



HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use OLMESARTAN MEDOXOMIL AND HYDROCHLOROTHIAZIDE TABLETS safely and effectively. See full prescribing information for OLMESARTAN MEDOXOMIL AND HYDROCHLOROTHIAZIDE TABLETS.
OLMESARTAN MEDOXOMIL AND HYDROCHLOROTHIAZIDE tablets, for oral use
Initial U.S. Approval: 2003

WARNING: FETAL TOXICITY
See full prescribing information for complete boxed warning.
 • When pregnancy is detected, discontinue olmesartan medoxomil and hydrochlorothiazide tablets as soon as possible (5.1, 8.1).
 • Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus (5.1, 8.1).

INDICATIONS AND USAGE
 Olmesartan medoxomil and hydrochlorothiazide tablets are a combination of olmesartan, an angiotensin II receptor blocker and hydrochlorothiazide, a thiazide diuretic indicated for the treatment of hypertension to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. (1)

Limitations of Use
 Olmesartan medoxomil and hydrochlorothiazide tablets are not indicated for initial therapy.

---DOSAGE AND ADMINISTRATION---
 • Recommended starting dose in patients not adequately controlled with olmesartan monotherapy, 40/12.5 mg (2)
 • Recommended starting dose in patients not adequately controlled with hydrochlorothiazide monotherapy, 20/12.5 mg (2)
 • Adjust dose after 2 to 4 weeks, as needed, to a maximum of 40 mg / 25 mg olmesartan / hydrochlorothiazide (2)

---DOSAGE FORMS AND STRENGTHS---
 Tablets: (olmesartan medoxomil and hydrochlorothiazide) 20/12.5 mg, 40/12.5 mg, 40/25 mg (3)

---CONTRAINDICATIONS---
 • Hypersensitivity to any component of olmesartan medoxomil and hydrochlorothiazide tablets (4)

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FULL PRESCRIBING INFORMATION
WARNING: FETAL TOXICITY
 • When pregnancy is detected, discontinue olmesartan medoxomil and hydrochlorothiazide tablets as soon as possible (see **Warnings and Precautions (5.1, 8.1)**, see **in specific populations (8.1)**).
 • Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus (see **Warnings and Precautions (5.1)**, see **in specific populations (8.1)**).

1 INDICATIONS AND USAGE
 Olmesartan medoxomil and hydrochlorothiazide tablets are indicated for the treatment of hypertension, to lower blood pressure (see **Dosage and Administration (2)**).
 Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular (CV) events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from wide variety of pharmacologic classes including the class to which this drug principally belongs. There are no controlled trials demonstrating risk reduction with olmesartan medoxomil and hydrochlorothiazide tablets.
 Control of high blood pressure should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, and limited alcohol intake. Many patients will require more than one drug to achieve blood pressure goals. For specific advice on goals and management, see published guidelines, such as those of the National High Blood Pressure Education Program's National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (NCEP).

5.1 Fetal Toxicity
 Olmesartan medoxomil and hydrochlorothiazide tablets are contraindicated in pregnant women. Use of drugs that act on the renin-angiotensin system (RAS) during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal mortality and death. Resulting oligohydramnios can be associated with fetal hypoplasia and skeletal deformations. Neonatal death, stillbirth, and death have been reported in association with fetal renal failure and death. When pregnancy is detected, discontinue olmesartan medoxomil and hydrochlorothiazide tablets in cases where no other etiology is found (5.8).

5.2 Hypotension in Volume or Salt-Depleted Patients
 In patients with hypotension or volume or salt depletion, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with hypotension or volume or salt depletion, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with hypotension or volume or salt depletion, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg.

5.3 Impaired Renal Function
 In patients with impaired renal function, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with impaired renal function, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with impaired renal function, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg.

