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Press Office

Press release

Merck Sharp & Dohme (Europe), Inc. withdraws its marketing authorisation application for Janacti (sitagliptin and pioglitazone) and related trade names

The European Medicines Agency has been formally notified by Merck Sharp & Dohme (Europe), Inc. of its decision to withdraw its application for a centralised marketing authorisation for the medicine Janacti (sitagliptin and pioglitazone) and related trade names, 100/30 mg and 100/45 mg fixed-dose combination tablets.

Janacti was intended to be used for the treatment of adult patients with type II diabetes mellitus.

The application for the marketing authorisation for Janacti was initially submitted to the Agency on 31 May 2011. At the time of the withdrawal it was under evaluation by the Committee for Medicinal Products for Human Use.

In its official letter, the company stated that they are basing their decision to withdraw the application on a review of the regulatory and commercial prospects for the fixed-dose combination product. There are currently no ongoing clinical trials with Janacti.

More information about Janacti and the stage of the scientific assessment procedure 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 14-17 November 2011.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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