



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 December 2010
EMA/804365/2010
Press Office

Press release

Thelin (sitaxentan) to be withdrawn due to cases of unpredictable serious liver injury

Clinical trials are also to be stopped

The European Medicines Agency has been informed of Pfizer's decision to voluntarily withdraw Thelin from the market worldwide further to new information on two cases of fatal liver injury. Pfizer has also decided to discontinue all ongoing clinical trials.

Thelin, which contains the active substance sitaxentan, has been authorised in the European Union (EU) since 2006 for the treatment of pulmonary arterial hypertension.

Thelin has been known to be associated with liver toxicity and since its initial marketing authorisation has been contra-indicated in patients with mild to severe hepatic impairment (Child-Pugh Class A-C) and elevated aminotransferases prior to initiation of treatment.

At this stage, patients taking Thelin or participating in Thelin studies are advised not to stop treatment and to consult their treating physician to review their treatment at their next scheduled appointment.

The Agency's scientific Committee for Medicinal Products for Human Use (CHMP) will look at this issue during their plenary meeting on 13–16 December 2010 and will provide detailed advice for patients and prescribers.

Notes

1. This press release, together with all related documents, is available on the Agency's website: http://www.ema.europa.eu/ema/index.jsp?curl=/pages/news_and_events/news/2010/12/news_detail_001161.jsp&murl=menus/news_and_events/news_and_events.jsp&mid=WC0b01ac058004d5c1
2. Thelin is currently marketed in 16 EU Member States, in Australia and in Canada.
3. More information on Thelin can be found in the European Public Assessment Report available on the Agency's website.



4. More information on the work of the European Medicines Agency can be found on its website:
www.ema.europa.eu

Contact our press officers

Monika Benstetter or Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu