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PRAC recommends restrictions on the use of codeine for cough and cold in children

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has recommended restrictions on the use of codeine-containing medicines for cough and cold in children because of the risk of serious side effects with these medicines, including the risk of breathing problems.

The PRAC recommended specifically that:

- Codeine should be contraindicated in children below 12 years. This means it must not be used in this patient group.
- Use of codeine for cough and cold is not recommended in children and adolescents between 12 and 18 years who have problems with breathing.
- All liquid codeine medicines should be available in child-resistant containers to avoid accidental ingestion.

The effects of codeine are due to its conversion into morphine in the body. Some people convert codeine to morphine at a faster rate than normal, resulting in high levels of morphine in their blood. High levels of morphine can lead to serious effects, such as breathing difficulties.

The PRAC considered that, although morphine-induced side effects may occur in patients of all ages, the way codeine is converted into morphine in children below 12 years is variable and unpredictable, making this population at special risk of such side effects. In addition, children who already have problems with their breathing may be more susceptible to respiratory problems due to codeine. The PRAC also noted that cough and cold are generally self-limiting conditions and the evidence that codeine is effective at treating cough is limited in children.

The PRAC further recommended that codeine must not be used in people of any age who are known to convert codeine into morphine at a faster rate than normal ('ultra-rapid metabolisers') nor in breastfeeding mothers, because codeine can pass to the baby through breast milk.

During its review, the PRAC consulted EMA's Paediatric Committee as well as healthcare professionals' organisations. The review was triggered by a previous review of codeine for pain relief in children, which resulted in several restrictions being introduced in order to ensure that only children for whom the benefits are greater than the risks are given the medicine for pain relief. As the reasons for these restrictions could also apply to the use of codeine for cough and cold in children, an EU-wide review of

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such use was initiated. The restrictions the PRAC has now recommended for codeine for cough and cold are largely in line with the previous recommendations for codeine when used for pain relief.

The PRAC recommendations will now be sent the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position and provide guidance to patients and healthcare professionals. In the meantime, 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 that is converted into morphine in the body. It is widely used for pain relief and for the treatment of the symptoms of coughs and colds. In the EU, codeine-containing medicines have been approved via national 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 active substances.

More about the procedure

The review of codeine when used for cough and cold in children was initiated in April 2014 at the request of the German medicines agency (BfArM), under Article 31 of Directive 2001/83/EC.

The review has been carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), EMA's Committee responsible for the evaluation of safety issues for human medicines, which has made a set of recommendations. As codeine-containing medicines are all authorised nationally, the PRAC recommendation will now be forwarded to the 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 warnings and contraindications being included in the prescribing information for these medicines.

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