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Press Office

Press release

European Medicines Agency recommends contraindications for suppositories containing terpenic derivatives

Terpenic-based anti-cough medicines no longer recommended for use in children under 30 months, children with a history of febrile convulsion or epilepsy and children with a recent history of anorectal lesion

The European Medicines Agency has recommended updating the product information for suppositories containing terpenic derivatives with new contraindications following the finalisation of a review of their use in children under 30 months by the Agency's Committee for Medicinal Products for Human Use (CHMP).

The Committee concluded that there was a risk of these medicines inducing neurological disorders, especially convulsions, in infants and small children and recommended that their use should be contraindicated in children under 30 months and in children with a history of epilepsy or febrile convulsion. It also concluded that there was a risk of these medicines causing local anorectal lesions (precancerous growths in the anus or rectum) and recommended their use should be contraindicated in children with a recent history of anorectal lesion.

Suppositories containing terpenic derivatives (including camphor, cineole, niaouli, wild thyme, terpineol, terpine, citral, menthol and essential oils of pine needle, eucalyptus and turpentine) are typically indicated for supportive treatment for mild acute bronchial disorders, particularly productive and non-productive cough.

The review procedure was initiated after the French medicines agency expressed concerns about the safety of suppositories containing terpenic derivatives, particularly the risk of serious neurological side effects such as convulsions in young children.

The Committee reviewed all available data including the benefit-risk assessment carried out by France, and information requested from the companies that market suppositories containing terpenic derivatives in the European Union. This included study data supporting the marketing authorisations

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and safety data including reports of side effects from post-marketing surveillance and the published literature.

The Committee's opinion has now been forwarded to the European Commission for the adoption of a decision.

Notes

1. This press release, along with all related documents, is available on the Agency's website.
2. The review procedure was initiated by France under Article 31 of Directive 2001/83/EC, as amended, following a national review in France of potential neurological risks, mainly convulsions in children. An Article 31 referral may be initiated in specific cases where the interest of the Community is involved. The expression 'Community interest' has a broad meaning but it refers particularly to the interests of the public health in the European Union, for example following concerns related to the quality, efficacy and/or safety of a medicinal product or new pharmacovigilance information.
3. In the EU suppositories containing terpenic derivatives are authorised by national procedures and are available without prescription. They are currently marketed in Belgium, France, Luxembourg, Finland, Italy, Portugal and Spain under various trade names.
4. All other opinions and documents adopted by the CHMP at their September 2011 plenary meeting will be published on Friday, 23 September 2011 at 12.00 noon UK time on a dedicated web page.
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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