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EMA reviewing risk of dosing errors with methotrexate

Review prompted by continued reports of overdose

The European Medicines Agency (EMA) has started a review of the risk of dosing errors with methotrexate medicines.

When used for inflammatory diseases, such as arthritis and psoriasis, methotrexate is taken once a week whereas for some types of cancer, the dose is higher and the medicine is used more frequently. Mistakes have led to some patients incorrectly receiving a dose every day instead of every week. As a result, patients have received too much of the medicine, with serious consequences in some cases.

The risk of dosing errors with methotrexate has been recognised for many years and several measures are already in place in some EU countries to reduce this risk, including the use of visual reminders on the medicine packs. However, a recent assessment[1] found that serious adverse events related to overdose, including fatalities, are still occurring. The Spanish medicines regulator, AEMPS, therefore asked EMA to further investigate the reasons why dosing errors continue to occur in order to identify measures to prevent them.

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) will now examine the available evidence and recommend whether further measures are needed to minimise the risk of dosing errors. The PRAC will also take into account the work of bodies specialising in patient safety.

More about the medicine

Methotrexate medicines are used to treat cancers such as acute lymphoblastic leukaemia (ALL) and various inflammatory conditions, including rheumatoid arthritis, juvenile idiopathic arthritis, psoriasis, and psoriatic arthritis.

Methotrexate can be taken orally or given by injection.

Most methotrexate medicines have been authorised via national procedures. They are marketed in all EU countries under several brand names including: Ledertrexate, Maxtrex, Metex and Metoject.

[1] This was in the context of a routine benefit-risk assessment, known as a periodic safety update report (PSUR) assessment.

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Jylamvo (for use by mouth) and Nordimet (for injection) are the only centrally authorised medicines containing methotrexate.

More about the procedure

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

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 an 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.