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EMA starts review of anxiety medicine Stresam (etifoxine)

EMA has started a review of Stresam (etifoxine), a medicine authorised in some EU countries for the treatment of anxiety disorders.

EMA's review follows the findings of a new study (AMETIS) on the effectiveness of Stresam in treating adjustment disorders (difficulty coping with a stressful event) with anxiety. The results of the study suggest that Stresam had similar effects to placebo (a dummy treatment).

In addition, an analysis of the available safety data for Stresam, including data from the AMETIS study and that collected through safety monitoring, found that some rare but serious side effects were still occurring, despite measures taken in 2014 to minimise their risk. They include serious skin reactions, liver damage, uterine bleeding between menstrual periods (mainly in women using oral contraceptives), and inflammation of the gut (lymphocytic colitis).

As a result, the French medicines agency requested a review of the benefits of Stresam in the context of the medicine's risks. EMA will now assess the available data and recommend whether the marketing authorisations for this product should be maintained, varied, suspended or revoked.

More about the medicine

Stresam is authorised in France, Malta, Bulgaria and Romania for the treatment of anxiety disorders. The medicine contains the active substance etifoxine. The exact way etifoxine works is not fully understood, but it is known to attach to the same targets (receptors) on nerve cells as GABA (gamma-amino butyric acid). GABA is a neurotransmitter (a chemical that nerve cells use to communicate) that blocks certain brain signals. Etifoxine mimics the effect of GABA both directly and indirectly, leading to a calming effect that helps to control the symptoms associated with anxiety.

Stresam is available as capsules that are taken daily for a few days up to a number of weeks.

In 2014, the French medicines agency put in place risk minimisation measures (update to the product information and letter to healthcare professionals) to mitigate the risk of certain side effects identified at that time. The company was also asked to perform additional studies, including the AMETIS study.

More about the procedure

The review of Stresam has been initiated at the request of France, under Article 31 of Directive 2001/83/EC.

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The review is being carried out by 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 CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.