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Review of nicotinic acid and related substances started

The European Medicines Agency has started a review of nicotinic acid and its related substances acipimox and xantinol nicotinate used to treat lipid (fat) disorders.

The review follows new data from a large study called HPS2-THRIVE, which looked at the long-term effect of the combination of nicotinic acid and laropiprant. The new data failed to show that the combination reduces the risk of major vascular events (such as heart attack and stroke), and a higher frequency of non-fatal but serious side effects was seen in patients taking the combination. As a result, the European Medicines Agency recommended the suspension of medicines containing the combination of nicotinic acid and laropiprant across the EU.[1]

As the data from the HPS2-THRIVE study may have implications for medicines containing only nicotinic acid or related substances, the European Medicines Agency will now assess the impact of the new data on the benefit-risk balance of these medicines, and will issue an opinion on whether the marketing authorisations for these medicines should be maintained, varied, suspended or withdrawn across the EU.

More about the medicine

Medicines containing nicotinic acid or related substances have been authorised in the EU via national procedures since the mid-1950s. Nicotinic acid is a naturally occurring substance used in low doses as a vitamin (known as niacin or vitamin B3). In higher doses, it reduces the levels of fat in the blood.

Nicotinic acid was also authorised in combination with laropiprant. Laropiprant has no effect on cholesterol but it reduces flushing, which is a known side effect of nicotinic acid.

In July 2013 it was established that nicotinic acid and xantinol nicotinate are not currently marketed in the EU to treat lipid disorders (xantinol nicotinate is authorised in some EU countries for oral use as a vasodilator, a medicine that widens the blood vessels). Therefore, since acipimox is the only substance related to nicotinic acid currently marketed in the EU to treat lipid disorders, the review will only cover medicines containing acipimox.

[1] More information can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Referrals/Tredaptive, Pelzont and Trevaclyn.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7129
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

More about the procedure

The review of nicotinic acid and its related substances acipimox and xantinol nicotinate has been initiated at the request of the Danish Health and Medicines Authority, under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. As medicines containing only nicotinic acid or related substances are all authorised nationally, the PRAC recommendation will be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position. The CMDh is a regulatory body that represents national medicines regulatory authorities of the EU Member States.