



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 July 2016
EMA/498114/2016

Public statement

Krystexxa

Withdrawal of the marketing authorisation in the European Union

On 30 June 2016 the European Commission withdrew the marketing authorisation for Krystexxa (pegloticase) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Crealta Pharmaceuticals Ireland Limited, which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Krystexxa was granted marketing authorisation in the EU on 8 January 2013 for treatment of chronic gout. The marketing authorisation was initially valid for a 5-year period.

The European Public Assessment Report (EPAR) for Krystexxa will be updated accordingly to indicate that the marketing authorisation is no longer valid.

