

# BiDil.

*Because you want more life to live.*



**BiDil**<sup>®</sup>

isosorbide dinitrate/hydralazine HCl



## Getting Started With BiDil

Your doctor has added BiDil to your current heart failure medicines because BiDil can help you to feel better, stay out of the hospital, and live longer. Heart failure is a condition that develops following an injury to the heart, such as long-term high blood pressure or a heart attack. Having heart failure means that your heart is getting weaker and doesn't work as well as it should. Heart failure may cause you to experience fatigue, shortness of breath, and swelling in your ankles and legs, often leading to hospitalization. This booklet is designed to provide you with valuable information about BiDil—to help you get off to a good start with your new medicine.

## What is BiDil?

BiDil is a prescription medicine that was recently approved by the Food and Drug Administration (FDA) for the treatment of heart failure—when taken in addition to other heart failure medications—in black patients. Only your doctor can tell you if BiDil is right for you.

## Has BiDil Been Proven to Work?

The benefits of BiDil were proven in the African-American Heart Failure Trial (A-HeFT). Patients in the A-HeFT study said they felt better and found it easier to function in their daily lives. In fact, compared with those patients taking the placebo (sugar pill) in A-HeFT, the patients taking BiDil had a significant additional improvement in their symptoms.

*Please see important safety information on pages 7-8 and full Prescribing Information enclosed.*

**SYMPTOMS  
IMPROVED**



**Significant improvement**

BiDil also reduced the likelihood of first hospitalization for heart failure by 39%—that's a 39% greater chance of staying out of the hospital longer compared with patients who aren't taking BiDil, and spending time with the people you care about.

**39%** **Reduction in hospitalization**



In A-HeFT, BiDil reduced the risk of death by 43% when it was taken along with the usual standard heart medicines.

**43%** **Reduction in death**



In the words of an A-HeFT patient who received BiDil:

*"I have come a long way from where I was before the A-HeFT trial. I know now that I have more life to live and feel blessed."*

*—Shirley Ford, a BiDil patient in A-HeFT*

*Patient experiences may vary, and the experiences set forth herein may not be representative of the way every patient will respond.*



## ***BiDil + 3 Steps = A Healthier Life***

There are 3 simple steps you can take to become healthier while taking BiDil. The first step is to make sure you take BiDil exactly as it was prescribed by your doctor. Next, it is important that you talk to your doctor. The more your doctor knows about you and your condition, the better he or she can help you. Last, but not least, take charge of your condition. You can help yourself by eating better and exercising. (The following section will provide you with more information on these 3 simple steps.)

### ***It's as Easy as 1,2,3***

#### ***1. Take BiDil as Prescribed by Your Doctor***

Your BiDil prescription will be started at a low dose (for example, one tablet or one-half tablet, 3 times a day). Eventually, the dosage may be increased. Often, when people feel better, they believe they are cured and stop taking their medications. However, there is no cure for heart failure.

In order to get the full benefits of BiDil and keep them, you must remain committed to adding BiDil to your current treatment as directed by your doctor. (Keep track of your medicines by filling out the "My Medicines" chart on page 11.)

#### ***2. Talk to Your Doctor***

You've heard that phrase before: "Talk to your doctor." This is important—this is about your heart, your life. The more your doctor knows about what's going on with you, how you're feeling, and how your medicines are affecting you, the better equipped he or she is to help you.

If you track your progress from the beginning of your BiDil treatment, it will be very helpful to you and to your doctor. Make note of how you are feeling—physically, mentally, and emotionally. As time goes by, it will be good to notice any changes in the way you feel.

You can take notes in the journal provided for you in this booklet (see pages 13-16). Be sure to bring the journal with you the next time you visit your doctor, so you can both talk about the progress you have made.

If you need help getting BiDil, ask your doctor about the NitroMed Cares™ Patient Support Program. This program was established to help uninsured patients get access to BiDil. (See page 12 for more information.)

*Please see important safety information on pages 7-8 and full Prescribing Information enclosed.*

*Be strong and of good courage.  
— The Bible, Joshua 1:9*



### **3. Take Charge of Your Condition**

#### ***Eat better. Feel better.***

Eating a well-balanced diet can make you healthier and happier. If you take control of what you choose to put in your mouth, it can make a world of difference to your health. Remember to also limit your salt intake. Eating well is good for the heart, body, and soul.

#### ***Exercise is good for the body and mind.***

You'll want to check with your doctor first and talk about an exercise routine that will work for you. You don't have to join a health club or a gym. Walking is one of the best forms of exercise around. No matter what your age, the more active you are now, the healthier you can be. Again, talk to your doctor first.

