

# OLMESARTAN MEDOXOMIL, AMLODIPINE, AND HYDROCHLOROTHIAZIDE TABLETS

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*To most, "generics" means bland, ordinary,  
and uninteresting. To us, it means the  
opportunity to be remarkable.*

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— MAKING —  
**GENERIC**  
REMARKABLE

## Available through your wholesaler:

### **NDC: 70436-014-04**

Cardinal Health: 6089866  
McKesson: 3066800  
Amerisource: 10305083

### **NDC: 70436-015-04**

Cardinal Health: 6089874  
McKesson: 3066818  
Amerisource: 10305140

### **NDC: 70436-016-04**

Cardinal Health: 6089882  
McKesson: 3066826  
Amerisource: 10305096

### **NDC: 70436-017-04**

Cardinal Health: 6089890  
McKesson: 3066842  
Amerisource: 10305101

### **NDC: 70436-018-04**

Cardinal Health: 6089808  
McKesson: 3066834  
Amerisource: 10305132

## PRODUCT DETAILS

- **Strength:**  
20 mg / 5 mg / 12.5 mg  
40 mg / 5 mg / 12.5 mg  
40 mg / 5 mg / 25 mg  
40 mg / 10 mg / 12.5 mg  
40 mg / 10 mg / 25 mg
- **Therapeutic Class:**  
Antihypertensive combination

### **NDC Numbers:**

20 mg / 5 mg / 12.5 mg |  
Bottle of 30 Tablets: 70436-014-04  
40 mg / 5 mg / 12.5 mg |  
Bottle of 30 Tablets: 70436-015-04  
40 mg / 5 mg / 25 mg |  
Bottle of 30 Tablets: 70436-016-04  
40 mg / 10 mg / 12.5 mg |  
Bottle of 30 Tablets: 70436-017-04  
40 mg / 10 mg / 25 mg |  
Bottle of 30 Tablets: 70436-018-04

See reverse side for important  
safety information.

To place an order or learn more,  
call **888-447-0095 (Toll Free)**  
or email [sales@slaterunpharma.com](mailto:sales@slaterunpharma.com)  
6am - 7pm CST (Monday - Friday)

## IMPORTANT SAFETY INFORMATION FOR: OLMESARTAN MEDOXOMIL, AMLODIPINE, AND HYDROCHLOROTHIAZIDE TABLETS

### **WARNING: Fetal Toxicity**

- **When pregnancy is detected, discontinue olmesartan medoxomil, amlodipine, and hydrochlorothiazide tablets as soon as possible.**
- **Drugs that act directly on the renin-angiotensin system (RAS) can cause injury and death to the developing fetus.**

Olmesartan Medoxomil, Amlodipine and Hydrochlorothiazide Tablets are contraindicated in patients with anuria, hypersensitivity to any component, or hypersensitivity to other sulfonamide-derived drugs. Do not co-administer aliskiren with olmesartan medoxomil, amlodipine, and hydrochlorothiazide tablets in patients with diabetes.

Olmesartan medoxomil, amlodipine, and hydrochlorothiazide tablets can cause fetal harm when administered to a pregnant woman. Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. Resulting oligohydramnios can be associated with fetal lung hypoplasia and skeletal deformations. Potential neonatal adverse effects include skull hypoplasia, anuria, hypotension, renal failure, and death. When pregnancy is detected, discontinue olmesartan medoxomil, amlodipine, and hydrochlorothiazide tablets as soon as possible.

In patients with an activated renin-angiotensin system, such as volume- and/or salt-depleted patients (e.g., those being treated with high doses of diuretics) symptomatic hypotension may be anticipated after initiation of treatment with olmesartan medoxomil. Initiate treatment with olmesartan medoxomil, amlodipine, and hydrochlorothiazide tablets under close medical supervision. If hypotension does occur, place the patient in the supine position and, if necessary, give an intravenous infusion of normal saline.

Patients, particularly those with severe obstructive coronary artery disease, may develop increased frequency, duration, or severity of angina or acute myocardial infarction upon starting calcium channel blocker therapy or at the time of dosage increase.

Impaired renal function was reported in 2.1% of subjects receiving olmesartan medoxomil, amlodipine, and hydrochlorothiazide tablets compared to 0.2% to 1.3% of subjects receiving dual combination therapy of olmesartan medoxomil and amlodipine, olmesartan medoxomil and hydrochlorothiazide or amlodipine and hydrochlorothiazide. If progressive renal impairment becomes evident consider withholding or discontinuing olmesartan medoxomil, amlodipine, and hydrochlorothiazide tablets.

Since amlodipine is extensively metabolized by the liver and the plasma elimination half-life ( $t_{1/2}$ ) is 56 hours in patients with severely impaired hepatic function, titrate slowly when administering to patients with severe hepatic impairment.

The most common adverse reactions (incidence  $\geq 2\%$ ) are dizziness, peripheral edema, headache, fatigue, nasopharyngitis, muscle spasms, nausea, upper respiratory tract infection, diarrhea, urinary tract infection, and joint swelling.

Please see the package insert for Olmesartan Medoxomil, Amlodipine and Hydrochlorothiazide Tablets for full prescribing information.