

Daiichi Sankyo Hypertension Franchise Fact Sheet

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- An estimated 78 million people, or about 1 in 3 U.S. adults, have hypertension (high blood pressure).¹ Research shows that lowering high blood pressure reduces the risk of both fatal and non-fatal cardiovascular events such as strokes and heart attacks. Most people with hypertension will require more than one antihypertensive medication to achieve and maintain blood pressure control.²⁻³
- Daiichi Sankyo, Inc. (DSI) is committed to the long-term health and wellness of patients, with a hypertension franchise that offers a wide range of hypertension therapies, programs and management tools to help patients work toward their goal blood pressure.

Hypertension Treatment Options

- The DSI portfolio of antihypertensive therapies offers a diverse treatment platform that provides blood pressure reductions for a wide variety of patients with hypertension. The portfolio includes 15 different dose strength combinations across four products, offering both physicians and patients the flexibility in finding a treatment to help them work toward blood pressure goals:
 - **BENICAR**® (olmesartan medoxomil) – The first drug in the DSI hypertension franchise, **BENICAR** is an angiotensin receptor blocker (ARB) that can provide blood pressure reductions to help achieve blood pressure goals.
 - **BENICAR HCT**® (olmesartan medoxomil, hydrochlorothiazide) – The combination of **BENICAR** and the diuretic, hydrochlorothiazide.
 - **AZOR**® (amlodipine, olmesartan medoxomil) – The dual combination of **BENICAR** and amlodipine, a calcium channel blocker (CCB).
 - **TRIBENZOR**® (olmesartan medoxomil, amlodipine, hydrochlorothiazide) – Combines three complementary agents – an ARB, CCB and diuretic – to help patients work toward their blood pressure goals.
- **BENICAR, BENICAR HCT, AZOR and TRIBENZOR** have more than 53 million patient-years of use worldwide since 2002 to treat hypertension.

Value-Added Programs to Help Patients Reach Goal

In addition to the prescription portfolio, DSI offers services to help patients work toward their hypertension goals. These include the following patient support programs:

- **Hypertension Care** – A comprehensive blood pressure program designed to help with some of the challenges of hypertensive patients. Components of this program include:
 - A patient reimbursement hotline

- A patient-focused blood pressure support hotline where patients learn more about high blood pressure and their medications from a registered nurse. The hotline does not provide medical advice and patients are advised to talk to their healthcare provider if they are seeking medical advice.
 - A co-pay card called *Savings that Last*. Over 650,000 patients enrolled to date with over \$100 million in savings since 2009 with the previous benefits.⁴
 - Additionally, DSI will pay for up to 3 add-on generic antihypertensives if an eligible patient does not reach blood pressure goal while on a DSI medication.
 - Product samples so that patients can find the right drug and dosage before they pay for an entire prescription. More than 127 million days of therapy were distributed in 2012.⁴
 - Distribution of blood pressure monitors so that patients can help track their blood pressure at home. A total of 85,000 blood pressure monitors have been distributed by DSI in the last 4 years.⁴
- **Right Fit Blood Pressure Program** – A customized patient education program that offers enrolled hypertension patients the option to receive educational articles, healthy recipes, daily medication reminders, refill reminders and practical diet and exercise tips. Eligible patients also can sign-up for the *Savings that Last* co-pay card and download a mobile app that provides these same educational resources and more to help manage hypertension. More than 600,000 patients have utilized these resources to date.⁴
 - **Medication Therapy Management Programs** – DSI, in partnership with both chain and independent pharmacies, provide services for patients such as hypertension education materials right at the pharmacy counter.

About Daiichi Sankyo

- The Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients in both mature and emerging markets.
- While maintaining its portfolio of marketed pharmaceuticals for hypertension, hyperlipidemia, and bacterial infections, the Group is engaged in the development of treatments for thrombotic disorders and focused on the discovery of novel oncology and cardiovascular-metabolic therapies. Furthermore, the Daiichi Sankyo Group has created a "Hybrid Business Model," which will respond to market and customer diversity and optimize growth opportunities across the value chain. For more information, please visit www.daiichisankyo.com.
- Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is a member of the Daiichi Sankyo Group. For more information on Daiichi Sankyo, Inc., please visit www.dsi.com.

Important Safety Information for BENICAR®, BENICAR HCT®, AZOR®, and TRIBENZOR®

WARNING: DO NOT TAKE BENICAR, BENICAR HCT, AZOR, OR TRIBENZOR DURING PREGNANCY

- BENICAR, BENICAR HCT, AZOR and TRIBENZOR can cause harm or death to an unborn baby
- Talk with your doctor about other ways to lower your blood pressure if you become pregnant
- If you get pregnant while taking BENICAR, BENICAR HCT, AZOR or TRIBENZOR, tell your doctor immediately

Please see the **WARNINGS AND PRECAUTIONS** sections of the Full Product Information about fetal toxicity.