5.4 Hypersensitivity Reactions
 In patients with hypersensitivity to any component of olmesartan medoxomil and hydrochlorothiazide tablets, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with hypersensitivity to any component of olmesartan medoxomil and hydrochlorothiazide tablets, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with hypersensitivity to any component of olmesartan medoxomil and hydrochlorothiazide tablets, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg.

5.5 Electrolyte and Metabolic Imbalances
 In patients with electrolyte and metabolic imbalances, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with electrolyte and metabolic imbalances, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with electrolyte and metabolic imbalances, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg.

5.6 Acute Myopia and Secondary Angle-Closure Glaucoma
 In patients with acute myopia and secondary angle-closure glaucoma, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with acute myopia and secondary angle-closure glaucoma, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with acute myopia and secondary angle-closure glaucoma, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg.

5.7 Systemic Lupus Erythematosus
 In patients with systemic lupus erythematosus, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with systemic lupus erythematosus, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with systemic lupus erythematosus, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg.

5.8 Sprue-Like Enteropathy
 In patients with sprue-like enteropathy, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with sprue-like enteropathy, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with sprue-like enteropathy, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg.

6 ADVERSE REACTIONS
 The following adverse reactions with olmesartan medoxomil and hydrochlorothiazide tablets are described elsewhere:
 • Hypotension in volume- or salt-depleted patients (see **Warnings and Precautions (5.2)**)
 • Impaired renal function (see **Warnings and Precautions (5.3)**)
 • Hypersensitivity reactions (see **Warnings and Precautions (5.4)**)
 • Electrolyte and metabolic imbalances (see **Warnings and Precautions (5.5)**)
 • Acute myopia and secondary angle-closure glaucoma (see **Warnings and Precautions (5.6)**)
 • Systemic lupus erythematosus (see **Warnings and Precautions (5.7)**)
 • Sprue-like enteropathy (see **Warnings and Precautions (5.8)**)

6.1 Clinical Trials Experience
 The following adverse reactions were observed in clinical studies of olmesartan medoxomil and hydrochlorothiazide tablets in patients with hypertension. The following adverse reactions were observed in clinical studies of olmesartan medoxomil and hydrochlorothiazide tablets in patients with hypertension. The following adverse reactions were observed in clinical studies of olmesartan medoxomil and hydrochlorothiazide tablets in patients with hypertension.

Adverse Reaction	Olmesartan/HCTZ (N=40)	HCTZ (N=40)	Placebo (N=40)
Nausea	3	2	1
Hyperkalemia	4	0	2
Dizziness	5	1	3
Upper Respiratory Infection	7	6	7

7.1 Agents Increasing Serum Potassium
 Olmesartan medoxomil and hydrochlorothiazide tablets with other drugs that increase serum potassium levels may result in hyperkalemia. Monitor serum potassium in such patients.

7.2 Lithium
 Increases in serum lithium concentrations and lithium toxicity have been reported during concomitant administration of lithium with angiotensin II receptor antagonists. Monitor serum lithium levels during concomitant use.

7.3 Non-steroidal Anti-inflammatory Agents Including Selective Cyclooxygenase-2 Inhibitors (COX-2 Inhibitors)
 Olmesartan medoxomil and hydrochlorothiazide tablets with other drugs that increase serum potassium levels may result in hyperkalemia. Monitor serum potassium in such patients.

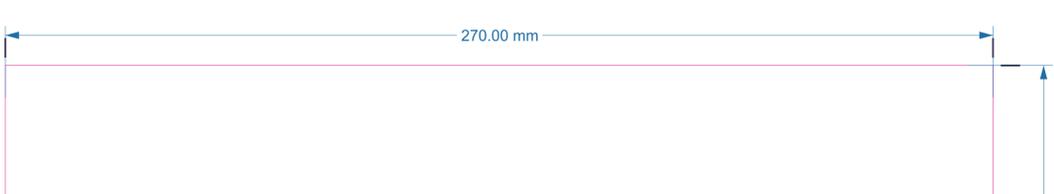
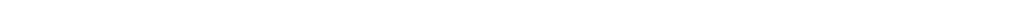
7.4 Dual Blockade of the Renin-Angiotensin System
 Dual blockade of the RAS with angiotensin receptor blockers, ACE inhibitors, or aliskiren is associated with increased risks of hypotension, hyperkalemia, and changes in renal function (including acute renal failure) compared to monotherapy. Most patients receiving the combination of two RAS inhibitors do not obtain any additional benefit compared to monotherapy. In general, avoid combined use of RAS inhibitors. Closely monitor blood pressure, renal function and electrolytes in patients on olmesartan medoxomil and hydrochlorothiazide tablets and other agents that affect the RAS.

