Pay $20 or Less
moxatag™
(amoxicillin extended-release tablets)

Your customers can now get MOXATAG®, the first and only FDA-approved once-daily extended release amoxicillin tablet, 775 mg, for $20 or less using a voucher card.*

- Strong Sales Support of MOXATAG, with a National Sales Force detailing, sampling, and leaving voucher cards ($20 maximum co-pay) with Health Care Professionals

- Each MOXATAG prescription yields a gross profit of $6.00 – $10.00†
  - Pharmacy receives an additional $2.50 processing fee for every voucher card redeemed

†based on AWP, average payor reimbursement fees, and average dispensing fees

- MOXATAG has no AB-rated equivalent¹

- Studies show compliance rates with once-daily dosing approach 100%²

MOXATAG is sold in 30 ct bottles (3 Rx’s per unit) and is available through your wholesaler – NDC # 11042-142-03

Voucher cards are also available for download at www.MOXATAG.com or by calling 1-877-363-8080.

*Voucher is valid for up to $45 off one prescription of MOXATAG. In some cases, patients could pay more than $20 if their out-of-pocket pay exceeds $65.
MOXATAG™ (amoxicillin extended-release) Tablets 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. MOXATAG should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. The full 10-day course of therapy should be completed for effective treatment. Patients taking MOXATAG should not chew or crush tablet.

Important Safety Information

- 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. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy. If an allergic reaction occurs, MOXATAG should be discontinued and appropriate therapy instituted.

- Clostridium 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. If CDAD is suspected or confirmed, MOXATAG should be discontinued and appropriate therapy instituted.

- The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur, MOXATAG should be discontinued and appropriate therapy instituted.

- The most common drug-related adverse reactions associated with MOXATAG observed in clinical studies are vulvovaginal mycotic infection (2.0%), diarrhea (1.7%), nausea (1.3%), vomiting (0.7%), abdominal pain (0.3%) and headache (1.0%).

Please see brief summary of Prescribing information attached.

For more information, please visit www.MOXATAG.com


U.S. Patents 6,544,555; 6,669,948; 6,723,341

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The following is a brief summary only; see full Prescribing Information for complete product information.

**INDICATIONS AND USAGE**

MOXATAG is a once-daily amoxicillin product indicated for the treatment of tonsillitis and/or pharyngitis secondary to Streptococcus pyogenes (S. pyogenes), more commonly referred to as 'strep throat', in adults and pediatric patients 12 years or 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.

**DOSEAGE AND ADMINISTRATION**

The recommended dose of MOXATAG is 775 mg once daily taken within 1 hour of finishing a meal for 10 days. MOXATAG should be taken 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.

Do not chew or crush tablet.

**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.

**WARNINGS AND PRECAUTIONS**

**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.

**Clostridium difficile Associated Diarrhea (CDAD)**

Clostridium 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.

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.

**Superinfections**

The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur, amoxicillin should be discontinued and appropriate therapy instituted.

**Mononucleosis Rash**

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

**Development of Drug-Resistant Bacteria**

Prescribing amoxicillin in the absence of proven or strongly suspected bacterial infection or treating prophylactically is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

**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 Clinitest®, Benedict’s Solution or Fehling’s Solution. Since this effect may also occur with amoxicillin, it is recommended that glucose tests based on enzymatic glucose oxidase reactions (such as Clinistix®) be used.

**ADVERSE REACTIONS**

In a controlled Phase 3 trial, 302 adult and pediatric patients (≥12 years) were treated with MOXATAG 775 mg once-daily for 10 days. The most frequently reported adverse reactions (>1%) which were suspected or probably drug-related were vaginal yeast infection (2.0%), diarrhea (1.7%), nausea (1.3%) and headache (1.0%).

**DRUG INTERACTIONS**

**Probencid**

Probencid decreases the renal tubular secretion of amoxicillin. Concurrent use of MOXATAG and probenecid may result in increased and prolonged blood levels of amoxicillin.

**Other Antibiotics**

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

**Oral Contraceptives**

As with other antibiotics, amoxicillin may affect the gut flora, leading to lower estrogen reabsorption and potentially resulting in reduced efficacy of combined oral estrogen/progesterone contraceptives.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy**

Pregnancy: Teratogenic Effects. Pregnancy Category B.

Reproduction studies have been performed in mice and rats at doses up to 2000 mg/kg (12.5 and 25 times the human dose in mg/m²) and have revealed no evidence of impaired fertility or harm to the fetus due to amoxicillin. 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**

It is not known whether use of amoxicillin in humans during labor or delivery has immediate or delayed adverse effects on the fetus, prolongs the duration of labor, or increases the likelihood that forceps delivery or other obstetrical intervention or resuscitation of the newborn will be necessary.

**Nursing Mothers**

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

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

**Geriatric Use**

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.

**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.

**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.

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

**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. The tablets are printed with “MB-111” on one side in black edible ink. MOXATAG is packaged in bottles as follows:

- Bottles of 30: 11042-142-03

**Presentation**

<table>
<thead>
<tr>
<th>NDC Code</th>
<th>Bottles of 30</th>
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<tbody>
<tr>
<td>11042-142-03</td>
<td>30</td>
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**Storage**

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