

EMA recommends restrictions on the use of codeine for cough & cold in children

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Information on codeine containing products for cough

Codeine is an opioid medicine widely used for pain relief and for the treatment of coughs and colds in adults and children.

In Malta the following products containing codeine are authorised for the treatment of dry cough and colds some of which are licensed for use in children under 12.

Active Ingredients	Product Name	Dose	Pharmaceutical Form	Classification	Authorisation Number	Licensed for use in children under 12
Codeine Phosphate	Codeine Linctus BP	15mg/5ml	Oral solution	POM	MA213/00301	no
Caffeine Codeine Phosphate Diphenhydramine Hydrochloride Paracetamol Phenylephrine Hydrochloride	Uniflu with Vitamin C Tablets	30 mg 10 mg 15 mg 500 mg 10 mg	Tablet	OTC	MA200/00501	no
Codeine Phosphate	Codinex	15mg/5ml	Oral Solution	POM	AA995/00201	yes
Dihydrocodeine bitartrate	Tosidrin	0.01 g/ml	Oral drops solution	POM	AA774/00201	yes
Phenyltoloxamine Codeine	Codipront	66 mg /200 mg per 90ml	Syrup	POM	AA937/00102	yes
Codeine Phosphate	Codeine Phosphate	30mg	Tablet	POM	AA841/00701	no
Phenyltoloxamine Codeine	Codipront	10mg 30mg	Capsule	POM	AA937/00101	no

Information from the European Medicines Agency about the safety concern

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 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.

In Malta

Healthcare professionals

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 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 PRAC recommendation will now be forwarded to the CMDh, which will adopt a final position.

For more information please visit www.ema.europa.eu

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on codeine containing medicines. Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form or online at <http://www.medicinesauthority.gov.mt/adrportal> or to the marketing authorisation holder or their local representatives.

Prof. John J Borg PhD (Bristol)
Post-licensing Director

Healthcare professionals and patients are encouraged to regularly check the Medicine Authority website for product safety updates as these are issued on an ongoing basis.