*"After BiDil was added to my therapy, my physical condition really improved. I now have the energy to spend more quality time with my family."*

*—Leland Ramey, an A-HeFT patient from Ohio*

*Patient experiences may vary, and the experiences set forth herein may not be representative of the way every patient will respond.*

*You must act as if it is impossible to fail.  
— Ashanti proverb*

### ***The History of BiDil***

The combination of the two drugs in BiDil was originally studied in a multiracial population. When the results were re-analyzed, an effect on survival was seen in black patients. Because more testing was necessary to make sure, the stage was set for the landmark A-HeFT study, the first and only heart failure clinical trial with an all-black population. A-HeFT was co-managed by the Association of Black Cardiologists and supported by the National Medical Association.

More than 1000 heart patients were enrolled in the A-HeFT study which took place from May 29, 2001 through July 19, 2004. All patients were self-identified as black and already receiving standard heart therapies, such as diuretics, digitalis, ACE inhibitors, angiotensin II receptor blockers, beta-blockers, and aldosterone antagonists. Patients were maintained on those standard medications, and either BiDil or a placebo (sugar pill) was added.

The trial results showed such a clear difference in the patients given BiDil that the trial was stopped early so that patients taking placebo could be offered the benefits of BiDil. The results were later published in the *New England Journal of Medicine*. In December 2004, the American Heart Association recognized BiDil as a major advancement in heart disease research.

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## **Important Safety Information**

### **Allergies**

Tell your doctor about any allergies you have, especially if you're sensitive to nitrates, such as nitroglycerin tablets or isosorbide dinitrate (Sorbitrate® or Isordil®). BiDil has a nitrate component, so you need to let your doctor know.

### **Other Medications**

Tell your doctor if you're taking any erectile dysfunction or pulmonary hypertension drugs, like Viagra®/Revatio™ (sildenafil), Levitra® (vardenafil), or Cialis® (tadalafil). Mixing these with BiDil may cause a sudden drop in blood pressure, fainting, chest pain, or heart attack.

Also, tell your doctor if you are taking any medication to decrease blood pressure because when taken with BiDil, blood pressure may become too low.

### **Alcohol**

Drinking alcohol when taking BiDil could make you feel very lightheaded. We recommend that you try to avoid drinking alcohol while taking BiDil.

Sorbitrate is a registered trademark of AstraZeneca LP; Isordil is a registered trademark of Wyeth Pharmaceuticals Inc.; Viagra is a registered trademark and Revatio is a trademark of Pfizer Inc.; Levitra is a registered trademark of Bayer HealthCare, GlaxoSmithKline, and Schering-Plough; Cialis is a registered trademark of Lilly ICOS LLC.

*I am the master of my fate: I am the captain of my soul.*

*— William Ernest Henley*

### **Most Common Side Effects**

- It is possible you'll get headaches, especially at first. For some patients, Tylenol® (acetaminophen) helped ease the discomfort. Keep your doctor posted on your headache progress and Tylenol use; he or she may want to adjust your dosage.
- If you experience dizziness, call your doctor.

### **Other Less Common Side Effects**

*Please make sure to tell your doctor about any of the signs or symptoms mentioned below or about any unusual events that worry you.*

- Drinking less fluids than your doctor recommends or losing fluid due to diarrhea, sweating, or vomiting may cause low blood pressure, lightheadedness, or fainting. If fainting occurs, stop taking BiDil and contact your doctor immediately.
- Lightheadedness may occur when standing, especially after sitting or lying down.
- If you experience achy and/or swollen joints, unexplained fever for more than a few days, skin rashes, chest pain, prolonged weakness or fatigue (even after a good night's sleep), or any other unexplained signs or symptoms, make sure to tell your doctor as they may be signs of a serious medical condition.

*You may also experience*

- rapid heartbeat that could lead to chest pain or aggravate chest pain
- numbness or tingling in the hands or feet

Tylenol is a registered trademark of McNeil Pharmaceuticals, a Division of McNeil PPC, Inc.

*Please see full Prescribing Information enclosed.*



## Weight Chart

A change in your weight can be a signal that your heart condition is worsening. Weigh yourself every day, at the same time of day. A good time to weigh yourself may be first thing in the morning

before you eat breakfast. Report any significant change in your weight to your doctor or nurse (usually 2–3 pounds in one day or 5 pounds in one week).

Weight	S	M	T	W	TH	F	S
Week 1							
Week 2							
Week 3							
Week 4							
Week 5							
Week 6							
Week 7							
Week 8							
Week 9							
Week 10							
Week 11							
Week 12							

## My Medicines

Ask your doctor or nurse for their assistance, if needed, in filling in this chart.

Name of medicine	What it looks like	How many pills?	How often?
BiDil	round orange tablet		

Please see important safety information on pages 7-8 and full Prescribing Information enclosed.

