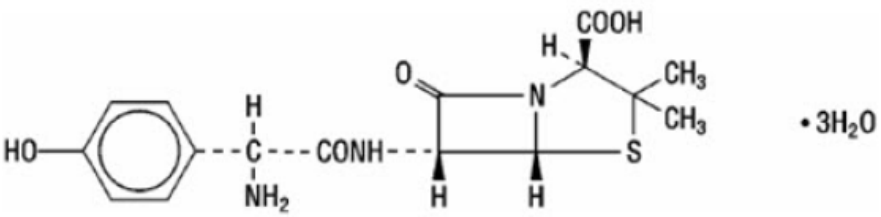
For additional information about overdose treatment, call a poison control center (1-800-222-1222).

11. DESCRIPTION

MOXATAG (amoxicillin extended-release tablets) for oral administration are provided as blue film-coated, oval shaped tablets that contain 775 mg of amoxicillin as the trihydrate and are printed with “MB- 111” on one side in black edible ink.

Amoxicillin is a semi-synthetic antibiotic, an analog of ampicillin, with bactericidal activity against gram-positive and gram-negative microorganisms.

Chemically, amoxicillin is (2 *S*,5 *R*,6 *R*)-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. Its chemical name is amoxicillin. It may be represented structurally as:



The amoxicillin molecular formula is $C_{16}H_{19}N_3O_5S \cdot 3H_2O$, and the molecular weight is 419.45.

MOXATAG is an extended release tablet formulation consisting of three components, one immediate-release and two delayed-release, each containing amoxicillin. The three components are combined in a specific ratio to prolong the release of amoxicillin from MOXATAG compared to immediate-release amoxicillin.

Each tablet contains amoxicillin, crospovidone, FD&C Blue #2 lake, hypromellose, hypromellose acetate succinate, iron oxide, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, polyethylene glycol 400, polyoxyl 35 castor oil, povidone, shellac, colloidal silicon dioxide, sodium lauryl sulfate, talc, titanium dioxide, and triethyl citrate.

12. CLINICAL PHARMACOLOGY

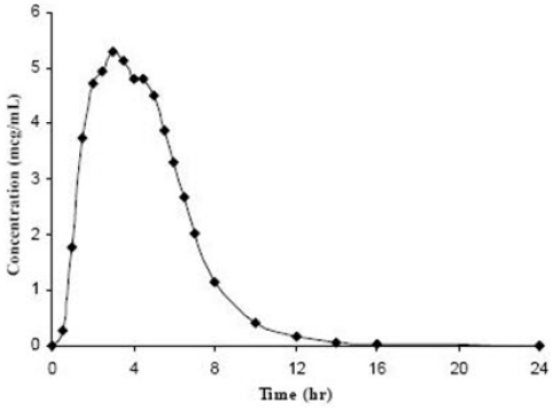
12.1 Mechanism of Action

Amoxicillin is an antibacterial drug *[see Microbiology (12.4)]*.

12.3 Pharmacokinetics

MOXATAG is an extended-release formulation of amoxicillin intended to provide once-daily dosing. Following the administration of MOXATAG with a low-fat meal in healthy subjects, mean amoxicillin $AUC_{0-\infty}$, C_{max}, and T_{max} values were 29.8 µg•h/mL, 6.6 µg/mL and 3.1 hours, respectively. The mean plasma concentration-time curve is shown below in Figure 1.

Figure 1. Mean Amoxicillin Plasma Concentrations Following a Single Oral Dose of MOXATAG With a Low-Fat Meal in Healthy Subjects (N=20)



Administration of MOXATAG with food decreases the rate, but not the extent of amoxicillin absorption. Compared to immediate-release amoxicillin suspension, the rate of amoxicillin absorption following administration of MOXATAG was slower, resulting in a lower C_{max} and longer T_{max}. Total amoxicillin exposure (AUC) achieved with MOXATAG is similar to that observed after oral administration of a comparable dose of immediate-release amoxicillin suspension.

Amoxicillin diffuses readily into most body tissues and fluids, with the exception of brain and spinal fluid, except when meninges are inflamed. Amoxicillin is approximately 20% protein bound in human serum.

Amoxicillin is primarily cleared by renal excretion. Approximately 60% of an oral dose of immediate-release amoxicillin is eliminated unchanged in urine. The half-life of amoxicillin after oral administration of MOXATAG is approximately 1.5 hours, similar to that of immediate-release amoxicillin. No accumulation of amoxicillin was observed after once-daily dosing of 775 mg of MOXATAG for 7 days.

Drug Interactions
In a study of healthy adult subjects, amoxicillin AUC was similar whereas C_{max} increased approximately 35% following the administration of lansoprazole with MOXATAG given with food.

Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use of MOXATAG and probenecid may result in increased and prolonged blood levels of amoxicillin. The clinical relevance of this finding has not been evaluated.

12.4 Microbiology

Mechanism of Action
Amoxicillin is similar to penicillin in its bacterial action against susceptible organisms during the stage of active multiplication. It acts through the inhibition of cell wall biosynthesis that leads to the death of the bacteria.

Resistance

To date there are no known mechanisms of resistance to penicillin or amoxicillin in *Streptococcus pyogenes*.

Antimicrobial Activity

MOXATAG has been shown to be active against most isolates of the following microorganism, both in vitro and in clinical infections *[see Indications and Usage (1)]*.