Do not take BENICAR, BENICAR HCT, AZOR, or TRIBENZOR if you:

- Take medicine that contains aliskiren and you have diabetes or kidney problems

Do not take BENICAR HCT or TRIBENZOR if you:

- Have less urine than normal or if you cannot urinate
- Are allergic to other sulfonamide type medicines
- Have severe kidney disease

Children that are less than 1 year of age must not receive BENICAR for high blood pressure.

Before taking BENICAR, BENICAR HCT, AZOR, or TRIBENZOR, tell your doctor if you are pregnant or plan to become pregnant. Also tell your doctor if you are breast-feeding or plan to breast-feed. A medicine in BENICAR HCT and TRIBENZOR can pass into your breast milk. This may harm your baby. You and your doctor should decide if you will take BENICAR, BENICAR HCT, AZOR, or TRIBENZOR or breast-feed. You should not do both.

Let your doctor know about any health conditions you may have

Tell your doctor if you are allergic to any of the ingredients in BENICAR, BENICAR HCT, AZOR, or TRIBENZOR (see Full Product Information for a list of the ingredients in BENICAR, BENICAR HCT, AZOR, or TRIBENZOR, as applicable). Also let your doctor know if you have any of the health conditions listed below:

Before you take these medicines:	Let your doctor know if you have these, or any other, medical conditions:
BENICAR	<ul style="list-style-type: none"> ▪ Kidney problems ▪ A lot of diarrhea or are vomiting
BENICAR HCT	<ul style="list-style-type: none"> ▪ Kidney or liver problems ▪ Lupus ▪ A lot of diarrhea or are vomiting ▪ History of allergy or bronchial asthma

AZOR	<ul style="list-style-type: none"> ▪ Kidney or liver problems ▪ Heart problems (including coronary heart disease and narrowing of the aortic valve) ▪ A lot of diarrhea or are vomiting
TRIBENZOR	<ul style="list-style-type: none"> ▪ Kidney or liver problems ▪ Lupus ▪ Heart problems (including coronary heart disease and narrowing of the aortic valve) ▪ A lot of diarrhea or are vomiting ▪ History of allergy or bronchial asthma

Tell your doctor about all the medicines you take

Some of your other medicines and BENICAR, BENICAR HCT, AZOR, or TRIBENZOR could affect each other. This may cause serious side effects.

These medicines may include prescription and nonprescription medicines, vitamins, and herbal supplements:

If you take BENICAR, tell your doctor if you also take:
<p>Water pills (diuretics) Other medicines for high blood pressure or a heart problem Potassium supplements or a salt substitute that contains potassium Pain or arthritis medicines, such as aspirin and nonsteroidal anti-inflammatory drugs (NSAIDs) Welchol® (colesevelam hydrochloride) Lithium for certain types of depression</p>
If you take BENICAR HCT, tell your doctor if you also take:
<p>Water pills (diuretics) Other medicines for high blood pressure or a heart problem Potassium supplements or a salt substitute that contains potassium Pain or arthritis medicines, such as aspirin and nonsteroidal anti-inflammatory drugs (NSAIDs) Welchol® (colesevelam hydrochloride) Diabetes medicine including insulin Narcotic pain medicine Sleeping pills and antiseizure medicines called <i>barbiturates</i> Lithium for certain types of depression Steroids Cholesterol-lowering medicines</p>
If you take AZOR, tell your doctor if you also take:

Water pills (diuretics)
Other medicines for high blood pressure or a heart problem
Potassium supplements or a salt substitute that contains potassium
Pain or arthritis medicines, such as aspirin and nonsteroidal anti-inflammatory drugs (NSAIDs)
Welchol® (colesevelam hydrochloride)
Simvastatin, a cholesterol-lowering drug
Lithium for certain types of depression

If you take TRIBENZOR, tell your doctor if you also take:

Water pills (diuretics)
Other medicines for high blood pressure or a heart problem
Potassium supplements or a salt substitute that contains potassium
Pain or arthritis medicines, such as aspirin and nonsteroidal anti-inflammatory drugs (NSAIDs)
Welchol® (colesevelam hydrochloride)
Diabetes medicine including insulin
Narcotic pain medicine
Sleeping pills and antiseizure medicines called *barbiturates*
Lithium for certain types of depression
Steroids
Cholesterol-lowering medicines (including simvastatin)

About alcohol and other drug interactions

If you are taking BENICAR HCT or TRIBENZOR, do not drink alcohol. Your blood pressure may become too low if you drink alcohol.

Some of your other medicines and BENICAR, BENICAR HCT, AZOR, or TRIBENZOR could affect each other. This may cause serious side effects. Take BENICAR, BENICAR HCT, AZOR, or TRIBENZOR as prescribed by your doctor. Talk with your doctor before you stop taking BENICAR, BENICAR HCT, AZOR, or TRIBENZOR.