7.5 Colesevelam Hydrochloride
 Concurrent administration of bile acid sequestrating agent colesevelam hydrochloride reduces the systemic exposure and peak plasma concentration of olmesartan. Administration of olmesartan at least 4 hours prior to colesevelam hydrochloride decreases the drug administration effect. Consider administering olmesartan at least 4 hours before the colesevelam hydrochloride dose (see **Clinical Pharmacology (12.3)**).

7.6 Use of Hydrochlorothiazide with Other Drugs
 When administered concurrently the following drugs may interact with thiazide diuretics:
 • Antidiabetic drugs (oral agents and insulin): Dosage adjustment of the antidiabetic drug may be required.
 • Antiarrhythmic agents: Shifting the dosage of hydrochlorothiazide and ion exchange resins (e.g., cholestyramine, colestipol) such as olmesartan medoxomil and hydrochlorothiazide tablets with 25 mg of hydrochlorothiazide, 40 mg of olmesartan medoxomil and hydrochlorothiazide tablets with 25 mg of hydrochlorothiazide. Inactive ingredients include hydroxypropyl cellulose, hydroxypropyl cellulose, iron oxide, iron oxide yellow, lactose monohydrate, low substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, talc and titanium dioxide.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
 Olmesartan medoxomil 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 mortality and death. Most epidemiologic studies examining fetal abnormalities after exposure to antihypertensive use in the first trimester have not distinguished drugs affecting the renin-angiotensin system from other antihypertensive agents.
 When pregnancy is detected, discontinue olmesartan medoxomil and hydrochlorothiazide tablets as soon as possible. Use alternative antihypertensive therapy during pregnancy.
 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%–4% and 15%–20%, respectively.
 • Clinical Considerations: Disease-associated maternal and/or embryonic/fetal risk for pre-eclampsia, gestational diabetes, premature delivery, and delivery complications (e.g., need for cesarean section and post-partum hemorrhage). Hypertension increases the maternal risk for pre-eclampsia, gestational diabetes and intrauterine death. Pregnant women with hypertension should be carefully monitored and managed accordingly.
 • Fetal/Neonatal Adverse Reactions: Oligohydramnios in pregnant women who use drugs affecting the renin-angiotensin system in the second and third trimesters of pregnancy can result in the following: reduced fetal renal function, decreased fetal renal tissue, fetal lung hypoplasia, skeletal deformations, including skull hypoplasia, hypoplasia, and death.
 Perform serial ultrasound examinations to assess the intra-amniotic environment. Fetal testing may be appropriate. Patients and physicians should be aware that oligohydramnios may not appear until after the fetus has sustained irreversible injury. Closely observe infants with histories of in utero exposure to olmesartan medoxomil and hydrochlorothiazide tablets for hypotension, oliguria, and hyperkalemia. If signs of hypotension occur, initiate measures to maintain adequate blood pressure and renal perfusion. Exchange transfusions or dialysis may be required as a means of reversing hypotension and supporting renal function (see **Use in Specific Populations (8.4)**).

