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EMA to review modified-release paracetamol

Measures to minimise risk and reduce harm of overdose to be considered

The European Medicines Agency is to review the benefits and risks of paracetamol modified- and prolonged-release tablets, which are available in several EU Member States and are designed to release paracetamol over a prolonged period of time. They are different from the usual immediate-release tablets of paracetamol (which release their active substance more quickly and are not included in this review).

The standard procedures for assessing and managing overdose and poisoning with paracetamol are designed for the immediate-release products. In recent years there have been a number of cases of overdose with certain modified-release paracetamol tablets which indicate that the standard procedures may not be entirely suited to treat overdoses with the latter products.

The review will be carried out by EMA's Pharmacovigilance Risk Assessment Committee (PRAC), following a request from the Swedish medicines regulator, the Medical Products Agency. The PRAC will evaluate available evidence to determine the risk of overdose with modified- and prolonged-release paracetamol, and whether any additional measures need to be taken. In the meantime, patients who have any concerns about their medication should discuss them with their healthcare professional.

More about the medicine

Paracetamol is a medicine that has been used for many years to relieve pain and fever in adults and children. Paracetamol-containing immediate release products have been authorised by national procedures in all EU Member States.

Products intended to have a longer action and containing paracetamol for modified- release are available in several EU Member States, as Alvedon 665 mg and associated names, and other modified- and prolonged-release paracetamol products are also available in some Member States. Some modified-release medicines contain paracetamol with other painkillers and these medicines are also covered by this review.

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More about the procedure

The review of modified-release paracetamol has been initiated at the request of Sweden, under Article 31 of Directive 2001/83/EC.

The review will be 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 sent to Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a position. The CMDh is a body representing EU Member States as well as Iceland, Liechtenstein and Norway. It is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.

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