

Codeine not to be used in children below 12 years for cough and cold

The CMDh has agreed by consensus new measures to minimize the risk of serious side effects, including breathing problems, with codeine-containing medicines when used for cough and cold in children. As a result of these new measures:

- Use of codeine for cough and cold is now 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 breathing problems.

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, even death.

The new measures follow a review by EMA's Pharmacovigilance Risk Assessment Committee (PRAC). 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 more 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 in children is limited.

In addition to the new measures for children, codeine must also 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, as codeine can harm the baby because it passes into breast milk.

Information for healthcare professionals

- Codeine for cough and cold is now contraindicated in children below 12 years,
- Codeine not recommended in children between 12 and 18 years with compromised respiratory function.
- Codeine is also contraindicated in women during breastfeeding and patients known to be CYP2D6 ultra-rapid metabolisers.

These new measures follow a review of available safety and efficacy data on codeine when used for cough and cold, including data from clinical studies, observational studies and meta-analyses, post-marketing data in Europe and other published literature on the use of codeine in children.