
## EMA confirms positive benefit-risk for antidepressant Valdoxan/Thymanax (agomelatine)

26/09/2014

Servier would like to inform healthcare professionals that the European Medicines Agency has completed a routine benefit-risk assessment of agomelatine and concluded that its benefits continue to outweigh the risks. However, the Agency has recommended that further measures should be introduced to minimise the risk of liver toxicity.

Changes in the product information will emphasise that liver function tests should be performed in patients both before starting the medicine and regularly during treatment. A patient booklet will be distributed to all patients taking agomelatine so that they are aware of main hepatic safety information and monitoring. Physicians will be provided with an update of the educational prescribers' guide.

The CHMP opinion will now be forwarded to the European Commission, which will issue a final decision.

For further information please refer to the official EMA communication.

tai suomeksi

http://www.fimea.fi/ajankohtaista/laaketurvallisuustiedotteet/laaketurvallisuustiedotteet_uutissivu/1/0/depressiolaake_valdoxan-hoidon_aikana_maksan_toimintaa_on_seurattava#sthash.7GO5gGJ1.dpuf