Aerobic bacteria

Gram-Positive Bacteria

Streptococcus pyogenes

The following in vitro data are available, but their clinical significance is unknown. At least 90 percent of the following bacteria exhibit an in vitro minimum inhibitory concentration (MIC) less than or equal to the susceptible breakpoint for amoxicillin (as determined by susceptibility tests using the class representative agents penicillin or ampicillin) against isolates of similar genus or organism group. However, the efficacy of amoxicillin in treating clinical infections caused by these bacteria has not been established in adequate and well-controlled clinical trials.

Aerobic bacteria

Gram-Positive Bacteria

Streptococcus spp. (Group B, C, and G; Beta-hemolytic)

Susceptibility Testing

For specific information regarding susceptibility test interpretive criteria, and associated test methods and quality control standards recognized by FDA for this drug, please see https://www.fda.gov/STIC.

13. NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate carcinogenic potential. Studies to detect mutagenic potential of amoxicillin alone have not been conducted; however, the following information is available from tests on a 4:1 mixture of amoxicillin and potassium clavulanate. Amoxicillin and potassium clavulanate were non-mutagenic in the Ames bacterial mutation assay, and the yeast gene conversion assay. Amoxicillin and potassium clavulanate were weakly positive in the mouse lymphoma assay, but the trend toward increased mutation frequencies in this assay occurred at doses that were also associated with decreased cell survival. Amoxicillin and potassium clavulanate were negative in the mouse micronucleus test, and in the dominant lethal assay in mice. Potassium clavulanate alone was tested in the Ames bacterial mutation assay and in the mouse micronucleus test, and was negative in each of these assays. In a multi-generation reproduction study in rats, no impairment of fertility or other adverse reproductive effects were seen at doses up to 500 mg/kg (approximately 6 times the human dose based on body surface area comparison).

14. CLINICAL STUDIES

In a randomized, parallel-group, multi-center, double-blind, double-dummy study in adults and pediatrics (age ≥ 12 years) with tonsillitis and/or pharyngitis secondary to *S. pyogenes*, MOXATAG 775 mg QD for 10 days was non-inferior to penicillin VK 250 mg QID for 10 days.

Using strict evaluability and microbiologic response criteria 4-8 days post-therapy, the following bacteriological eradication rates and statistical outcomes in the per-protocol (PPb) and modified intent-to-treat (mITT) populations were obtained (Table 3). The mITT population included all randomized patients with a positive throat culture for *S. pyogenes* at baseline. The PPb population included mITT patients who had post-therapy cultures, were compliant with treatment, and didn't have major protocol violations.

Table 3. Bacteriological Eradication Rates in Patients with Tonsillitis and/or Pharyngitis

Study Population	MOXATAG	Penicillin VK	Rate Difference 95% CI (%)
PPb	198/233 (85.0%)	191/229 (83.4%)	1.6 (-5.1, 8.2)
mITT	204/256 (79.7%)	206/264 (78.0%)	1.7 (-5.4, 8.7)

16. HOW SUPPLIED/STORAGE AND HANDLING

MOXATAG tablets for oral administration are provided as blue film-coated, oval-shaped tablets that contain 775 mg of amoxicillin as the trihydrate. The tablets are printed with "MB-111" on one side in black edible ink. MOXATAG is packaged in bottles as follows:

Bottles of 30	NDC 58463-002-30
Bottles of 10	NDC 58463-002-10

Storage
Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [See USP Controlled Room Temperature.]

17. PATIENT COUNSELING INFORMATION

Instructions for Administration of MOXATAG
Inform patients that the recommended dose of MOXATAG is 775 mg once daily taken with food for 10 days. MOXATAG should be taken within 1 hour of finishing a meal and at approximately the same time every day. The full 10-day course of therapy should be completed for effective treatment of tonsillitis and/or pharyngitis secondary to *S. pyogenes.* Patients should be instructed not to chew or crush the tablet. No other forms of immediate-release amoxicillin can be substituted for MOXATAG.

Hypersensitivity Reactions
Inform patients that serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported while on penicillin therapy. Patients should be questioned regarding any

hypersensitivity reactions to penicillins, cephalosporins or other allergens. Whenever such reactions occur, the patient should be instructed to contact their physician immediately. Serious anaphylactic reactions require immediate emergency treatment with epinephrine. Oxygen, intravenous steroids, and airway management, including intubation, should also be administered as indicated.

Severe Cutaneous Adverse Reactions
Advise patients about the signs and symptoms of serious skin manifestations. Instruct patients to stop taking MOXATAG immediately and promptly report the first signs or symptoms of skin rash, mucosal lesions, or any other sign of hypersensitivity *[see Warnings and Precautions (5.2)]*.

Diarrhea
Inform patients that diarrhea is a common problem caused by antibacterial drugs which usually ends when the antibacterial drug is discontinued. Sometimes after starting treatment with antibacterial drugs, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibacterial drug. If this occurs, patients should contact their physician as soon as possible.

Antibacterial Resistance
Patients should be counseled that antibacterial drugs including MOXATAG should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When MOXATAG is 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 MOXATAG or other antibacterial drugs in the future.

Manufactured in Ireland for:
Pragma Pharmaceuticals, LLC.
Distributed by: Fera Pharmaceuticals, LLC
Locust Valley, N.Y. 11560
PPI-002