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EMA recommends immediate suspension and recall of multiple sclerosis medicine Zinbryta

Evidence indicates risk of serious inflammatory brain disorders

The European Medicines Agency (EMA) has recommended the immediate suspension and recall of the multiple sclerosis medicine Zinbryta (daclizumab beta) following 12 reports of serious inflammatory brain disorders worldwide, including encephalitis and meningoencephalitis. Three of the cases were fatal.

A preliminary review of the available evidence indicates that immune reactions observed in the reported cases may be linked to the use of Zinbryta. Zinbryta may also be linked to severe immune reactions affecting several other organs.

To protect patients' health, EMA is recommending the immediate suspension of the medicine's marketing authorisation in the EU and a recall of batches from pharmacies and hospitals.

No new patients should start treatment with Zinbryta. Healthcare professionals should immediately contact patients currently being treated with Zinbryta and should stop their treatment and consider alternatives. Patients stopping treatment must be followed up for at least 6 months (see more details below).

EMA's recommendation to suspend Zinbryta and recall the product is being sent to the European Commission for a legally binding decision.

The company that markets Zinbryta (Biogen Idec Ltd) has already voluntarily requested a withdrawal of the medicine's marketing authorisation and informed EMA of its intention to stop clinical studies.

Information for patients

- If you are being treated with Zinbryta, contact your doctor to discuss your treatment**.**
- Do not take another injection of Zinbryta.
- Tell your doctor immediately if you have or experience symptoms such as persistent high temperature, severe headache, nausea (feeling sick), tiredness, yellowing of the skin or eyes and vomiting. These could be signs of a reaction to Zinbryta.
- Your doctor will carry out regular blood tests for up to 6 months after stopping treatment to check for side effects.

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- If you are in a clinical study with Zinbryta, contact the doctor treating you in the study.

Information for healthcare professionals

- Do not start any new patients on Zinbryta.
- Contact your patients currently being treated with Zinbryta as soon as possible and stop their treatment. Consider alternative treatments as appropriate.
- Patients stopping treatment should be monitored at least monthly and more frequently as clinically indicated for up to 6 months after the last dose of Zinbryta.
- Advise patients to immediately report symptoms of liver injury such as prolonged fever, severe headache, tiredness, jaundice, nausea or vomiting. These reactions can occur for 6 months after treatment has been stopped.
- A recall of Zinbryta will take place from pharmacies and hospitals across the EU.

To date EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has reviewed 12 cases of immune-mediated inflammatory disorders, including encephalitis. Most cases occurred within 8 months of starting treatment.

A previous PRAC review in 2017 found that unpredictable and potentially fatal immune-mediated liver injury can occur with Zinbryta for up to 6 months after stopping treatment and concluded that patients stopping treatment should be followed up.

Available evidence also indicates that Zinbryta could be linked to other immune-mediated disorders, such as blood dyscrasias, thyroiditis or glomerulonephritis.

EMA will complete its in-depth review and make public the final outcome.

More about the medicine

Zinbryta was authorised in 2016 for treating relapsing forms of multiple sclerosis. Following a 2017 review of the medicine's effects on the liver, the use of the medicine was restricted to patients who have tried at least two other disease-modifying treatments and cannot be treated with any other multiple sclerosis treatments.

To date over 8,000 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.

The initial 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's recommendation to suspend Zinbryta and recall the product is being sent to the European Commission for a legally binding decision.

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