

QSM/MC/IEA.120

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Information Exchange System**Alert No. 120****Toremifene should not be used in patients at risk of QT-prolongation or other heart problems: recommendation from the European Medicines Agency¹**

The European Medicines Agency (EMA) is advising against the use of toremifene in patients with prolonged QT intervals and other heart problems including electrolyte disturbances (particularly hypokalaemia), clinically relevant bradycardia, clinically relevant heart failure with reduced left-ventricular ejection fraction, and a history of symptomatic arrhythmia. Additionally, toremifene may not be used in patients who already have prolonged QT-intervals or together with other medicines known to prolong the QT-interval.

This recommendation is based on a review of toremifene by EMA's Committee for Medicinal Products for Human Use (CHMP). The Committee reviewed the effects of toremifene on the heart because of concerns that the medicine could cause QT prolongation. The CHMP has concluded that although the overall benefits of toremifene are greater than its risks, the use should be restricted in patients at risk of QT-prolongation or other heart problems.

Toremifene has been authorized in the European Union (EU) since 1996 and is marketed in 18 EU Member States. It is used to treat hormone-dependent metastatic breast cancer in postmenopausal women.

The EMA is advising physicians to prescribe toremifene according to this updated product information.

(Toremifene is available in Argentina, Australia, Austria, Belgium, Brazil, China, Colombia, Dominican Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Latvia, Lebanon, Lithuania, Luxembourg, Mexico, New Zealand, Peru, Puerto Rico, Republic of Korea, Russian Federation, South Africa, Switzerland, Thailand, Ukraine, United Kingdom, United States, Uruguay, Venezuela².)

References:

1. European Medicines Agency recommends new contraindication for Fareston (toremifene). EMA Press Office, 22 January 2009 (www.ema.europa.eu).
2. WHO Drug Dictionary Enhanced, 1 December 2008 (www.who-umc.org).