In addition to the adverse events in the table, the following events occurred at a rate of 1% but were at least as frequent in the placebo group: influenza-like symptoms, dyspepsia, myalgia, urinary tract infection, abdominal pain, headache, dizziness, pain, fatigue, coughing, hypertension, chest pain, nausea, weight decreased, and vomiting. Overdoses of this drug by accident of therapy because of adverse events was reported in 2.8% of 1,450 patients treated with MICARDIS tablets and 8.1% of 360 placebo patients in placebo-controlled clinical trials.

The incidence of adverse events was not dose-related and did not correlate with gender, age, or race of patients.

The incidence of cough occurring with telmisartan in 6 placebo-controlled trials was identical to that noted for placebo-treated patients (1.6%). In addition to those listed above, adverse events that occurred in more than 2% of patients treated with MICARDIS tablets in controlled or open trials are listed below. It cannot be determined whether these events were causally related to MICARDIS tablets:

Autoimmune: Nervous System: impotence, increased sweating, flushing.

Body as a Whole: allergy, fever, leg pain, malaise.

Cardiovascular: palpitation, dyspnea, edema, left ventricle hypertrophy, paroxysmal atrial fibrillation, ventricular tachycardia, palpitations, syncope, tachycardia, abnormal QRS complex, conduction disturbance, palpitation, ventricular fibrillation.

Digestive: anorexia, flatulence, constipation, gastritis, vomiting, panhypogastria.

Endocrine: hyperglycemia, increased prolactin, hypoglycemia, impotence, increased sweating, flushing.

Gastrointestinal: abdominal pain, anorexia, anorexia nect area, dyspepsia, diarrhea, eructation, flatulence, gastritis, hunger, increased appetite, nausea, vomiting.

Genitourinary: abnormal ejaculation, breast enlargement, hematuria, impotence, increased sweating, flushing.

Musculoskeletal: arthralgia, arthritis, leg cramps, myalgia, tendinitis, tenosynovitis, torticollis.

Psychiatric: anxiety, depression, nervousness; Resistance Mechanism: infection, fungal infection, abscess, otitis media; Respiratory: asthma, bronchitis, dyspnea, dyspnea on exertion, skin, dermographia, rash, eczema, pruritus; Urinary: microlithiasis, frequency, cystitis; Vascular: cerebrovascular disorder; and Special Senses: abnormal vision, conjunctivitis, tinnitus, earache.

During initial clinical studies, a single case of angioedema was reported among a total of 3,718 patients treated.

Clinical Laboratory Findings

In placebo-controlled clinical trials, clinically relevant changes in standard laboratory test parameters were rarely associated with administration of MICARDIS tablets.

Hemoglobin: A greater than 2 g/dl decrease in hemoglobin was observed in 0.9% telmisartan patients compared with 0.3% placebo patients. No patients discontinued therapy due to anemia.

Creatinine: greater than 0.5 mg/dl increase in serum creatinine was noted in 4.9% telmisartan patients compared with 0.3% placebo patients. One telmisartan treated patient discontinued therapy due to increases in creatinine and blood urea nitrogen.

Liver Enzymes: Occasional elevations of liver enzymes occurred in patients treated with telmisartan. Marked elevations of ALT at a higher frequency with placebo. No telmisartan-treated patients discontinued therapy due to abnormalities of hepatic function.

Cardiovascular Risk Reduction

Because common adverse reactions were well characterized in studies of telmisartan, the common and serious adverse events were recorded in subsequent studies of telmisartan for cardiovascular risk reduction. In TRANSCEND (N=5026), 4 years and 8 months of follow-up), discontinuations for adverse events were 8.4% on telmisartan and 7.6% on placebo. The only serious adverse events that occurred at a difference of at least 1% more common on telmisartan were intermittent claudication (7% vs 6%) and skin ulcer (3% vs 2%).

Postmarketing Experience

The following adverse reactions have been identified during post-approval use of MICARDIS. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate either their frequency or establish a causal relationship to drug exposure.

Effects of ARVs

Confusion, depression, and anorexia have been reported in patients treated with ARVs. When anti-HIV drugs may be causing a patient’s mood disorder, consider subtracting a drug from the regimen, Dr. Robert B. Daroff Jr. advised.

The kind of psychotherapy the patient receives seems to be less important than the quality of the relationship between the therapist and the patient, “which suggests that there is great power in the relationship you build with your patients,” he added.

Disclosures: Dr. Daroff said that he had no relevant conflicts of interest.

Psychiatric Side Effects of ARVs

Didanosine: Nervousness, anxiety, confusion, insomnia.

Lamivudine: Insomnia, mania.

Stavudine: Confusion, depression, anxiety, mania, insomnia.

Zidovudine (AZT): Mania, depression, anxiety, insomnia, confusion, agitation.

Raltegravir: May worsen preexisting depression.

Efavirenz: Stepped-up dosing reduces neurocognitive side effects seen in clinical trials.

Source: Dr. Daroff.

In addition to potential patients determining the severity of their symptoms based on Centers for Disease Control and Prevention guidelines, the program provides tools that physicians can use to monitor those symptoms.

For more information about the program, visit www.AMAfluhelp.org.

Online Program for Flu Assessment

The American Medical Association has begun offering a Web-based flu-assessment program.

In addition to helping patients determine the severity of their symptoms based on Centers for Disease Control and Prevention guidelines, the program provides tools that physicians can use to monitor those symptoms.