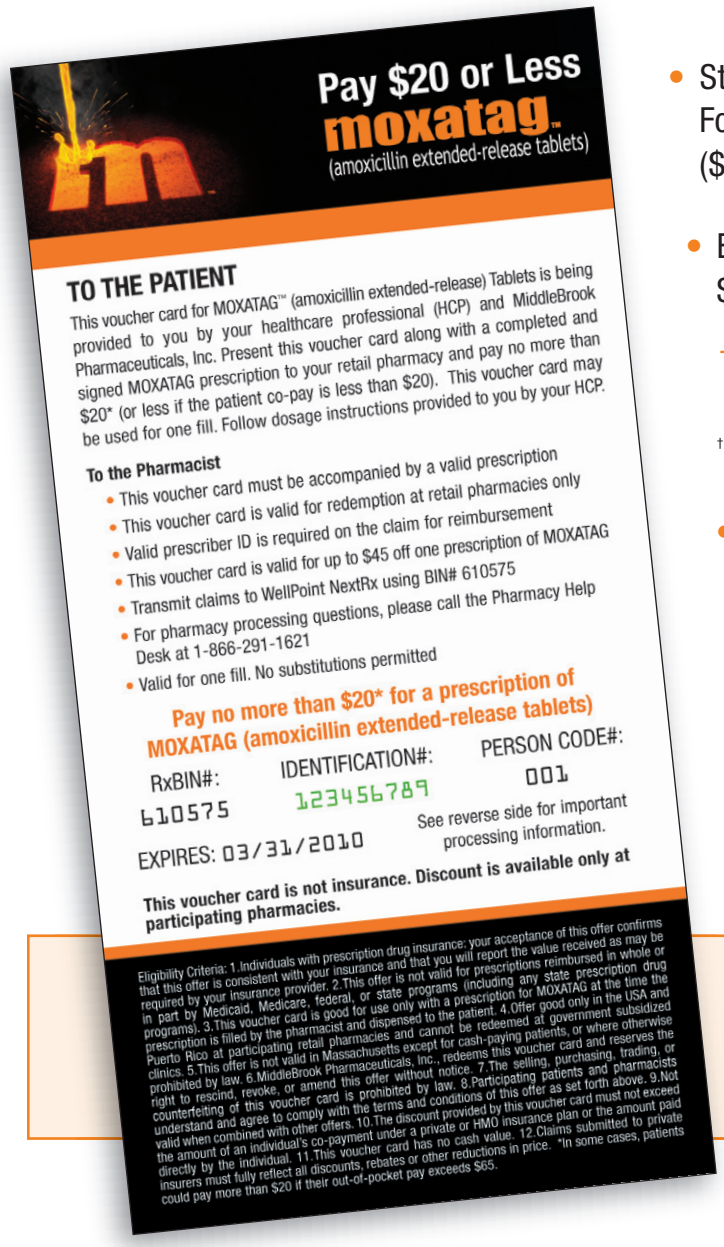
Pay $20 or Less

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.*



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(amoxicillin extended-release tablets)

TO THE PATIENT

This voucher card for MOXATAG™ (amoxicillin extended-release) Tablets is being provided to you by your healthcare professional (HCP) and MiddleBrook Pharmaceuticals, Inc. Present this voucher card along with a completed and signed MOXATAG prescription to your retail pharmacy and pay no more than $20* (or less if the patient co-pay is less than $20). This voucher card may be used for one fill. Follow dosage instructions provided to you by your HCP.

To the Pharmacist

- This voucher card must be accompanied by a valid prescription
- This voucher card is valid for redemption at retail pharmacies only
- Valid prescriber ID is required on the claim for reimbursement
- This voucher card is valid for up to $45 off one prescription of MOXATAG
- Transmit claims to WellPoint NextRx using BIN# 610575
- For pharmacy processing questions, please call the Pharmacy Help Desk at 1-866-291-1621
- Valid for one fill. No substitutions permitted

Pay no more than $20* for a prescription of MOXATAG (amoxicillin extended-release tablets)

RxBIN#: 610575 IDENTIFICATION#: 123456789 PERSON CODE#: 001

EXPIRES: 03/31/2010

See reverse side for important processing information.

This voucher card is not insurance. Discount is available only at participating pharmacies.

Eligibility Criteria: 1.Individuals with prescription drug insurance: your acceptance of this offer confirms that this offer is consistent with your insurance and that you will report the value received as may be required by your insurance provider. 2.This offer is not valid for prescriptions reimbursed in whole or in part by Medicaid, Medicare, federal, or state programs (including any state prescription drug programs). 3.This voucher card is good for use only with a prescription for MOXATAG at the time the prescription is filled by the pharmacist and dispensed to the patient. 4.Offer good only in the USA and Puerto Rico at participating retail pharmacies and cannot be redeemed at government subsidized clinics. 5.This offer is not valid in Massachusetts except for cash-paying patients, or where otherwise prohibited by law. 6.MiddleBrook Pharmaceuticals, Inc., redeems this voucher card and reserves the right to rescind, revoke, or amend this offer without notice. 7.The selling, purchasing, trading, or counterfeiting of this voucher card is prohibited by law. 8.Participating patients and pharmacists understand and agree to comply with the terms and conditions of this offer as set forth above. 9.Not valid when combined with other offers. 10.The discount provided by this voucher card must not exceed the amount of an individual's co-payment under a private or HMO insurance plan or the amount paid directly by the individual. 11.This voucher card has no cash value. 12.Claims submitted to private insurers must fully reflect all discounts, rebates or other reductions in price. *In some cases, patients could pay more than $20 if their out-of-pocket pay exceeds $65.

- 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 equivalent[1]
- 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.

once-daily

moxatag™

(amoxicillin extended-release tablets)

TABLET AND BOTTLE SHOWN ARE NOT ACTUAL SIZE

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

References: 1. Food and Drug Administration. Orange Book: approved drug products with therapeutic equivalence evaluations. **2.** Kardas P. Patient compliance with antibiotic treatment for respiratory tract infections. *J Antimicrob Chemother.* 2002;49(6):897-903.

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

MiddleBrook PHARMACEUTICALS®

moxatag™
(amoxicillin extended-release tablets)
775 mg

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

RX ONLY

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.

DOSAGE 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 are vaginal yeast infection (2.0%), diarrhea (1.7%), nausea (1.3%) and headache (1.0%).

DRUG INTERACTIONS

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.

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: 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/m^2) 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.

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.

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.

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

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:

Presentation	NDC Code
Bottles of 30	11042-142-03

Storage

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

MiddleBrook
PHARMACEUTICALS®
Germantown, Maryland 20876 USA

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