8.2 Lactation
 Olmesartan medoxomil and hydrochlorothiazide tablets did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at a low dose of the dosing regimen, reflecting the greater frequency of decreased hepatic, renal or cardiac function and concomitant diseases or other drug therapy.
 Olmesartan and hydrochlorothiazide are substantially excreted by the kidney, and the risk of toxic reactions to olmesartan medoxomil and hydrochlorothiazide tablets may be greater in patients with impaired renal function or progressive liver disease.
8.4 Pediatric Use
 Safety and effectiveness of olmesartan medoxomil and hydrochlorothiazide tablets in pediatric patients have not been established.
8.5 Geriatric Use
 Safety and effectiveness of olmesartan medoxomil and hydrochlorothiazide tablets did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at a low dose of the dosing regimen, reflecting the greater frequency of decreased hepatic, renal or cardiac function and concomitant diseases or other drug therapy.
8.6 Renal Impairment
 Safety and effectiveness of olmesartan medoxomil and hydrochlorothiazide tablets in patients with impaired renal function or progressive liver disease.
8.7 Hepatic Impairment
 Olmesartan medoxomil and hydrochlorothiazide tablets did not include sufficient numbers of subjects with mild to severe liver disease.
10 OVERDOSAGE
 Olmesartan medoxomil and hydrochlorothiazide tablets are a combination of an angiotensin II receptor antagonist (AT1 antagonist), olmesartan medoxomil, and a thiazide diuretic, hydrochlorothiazide (HCTZ).
 Olmesartan medoxomil is H-15490-5-Carboxylic Acid, 4-Hydroxy-1-Methylpiperidine-2-Propyl-1-Ethyl-1H-tetrazol-5(1H)-1-ylidene-4-(Methylthio)-5-Methyl-2-Oxo-1,3-Dioxo-4,5-Dihydro-1H-Methyl Ester. Its empirical formula is C₂₄H₃₂N₄O₄ and its structural formula is:



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INDICATIONS AND USAGE
 Olmesartan medoxomil and hydrochlorothiazide tablets are a combination of olmesartan, an angiotensin II receptor blocker and hydrochlorothiazide, a thiazide diuretic indicated for the treatment of hypertension to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. (1)

Limitations of Use
 Olmesartan medoxomil and hydrochlorothiazide tablets are not indicated for initial therapy.

---DOSAGE AND ADMINISTRATION---
 • Recommended starting dose in patients not adequately controlled with olmesartan monotherapy, 40/12.5 mg (2)
 • Recommended starting dose in patients not adequately controlled with hydrochlorothiazide monotherapy, 20/12.5 mg (2)
 • Adjust dose after 2 to 4 weeks, as needed, to a maximum of 40 mg / 25 mg olmesartan / hydrochlorothiazide (2)

---DOSAGE FORMS AND STRENGTHS---
 Tablets: (olmesartan medoxomil and hydrochlorothiazide) 20/12.5 mg, 40/12.5 mg, 40/25 mg (3)

---CONTRAINDICATIONS---
 • Hypersensitivity to any component of olmesartan medoxomil and hydrochlorothiazide tablets (4)

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 • Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus (see **Warnings and Precautions (5.1)**, see **in specific populations (8.1)**).

1 INDICATIONS AND USAGE
 Olmesartan medoxomil and hydrochlorothiazide tablets are indicated for the treatment of hypertension, to lower blood pressure (see **Dosage and Administration (2)**).
 Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular (CV) events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from wide variety of pharmacologic classes including the class to which this drug principally belongs. There are no controlled trials demonstrating risk reduction with olmesartan medoxomil and hydrochlorothiazide tablets.
 Control of high blood pressure should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, and limited alcohol intake. Many patients will require more than one drug to achieve blood pressure goals. For specific advice on goals and management, see published guidelines, such as those of the National High Blood Pressure Education Program's National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (NCEP).

