

SPINE SAFETY CAUTIONARY NOTICE:

**Information for Healthcare Professionals:  
Multaq (dronedarone hydrochloride) tablets:  
Labeling Changes**

According to MedWatch, FDA notified healthcare professionals of labeling changes for Multaq (dronedarone hydrochloride) tablets. The following has been added to the labeling:

*June 2011*

## **ADVERSE REACTION**

### ***Postmarketing Experience***

- Respiratory: Postmarketing cases of interstitial lung disease including pneumonitis and pulmonary fibrosis have been reported.

*March 2011*

## **DRUG INTERACTIONS**

### ***Effects of Dronedarone on Other Drugs***

- Warfarin and losartan (CYP 2C9 substrates) (section revised)
- Losartan: No interaction was observed between dronedarone and losartan.
- Warfarin: When healthy subjects were administered dronedarone 600 mg twice daily, exposure to S-warfarin was higher than when warfarin was administered alone (1.2-fold). Exposure to R-warfarin was unchanged and there were no clinically significant increases in INR. More patients experienced clinically significant INR elevations ( $\geq 5$ ) usually within 1 week after starting dronedarone vs. placebo in patients taking oral anticoagulants in ATHENA. However, no
- excess risk of bleeding was observed in the dronedarone group. Postmarketing cases of increased INR with or without bleeding events have been reported in warfarin-treated patients initiated on dronedarone. Monitor INR after initiating dronedarone in patients taking warfarin.

*February 2011*

## **WARNINGS AND PRECAUTIONS**

### ***Patients with New or Worsening Heart Failure***

- Postmarketing cases of new onset and worsening heart failure have been reported during treatment with Multaq. Advise patients to consult a physician if they develop signs or symptoms of heart failure, such as weight gain, dependent edema, or increasing shortness of breath. If heart failure develops or worsens, consider the suspension or discontinuation of Multaq.

### ***Liver Injury***

- Hepatocellular liver injury, including acute liver failure requiring transplant, has been reported in patients treated with Multaq in the post-marketing setting. Advise patients treated with Multaq to report immediately symptoms suggesting hepatic injury (such as anorexia, nausea, vomiting, fever, malaise, fatigue, right upper quadrant pain, jaundice, dark urine, or itching). Consider obtaining periodic hepatic serum enzymes, especially during the first 6 months of treatment. It is not known whether routine periodic monitoring of serum enzymes will prevent the development of severe liver injury. ...

## **ADVERSE REACTIONS**

### ***Postmarketing Experience***

#### ***Hepatic***

- Serum hepatic enzymes and serum bilirubin increase: Hepatocellular liver injury, including acute liver failure requiring transplant, has been reported.

#### ***Cardiac***

- Postmarketing cases of new onset and worsening heart failure have been reported during treatment with Multaq.

## **PATIENT COUNSELING INFORMATION**

- Advise patients to immediately report any symptoms of potential liver injury (such as anorexia, nausea, vomiting, fever, malaise, fatigue, right upper quadrant abdominal discomfort, jaundice, dark urine or itching) to their physician.

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS website at

<http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.