18 May 2018
EMA/286850/2018

EMA review of Zinbryta confirms medicine's risks outweigh its benefits

Multiple sclerosis medicine no longer authorised and has been recalled from hospitals and pharmacies

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has confirmed that the multiple sclerosis medicine Zinbryta (daclizumab beta) poses a risk of serious and potentially fatal immune reactions affecting the brain, liver and other organs.

Patients could be at risk from the start of treatment and for several months after stopping treatment, and it is not possible to predict which patients will be affected. The PRAC therefore confirmed its previous conclusions that risks of Zinbryta outweigh its benefits for patients with multiple sclerosis.

Healthcare professionals should continue monitoring patients who have been treated with Zinbryta in line with recommendations issued in March 2018.

There are no immediate consequences of the PRAC's review as Zinbryta is no longer authorised in the EU. On 27 March 2018, the marketing authorisation was withdrawn at the request of Biogen Idec Ltd, the company that marketed the medicine. Zinbryta is no longer available in hospitals and pharmacies in the EU.

A full assessment report on the review will be published shortly.

More about the medicine

Zinbryta is a medicine that was authorised in 2016 for treating relapsing forms of multiple sclerosis. To date over 10,000 patients have been treated with Zinbryta worldwide. The majority of EU patients have been treated in Germany.

More about the procedure

The review of Zinbryta was initiated following a request from the European Commission on 26 February 2018, under Article 20 of Regulation (EC) No 726/2004.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

On 6 March 2018, while the review was ongoing, EMA's Pharmacovigilance Risk Assessment Committee (PRAC) recommended suspension of the marketing authorisation of Zinbryta and a recall of the product. The European Commission issued a legally binding decision to suspend the marketing authorisation on 8 March 2018.

On 27 March 2018, the European Commission withdrew the marketing authorisation of the medicine at the request of the marketing authorisation holder Biogen Idec Ltd.

The PRAC has now concluded its review of the available evidence on Zinbryta. The PRAC report will be sent to EMA's Committee for Medicinal Products for Human Use (CHMP).

As the medicine is no longer authorised in the EU no further action will be taken by the European Commission.