Know about possible side effects

For BENICAR, BENICAR HCT, AZOR, and TRIBENZOR

Serious side effects may include injury or death to an unborn baby; low blood pressure (hypotension), which may cause you to feel faint or dizzy; and kidney problems, which may get worse in people with kidney disease. If you have kidney problems, you may need blood tests, and your doctor may need to lower your dose. Tell your doctor if you get swelling in your feet, ankles, or hands, or have unexplained weight gain. These may be signs of kidney problems. If you have heart failure, your doctor should also check your kidney function before prescribing these medicines. Tell your doctor if you are experiencing these symptoms.

Serious side effects may also include severe, chronic diarrhea with considerable weight loss, which may develop months to years after starting BENICAR, BENICAR HCT, AZOR, or TRIBENZOR. Tell your doctor if you are experiencing these symptoms.

Additional side effects for BENICAR and BENICAR HCT only

Because of the thiazide diuretic (water pill), an ingredient in BENICAR HCT, other serious side effects may include allergic reactions and changes in body salts (such as sodium and potassium) and fluids. Tell your doctor if you have these signs and symptoms: dry mouth, thirst, weakness, tiredness or sleepiness, restlessness, confusion, seizures, muscle pains or cramps, muscle tiredness, dizziness or fainting, having little or no urine output, fast heartbeat, or nausea and vomiting.

The thiazide diuretic in BENICAR HCT can also cause eye problems, which may lead to vision loss. Symptoms can happen within hours to weeks of starting BENICAR HCT. Tell your doctor if you have a decrease in vision or eye pain.

The most common side effect of BENICAR and BENICAR HCT was dizziness. Other side effects of BENICAR HCT included upper respiratory tract infections, more uric acid in the blood, and nausea.

Additional side effects for AZOR only

Because of amlodipine, an ingredient in AZOR, other serious side effects may include worsening chest pain or heart attack. Get medical help right away if you have chest pain that gets worse or does not go away.

The most common side effect of AZOR was swelling from fluid buildup in the body. Other less common side effects were blood pressure that is too low; blood pressure that becomes too low after standing up too quickly; rash; itching; pounding or racing heartbeat; more frequent urination; and excessive urination at night. Other side effects may include headache, dizziness, and redness of the face and neck (flushing).

Do not take AZOR as your first medicine for the treatment of your high blood pressure if you have liver problems or if you are 75 years of age and older.

Additional side effects for TRIBENZOR only

Because of amlodipine, an ingredient in TRIBENZOR, other serious side effects may include chest pain that gets worse or heart attack. Get medical help right away if you have chest pain that gets worse or does not go away. TRIBENZOR also contains a thiazide diuretic (water pill), which may cause allergic reactions and changes in body salts (such as sodium and potassium) and fluids. Tell your doctor if you have signs of a change in body salts and body fluids. Signs of a change include: dry mouth, thirst, weakness, tiredness or sleepiness, or restlessness. These signs may also include confusion, seizures, muscle pains or cramps, muscle tiredness, dizziness or fainting, having little or no urine, fast heartbeat, and nausea and vomiting. The thiazide diuretic in TRIBENZOR can also cause eye problems which may lead to vision loss. Symptoms can happen within hours to weeks of starting TRIBENZOR. Tell your doctor right away if you have decrease in vision or eye pain.

The most common side effects of TRIBENZOR include dizziness; swelling of the ankles, feet, and hands; headache; tiredness; stuffy or runny nose and sore throat; muscle twitching (spasms); nausea; upper respiratory tract infection; diarrhea; urinary tract infection; and swelling of the joints.

Tell your doctor if you have any side effect that bothers you or does not go away. Not all the possible side effects of BENICAR, BENICAR HCT, AZOR, or TRIBENZOR have been mentioned in the Important Safety Information. For more information, talk with your doctor or pharmacist. Call your doctor for medical advice about side effects.

To report side effects, contact Daiichi Sankyo, Inc., at 1-877-437-7763 or the FDA at 1-800-332-1088 or www.fda.gov/medwatch.

DSHN14101188

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Please see Full Prescribing Information for [BENICAR](#), [BENICAR HCT](#), [AZOR](#), and [TRIBENZOR](#).

References

¹ American Heart Association. Heart Disease and Stroke Statistics: 2014. *Circulation*. 2014. 127:e28-e268.

² James PA, Oparil S, Carter BL et al. 2014 evidence-based guideline for the management of high blood pressure in adults: report from the panel members appointed to the Eighth Joint National Committee (JNC 8). *JAMA*. 2014 Feb 5;311(5):507-20.

³ Weber MA, Schiffrin EL, White WB et al. Clinical practice guidelines for the management of hypertension in the community: a statement by the American Society of Hypertension and the International Society of Hypertension. *J Clin Hypertens (Greenwich)*. 2014 Jan;16(1):14-26.

⁴ Data on file. Daiichi Sankyo, Inc., Parsippany, NJ.