At High Risk For Heart Attack Or Stroke But Having Trouble With Your Medication?

(NAPSA)—An estimated 80 million people in the United States have one or more forms of cardiovascular disease. It causes about one in every three deaths in the United States. But there are medications that can help.

What is important to know is that not every drug works as well for every patient and your doctor can help identify the treatment that is best for you. While all drugs have side effects, sometimes these side effects are too much for some patients to handle. And even though a drug protects their health, some patients may even stop taking it as prescribed.

As a potential option for these patients, the Food and Drug Administration recently approved a new use for a prescription medication currently used to treat high blood pressure, which is also a risk factor for cardiovascular disease. The treatment, called Micardis® (telmisartan) Tablets 80 mg, is now approved for reduction of the risk for heart attack, stroke or death from cardiovascular causes in high-risk patients 55 years or older who are unable to take a class of medications called angiotensin-converting enzyme, or ACE, inhibitors. You can talk to your doctor about what "high risk" means.

Until now, there were limited alternatives to an ACE inhibitor for cardiovascular risk reduction. However, some studies estimate that up to 20 percent of patients who take an ACE inhibitor experience side effects, usually cough.

All medications have risks as well as benefits, and it is not clear why some medications cause side effects in some patients but not others. If you are one of those who do experience significant side effects, you need to talk with your doctor to find the right treatment for you.

MICARDIS is not for pregnant women. Taking MICARDIS during pregnancy can cause injury and even death to an unborn baby. The most serious side effects with MICARDIS are low blood pressure and kidney problems. Other rare but serious side effects may occur. Before taking MICARDIS, tell your doctor if you have liver, kidney or heart problems, and about all other medications you are taking.

Please visit www.mymicardis.com for full Prescribing Information with Boxed Warning, for MICARDIS.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call (800) FDA-1088.

Editors' Note:

About Micardis® (telmisartan/amlodipine) Tablets.

Telmisartan is marketed in the U.S. as MICARDIS Tablets by Boehringer Ingelheim Pharmaceuticals, Inc.

MICARDIS is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

MICARDIS is indicated for reduction of the risk of myocardial infarction, stroke, or death from cardiovascular causes in patients 55 years of age or older at high risk of developing major cardiovascular events who are unable to take ACE inhibitors. High risk for cardiovascular events can be evidenced by a history of coronary artery disease, peripheral arterial disease, stroke, transient ischemic attack, or high-risk diabetes (insulin-dependent or non-insulin dependent) with evidence of end-organ damage. MICARDIS can be used in addition to other needed treatment (such as antihypertensive, antiplatelet or lipid-lowering therapy). Studies of telmisartan in this setting do not exclude that it may not preserve a meaningful fraction of the effect of the ACE inhibitor to which it was compared. Consider using the ACE inhibitor first, and, if it is stopped for cough only, consider re-trying the ACE inhibitor after the cough resolves. Use of telmisartan with an ACE inhibitor is not recommended.

WARNING: AVOID USE IN PREGNANCY

When used in pregnancy, drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus. When pregnancy is detected, MICARDIS tablets should be discontinued as soon as possible [see Warnings and Precautions].

In patients with an activated renin-angiotensin system, such as volume- and/or salt-depleted patients, symptomatic hypotension may occur after initiation of therapy with MICARDIS Tablets. This condition should be corrected prior to administration of MICARDIS Tablets, or treatment should start under close medical supervision.

As the majority of telmisartan is eliminated by biliary excretion, patients with biliary obstructive disorders or hepatic insufficiency can be expected to have reduced clearance. MICARDIS Tablets should be used with caution in these patients.

In patients whose renal function may depend on the activity of the renin-angiotensin-aldosterone system (e.g., patients with severe CHF), treatment with angiotensin-converting enzyme inhibitors and angiotensin receptor antagonists has been associated with oliguria and/or progressive azotemia and (rarely) with acute renal failure and/or death. Similar results may be anticipated in patients treated with MICARDIS Tablets.

In studies of ACE-inhibitors in patients with renal artery stenosis, increases in serum creatinine or blood urea nitrogen were observed. An effect similar to that seen with ACE inhibitors should be anticipated with MICARDIS Tablets.

Dual blockade of the renin-angiotensin-aldosterone system (e.g., by adding an ACE-inhibitor to an angiotensin II receptor antagonist) should be used with caution and should include close monitoring of renal function. Concomitant use of telmisartan and ramipril is not recommended.

The most common adverse events occurring with MICARDIS Tablets at a rate of ≥1% and greater than placebo, respectively, were: upper respiratory tract infection (URTI) (7%, 6%), back pain (3%, 1%), sinusitis (3%, 2%), diarrhea (3%, 2%), and pharyngitis (1%, 0%). In a clinical trial for cardiovascular risk reduction, 8.4% patients treated with telmisartan discontinued due to adverse events compared to 7.6% treated with placebo. Serious adverse events at least 1% more common on telmisartan than placebo were intermittent claudication (7% vs 6%) and skin ulcer (3% vs 2%).

With MICARDIS monotherapy and other angiotensin II receptor blockers and ACE inhibitors in general, BP response in blacks is noticeably less than in Caucasians.

No overall differences in effectiveness and safety of MICARDIS were observed in elderly patients compared to younger patients, but greater sensitivity of some older individuals cannot be ruled out.

In nursing mothers, nursing or MICARDIS should be discontinued.

For more information about MICARDIS or to receive a package insert please contact Boehringer Ingelheim Pharmaceuticals Inc. Drug Information Unit at 1-800-542-6257, option #4.