11 April 2014
EMA/209409/2014

Start of review of codeine-containing medicines when used for cough and cold in children

The European Medicines Agency has started a review of codeine-containing medicines when used for cough and cold in children (aged below 18 years). This follows a previous review[1] of these medicines when used for pain relief in children, which was triggered by concerns over the risk of morphine toxicity.

Codeine is converted into morphine in the body by an enzyme called CYP2D6. It is well-known that some patients who are 'CYP2D6 ultra-rapid metabolisers' convert codeine to morphine at a faster than normal rate, resulting in higher than normal levels of morphine in their blood. High levels of morphine can lead to toxic effects such as breathing difficulties.

Following the previous review, several measures were introduced in order to minimise the risk of morphine toxicity when using codeine for pain relief. These included a recommendation that children with conditions associated with breathing problems should not use codeine. As the reasons for this recommendation may also apply to the use of codeine for cough and cold in children, the German medicines agency (BfArM) has now requested an EU-wide review of such use.

The European Medicines Agency will now evaluate the available evidence on the benefit-risk balance of codeine-containing medicines when these medicines are used for cough and cold in children.

While the review is ongoing patients or their carers should speak to their doctor or pharmacist if they have any questions or concerns.

More about the medicine

Codeine is an opioid medicine widely used for pain relief and for the treatment of coughs and colds in adults and children. In the EU, codeine-containing medicines have been approved via national

[1] Restrictions on use of codeine for pain relief in children – CMDh endorses PRAC recommendation: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Codeine-containing_medicines/human_referral_prac_000008.jsp&mid=WC0b01ac05805c516f

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procedures, and are available either on prescription or over the counter in the different Member States. Codeine is marketed as a single-ingredient medicine or in combination with other substances.

More about the procedure

The review of codeine when used for cough and cold in children has been initiated at the request of Germany, 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. As codeine-containing medicines are all authorised nationally, the PRAC recommendation will be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position. The CMDh, a body representing EU Member States, is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.

A previous review was carried out in 2012-2013 by the PRAC, to evaluate the risk of toxicity with codeine-containing medicines when used for pain relief in children. This led to the existing warnings and contraindications being included in the prescribing information for these medicines.