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Possible risks of liver injury with dronedarone

The 2010 ESC Practice Clinical Guidelines for the management of atrial fibrillation was a complete revision of the 2006 version, with new recommendations on classification, assessment of stroke risk, and choice of antiarrhythmic therapy. Following the completion of several large-scale clinical trials, dronedarone was included in the Guideline with recommendations for its appropriate use in long-term rhythm control based on class I/level A evidence (1).

The ESC is now aware that the Food and Drug Administration (2) in the USA and European Medicines Agency (3) have each issued a drug safety notice detailing the possible risk of severe liver complications in patients taking dronedarone.

According to the EMA, the alert was based on 'two cases of serious liver injury in patients taking Multaq [dronedarone], for which a causal relationship with the medicine could not be excluded'. The Task Force for the Management of Atrial Fibrillation of the ESC is monitoring the status of dronedarone, along with all other clinical developments relevant to atrial fibrillation. This information will be incorporated in the next update of the ESC Practice Clinical Guidelines.

1. ESC Guidelines for the management of atrial fibrillation.European Heart Journal 2010; 31: 2369-2429.
http://www.escardio.org/guidelines-surveys/esc-guidelines/GuidelinesDocuments/guidelines-afib-FT.pdf

2. FDA Drug Safety Communication: Severe liver injury associated with the use of dronedarone (marketed as Multaq).
http://www.fda.gov/Drugs/DrugSafety/ucm240011.htm

3. Questions and answers on the possible risk of liver injury with Multaq (dronedarone).
http://www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/human/001043/WC500101075.pdf

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