SFDA SAFTEY COMMUNICATION

Nov 10th , 2012

Saudi Food and Drug Authority (SFDA) PRESS RELEASE- Use of Gilenya® and Cardiovascular Adverse Events after the First Dose

The Saudi Food and Drug Authority (SFDA) would like to inform health care professionals that the SFDA has evaluated the recent safety issue concerning the risk of death and cardiovascular event that were reported after the first dose of multiple sclerosis drug Gilenya® (fingolimod).

Gilenya® is an oral medication for the treatment of relapsing forms of multiple sclerosis (MS) in adults.

The evaluation was included a reported case of patient with multiple sclerosis who died within 24 hours after receiving the first dose of Gilenya®, clinical studies and several cases of bradycardia and atrioventicular block that have been reported after the 1st dose of Gilenya®.

As a result, there was an increase in the cardiovascular events reporting rate in patients who receive the 1st dose of Gilenya®. In addition, two clinical studies showed an increase in the incidence of bradycardia after the 1st dose of Gilenya® administration and in both studies the incidence of bradycardia was higher for patients receiving higher doses of Gilenya®.

Considerations that should be taken by health care professionals:

1. The use of Gilenya® should be contraindicated in patients with :
    a. Recent (within the last 6 months) occurrence of: myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
    b. History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker
    c. Baseline QTc interval ≥500 ms
    d. Treatment with Class Ia or Class III anti-arrhythmic drugs

2. First dose monitoring should include the followings :
    a. Observe all patients for signs and symptoms of bradycardia for at least 6 hours after first dose with hourly pulse and blood pressure measurement. Obtain Electrocardiogram (ECG) prior to dosing and at the end of the observation period.
    b. Patients who develop a heart rate <45 bpm, or a new onset 2nd degree or higher atrioventricular block should be monitored until resolution of the finding. Patients at lowest post-dose heart rate at the end of the observation period should be monitored until heart rate increases.
    c. In patients experiencing symptomatic bradycardia, begin continuous ECG monitoring until the symptoms have resolved; if pharmacological intervention is required to treat bradycardia, continuous ECG monitoring should continue overnight in a medical facility, and first-dose monitoring procedures should be repeated for the second dose.
    d. Patients at higher risk of symptomatic bradycardia or heart block because of a coexisting medical condition or certain concomitant medications should be observed overnight with continuous ECG monitoring.
    e. Patients with prolonged QTc interval at baseline or during the observation period, or taking drugs with known risk of torsades de pointes should be observed overnight with continuous ECG monitoring.

Report Adverse Drug Reactions (ADRs) to the Saudi FDA

The SFDA urges both healthcare professionals and patients to report ADRs resulted from using such a medication and other medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance and Drug Safety Center (NPC)
Saudi Food and Drug Authority-Drug sector
3292 Northern Ring Road
Al Nafal District
Riyadh 13312 – 6288
Kingdom of Saudi Arabia
Toll Free: 8002490000
Tel: 012038222 ext. 2354, 2317
Fax: 012057662
Email: NPC.Drug@sfda.gov.sa
Website: www.sfda.gov.sa/NPC