5.1 Fetal Toxicity
 Olmesartan medoxomil and hydrochlorothiazide tablets are contraindicated in pregnant women. Use of drugs that act on the renin-angiotensin system (RAS) during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal mortality and death. Resulting oligohydramnios can be associated with fetal hypoplasia and skeletal deformations. Neonatal death, stillbirth, and death have been reported in association with fetal renal failure and death. When pregnancy is detected, discontinue olmesartan medoxomil and hydrochlorothiazide tablets in cases where no other etiology is found (5.8).

5.2 Hypotension in Volume or Salt-Depleted Patients
 In patients with hypotension or volume or salt depletion, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with hypotension or volume or salt depletion, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with hypotension or volume or salt depletion, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg.

5.3 Impaired Renal Function
 In patients with impaired renal function, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with impaired renal function, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with impaired renal function, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg.

5.4 Hypersensitivity Reactions
 In patients with hypersensitivity to any component of olmesartan medoxomil and hydrochlorothiazide tablets, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with hypersensitivity to any component of olmesartan medoxomil and hydrochlorothiazide tablets, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with hypersensitivity to any component of olmesartan medoxomil and hydrochlorothiazide tablets, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg.

5.5 Electrolyte and Metabolic Imbalances
 In patients with electrolyte and metabolic imbalances, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with electrolyte and metabolic imbalances, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with electrolyte and metabolic imbalances, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg.

5.6 Acute Myopia and Secondary Angle-Closure Glaucoma
 In patients with acute myopia and secondary angle-closure glaucoma, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with acute myopia and secondary angle-closure glaucoma, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with acute myopia and secondary angle-closure glaucoma, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg.

5.7 Systemic Lupus Erythematosus
 In patients with systemic lupus erythematosus, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with systemic lupus erythematosus, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with systemic lupus erythematosus, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg.

5.8 Sprue-Like Enteropathy
 In patients with sprue-like enteropathy, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with sprue-like enteropathy, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg. In patients with sprue-like enteropathy, the maximum tolerated dose of olmesartan medoxomil and hydrochlorothiazide tablets is 20/12.5 mg.

6 ADVERSE REACTIONS
 The following adverse reactions with olmesartan medoxomil and hydrochlorothiazide tablets are described elsewhere:
 • Hypotension in volume- or salt-depleted patients (see **Warnings and Precautions (5.2)**)
 • Impaired renal function (see **Warnings and Precautions (5.3)**)
 • Hypersensitivity reactions (see **Warnings and Precautions (5.4)**)
 • Electrolyte and metabolic imbalances (see **Warnings and Precautions (5.5)**)
 • Acute myopia and secondary angle-closure glaucoma (see **Warnings and Precautions (5.6)**)
 • Systemic lupus erythematosus (see **Warnings and Precautions (5.7)**)
 • Sprue-like enteropathy (see **Warnings and Precautions (5.8)**)

6.1 Clinical Trials Experience
 The following adverse reactions were observed in clinical studies of olmesartan medoxomil and hydrochlorothiazide tablets in patients with hypertension. The following adverse reactions were observed in clinical studies of olmesartan medoxomil and hydrochlorothiazide tablets in patients with hypertension. The following adverse reactions were observed in clinical studies of olmesartan medoxomil and hydrochlorothiazide tablets in patients with hypertension.

Adverse Reaction	Olmesartan/HCTZ (N=40)	HCTZ (N=40)	Placebo (N=40)
Nausea	3	2	1
Hyperkalemia	4	0	2
Dizziness	5	1	3
Upper Respiratory Infection	7	6	7

7.1 Agents Increasing Serum Potassium
 Olmesartan medoxomil and hydrochlorothiazide tablets with other drugs that increase serum potassium levels may result in hyperkalemia. Monitor serum potassium in such patients.

7.2 Lithium
 Increases in serum lithium concentrations and lithium toxicity have been reported during concomitant administration of lithium with angiotensin II receptor antagonists. Monitor serum lithium levels during concomitant use.

7.3 Non-steroidal Anti-inflammatory Agents Including Selective Cyclooxygenase-2 Inhibitors (COX-2 Inhibitors)
 Olmesartan medoxomil and hydrochlorothiazide tablets with other drugs that increase serum potassium levels may result in hyperkalemia. Monitor serum potassium in such patients.

