



European Medicines Agency
Press office

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PRESS RELEASE

Idea AG withdraws its marketing authorisation application for Diractin (ketoprofen)

The European Medicines Agency (EMA) has been formally notified by Idea AG of its decision to withdraw its application for a centralised marketing authorisation for the medicine Diractin (ketoprofen) 22.9 mg gel. Diractin was expected to be used for the symptomatic treatment of inflammation and pain in osteoarthritis.

The application for the marketing authorisation for Diractin was submitted to the EMA on 23 May 2007. 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 the withdrawal of the application was based on the grounds that the efficacy of the medicine at the proposed dose has not been sufficiently demonstrated and that this concern has been identified as a major clinical issue.

More information about Diractin 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 EMA website in due course.

-- ENDS --

Notes:

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. This press release, together with other information on the work of the EMA, can be found on the EMA website: www.ema.europa.eu

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