20 April 2011
EMA/322628/2011
Press Office

Press release

NicOx S.A. withdraws its marketing authorisation application for Beprana (naproxcinod)

The European Medicines Agency has been formally notified by NicOx S.A. of its decision to withdraw its application for a centralised marketing authorisation for the medicine Beprana (naproxcinod), 375 mg hard capsules.

Beprana was intended to be used for the relief of the signs and symptoms of osteoarthritis of the knee and hip in adults.

The application for the marketing authorisation for Beprana was initially submitted to the Agency on 21 December 2009. At the time of the withdrawal it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that their decision to withdraw the application was based on the fact that the CHMP considers that the data provided do not allow the it to conclude on a positive benefit-risk balance.

More information about Beprana and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company will be published on the Agency's website after the next CHMP meeting on 16–19 May 2011.

Notes

1. This press release is available on the Agency's website.
2. The CHMP Assessment Report will be published on the Agency's website at later stage.
3. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
4. The company informed the CHMP that withdrawal does not have any consequences on any ongoing clinical trials or compassionate use program.

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

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