## Patient Assistance Program



NitroMed has established NitroMed Cares™, for those patients who are concerned about whether or not they can afford treatment with BiDil. NitroMed Cares™ offers two assistance programs for access to BiDil:

**1. The NitroMed Cares™ Uninsured Patient Program**, designed to help uninsured patients gain **free** access to BiDil. Eligible patients can receive up to a 90-day **free** supply of BiDil every three months, sent either to their doctor's office or sent directly to their home. Eligible patients are those who do not have prescription drug insurance coverage. Applications for this program are found on [www.bidil.com](http://www.bidil.com) and must be completed by you and your physician.

**2. The NitroMed Cares™ BiDil Access Card Program**, designed to cover **all** of your co-pay (for eligible insured patients\*) for a prescription of BiDil. Eligible insured patients can get up to 6 months of BiDil and NitroMed will cover **all** of your co-pay. The BiDil Access Card is available at your physician's office. For more information, visit [www.bidil.com](http://www.bidil.com).

\*Patients receiving outpatient prescription drugs through Medicare Part D, Medicaid or other state or federal supported prescription drug programs or other similar programs are ineligible for participation in NitroMed Cares. In MA & MI, insured patients are not eligible for co-pay assistance.

*I am sick and tired of being sick and tired.  
— Fannie Lou Hamer*



## ***Patient Journal***

### ***Week 1***

Jot down those things that can help you keep track of how you're doing: helpful thoughts and new insights; your stamina and ability to exercise; and your feelings toward others and (very important!) yourself. Keeping a journal can help you see where your pitfalls are and where your strengths lie.

### ***Week 2***

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*Nothing great was ever achieved without enthusiasm.*  
— Ralph Waldo Emerson

*Fill the cup that clears  
Today of past regrets and future fears*  
— Omar Khayyám





## Glossary

**ACE (angiotensin-converting enzyme) inhibitors** — drugs that prevent the production of a substance that rises to higher levels in heart failure and is considered harmful.

**Aldosterone antagonist** — a medication that both works like a diuretic and helps to balance important electrolytes (such as potassium).

**Angina** — the medical term for chest pain or discomfort due to coronary heart disease.

**Anticoagulants** — blood thinners that help prevent blood clots.

**ARB (angiotensin receptor blocker)** — a medication that blocks a harmful substance in heart failure.

**Beta-blockers** — if a heart is weak, it will beat faster to make up for the weakness. Beta-blockers help keep the heart from beating too fast and also help lower blood pressure.

**Coronary artery disease** — hardening of the arteries, leading to decreased blood flow.

**Digitals** — a medication that may help the heart pump better.

**Diuretics** — also called “water pills,” help get rid of extra fluid and salt by increasing the amount of urine the body produces. Increasing urine helps decrease fluid that collects in the “wrong” places, such as in the feet, ankles, and lungs (see “sodium”).

**Electrocardiogram (EKG or ECG)** — measures your heartbeat in order to detect whether the heart is damaged. Wires are attached to small stickers, which are placed on your arms, legs, and chest. A machine then records your heart’s activity and shows it as a pattern on screen.

**Echocardiogram (ECHO)** — using sound waves, an ECHO detects how efficiently your heart pumps blood.

**Edema** — fluid build-up in the body.

**Ejection fraction** — heart pump function is usually measured using a number called the ejection fraction. The ejection fraction refers to the percentage of blood that is pumped out of the heart each time it beats. A normal heart pumps out or “ejects” about 50-65% of the blood inside. If the heart is damaged, the ejection fraction can fall below 40%. An echocardiogram (see above) is the test most commonly used to evaluate heart pump function.

**Heart attack (sometimes called a myocardial infarction or coronary thrombosis)** — occurs when the blood supply to part of the heart muscle itself is severely reduced or stopped as in coronary artery disease.

**Heart failure** — is a condition in which the heart’s muscle becomes weakened after it is injured from something like a heart attack or high blood pressure and gradually loses its ability to pump enough blood throughout the body.

**High blood pressure (or hypertension)** — defined in an adult as a systolic pressure of 140 mm Hg or higher and/or a diastolic pressure of 90 mm Hg or higher. Blood pressure is measured in millimeters of mercury (mm Hg).

**Sodium (salt)** — makes the body retain water, which can intensify the fluid buildup that occurs in heart failure. Extra fluid (see “edema”) makes extra weight, and the heart has to work even harder to pump blood. The body needs only a very small amount of salt.

**Vasodilators** — dilate, or widen, blood vessels, allowing blood to flow more easily.





## More information:

- Talk to your doctor or pharmacist
- Visit [www.Bidil.com](http://www.Bidil.com)
- Call this toll-free number: 1-888-MYBIDIL

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isosorbide dinitrate/hydralazine HCl

**More Life to Live**<sup>™</sup>