7.4 Dual Blockade of the Renin-Angiotensin System
 Dual blockade of the RAS with angiotensin receptor blockers, ACE inhibitors, or aliskiren is associated with increased risks of hypotension, hyperkalemia, and changes in renal function (including acute renal failure) compared to monotherapy. Most patients receiving the combination of two RAS inhibitors do not obtain any additional benefit compared to monotherapy. In general, avoid combined use of RAS inhibitors. Closely monitor blood pressure, renal function and electrolytes in patients on olmesartan medoxomil and hydrochlorothiazide tablets and other agents that affect the RAS.

7.5 Colesevelam Hydrochloride
 Concurrent administration of bile acid sequestrating agent colesevelam hydrochloride reduces the systemic exposure and peak plasma concentration of olmesartan. Administration of olmesartan at least 4 hours prior to colesevelam hydrochloride decreases the drug administration effect. Consider administering olmesartan at least 4 hours before the colesevelam hydrochloride dose (see **Clinical Pharmacology (12.3)**).

7.6 Use of Hydrochlorothiazide with Other Drugs
 When administered concurrently the following drugs may interact with thiazide diuretics:
 • Antidiabetic drugs (oral agents and insulin): Dosage adjustment of the antidiabetic drug may be required.
 • Antiarrhythmic agents: Shifting the dosage of hydrochlorothiazide and ion exchange resins (e.g., cholestyramine, colestipol) such as olmesartan medoxomil and hydrochlorothiazide tablets with 25 mg of hydrochlorothiazide, 40 mg of olmesartan medoxomil and hydrochlorothiazide tablets with 25 mg of hydrochlorothiazide. Inactive ingredients include hydroxypropyl cellulose, hydroxypropyl cellulose, iron oxide, iron oxide yellow, lactose monohydrate, low substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, talc and titanium dioxide.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
 Olmesartan medoxomil 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 mortality and death. Most epidemiologic studies examining fetal abnormalities after exposure to antihypertensive use in the first trimester have not distinguished drugs affecting the renin-angiotensin system from other antihypertensive agents.
 When pregnancy is detected, discontinue olmesartan medoxomil and hydrochlorothiazide tablets as soon as possible. Use alternative antihypertensive therapy during pregnancy.
 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%–4% and 15%–20%, respectively.
 • Clinical Considerations: Disease-associated maternal and/or embryonic/fetal risk for pre-eclampsia, gestational diabetes, premature delivery, and delivery complications (e.g., need for cesarean section and post-partum hemorrhage). Hypertension increases the maternal risk for pre-eclampsia, gestational diabetes and intrauterine death. Pregnant women with hypertension should be carefully monitored and managed accordingly.
 • Fetal/Neonatal Adverse Reactions: Oligohydramnios in pregnant women who use drugs affecting the renin-angiotensin system in the second and third trimesters of pregnancy can result in the following: reduced fetal renal function, decreased fetal renal tissue, fetal lung hypoplasia, skeletal deformations, including skull hypoplasia, hypoplasia, and death.
 Perform serial ultrasound examinations to assess the intra-amniotic environment. Fetal testing may be appropriate. Patients and physicians should be aware that oligohydramnios may not appear until after the fetus has sustained irreversible injury. Closely observe infants with histories of in utero exposure to olmesartan medoxomil and hydrochlorothiazide tablets for hypotension, oliguria, and hyperkalemia. If signs of hypotension occur, initiate measures to maintain adequate blood pressure and renal perfusion. Exchange transfusions or dialysis may be required as a means of reversing hypotension and supporting renal function (see **Use in Specific Populations (8.4)**).

8.2 Lactation
 Olmesartan medoxomil and hydrochlorothiazide tablets did not include sufficient numbers of subjects aged 65 and older to