4. THE REMS WEBSITE

MULTAQ (dronedarone): REMS Information for Health Care Professionals

The Food and Drug Administration has required a Risk Evaluation and Mitigation Strategy (REMS) for MULTAQ. A REMS is a strategy to manage known or potential serious risks(s) associated with a drug product, and is required by the Food and Drug Administration to ensure that the benefits of the drug outweigh its risks.

The MULTAQ REMS program, also referred to as MAPT, is designed to inform healthcare professionals, including cardiologists, electrophysiologists, hospitals, internal medicine, family practice physicians, and hospital, clinical, and retail pharmacists about the risks with MULTAQ. Additionally, nurse practitioners and physician assistants who work in offices of the above-mentioned physicians will also be targeted.

To learn more about the serious risks of MULTAQ, CLICK HERE for full Prescribing Information, including boxed WARNING.

The goals of the MULTAQ REMS are:
- To prevent MULTAQ use in patients with:
  - Symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV heart failure
  - Permanent atrial fibrillation (AF) who will not or cannot be cardioverted into normal sinus rhythm
- To inform healthcare professionals about the serious risks of MULTAQ, including:
  - Increased risk of cardiovascular death in patients with symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV heart failure
  - Increased risk of cardiovascular death, heart failure, and stroke in patients with permanent AF
  - Signs and symptoms of liver injury and hepatic failure

Materials for Healthcare Providers:

Download the MCP Information Sheet
Download the HCFA Checklist
Download the HCP Letter - MCP & HCFA

To read the FDA Drug Safety Communication: Severe liver injury associated with the use of dronedarone (marketed as MULTAQ), please CLICK HERE.

To read the FDA Drug Safety Communication: Review update of MULTAQ (dronedarone) and increased risk of death and severe cardiovascular adverse events, please CLICK HERE.

©2011-2013 sanofi-aventis U.S. LLC
All rights reserved. LEGAL DISCLOSURE INFORMATION and PRIVACY POLICY
Questions or comments? CLICK HERE to contact us.

Reference ID: 3473044
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MARY R SOUTHWORTH
03/19/2014