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EMA reviews multiple sclerosis medicine Zinbryta

Review follows case of fulminant liver failure

The European Medicines Agency (EMA) has started a review of the medicine Zinbryta (daclizumab) used to treat adults with relapsing forms of multiple sclerosis (a disease in which inflammation damages the protective sheath around the nerve cells in the brain and spinal cord). The review follows the death from fulminant liver failure of a patient who was treated with Zinbryta in an ongoing observational study, as well as four cases of serious liver injury.

The risk of liver damage with Zinbryta was already known at time of its approval in July 2016, and several measures had been taken to manage this risk, including providing educational materials for healthcare professionals and for patients on how to prevent or reduce liver damage.

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) will now evaluate all available data and determine whether there are any implications for the use of the product and if there is a need to introduce any new measures to minimise this risk.

While the review is ongoing, healthcare professionals using Zinbryta should closely monitor their patients and discuss with them the risk of liver damage and possible symptoms. Patients should contact their doctor promptly should they develop any symptoms of liver problems, such as unexplained nausea, vomiting, abdominal pain, tiredness, loss of appetite, yellowing of the skin and eyes, and dark urine.

More about the medicine

Zinbryta is a medicine used to treat adults with relapsing forms of multiple sclerosis. Multiple sclerosis is a disease in which inflammation damages the protective sheath around the nerve cells in the brain and spinal cord. Relapsing means that the patient has flare-ups of the symptoms.

Zinbryta is available as a solution for injection in pre-filled pens and syringes. It is injected under the skin once a month.

Zinbryta contains the active substance daclizumab and was authorised in the EU in July 2016. More information can be found here.

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More about the procedure

The review of Zinbryta has been initiated at the request of the European Commission, under Article 20 of Regulation (EC) No 726/2004.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. The PRAC recommendations will then be forwarded to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion.

The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.