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PRESS RELEASE

European Medicines Agency recommends suspension of marketing authorisations for carisoprodol-containing medicinal products

The European Medicines Agency (EMA) has recommended the suspension of marketing authorisations for all medicinal products containing carisoprodol. Carisoprodol products are available in 12 Member States under prescription, mainly for the treatment of acute lower back pain.

Finalising its review, the Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the risks of these medicines are greater than their benefits, and recommended the suspension of marketing authorisations in those Member States where the product is approved.

The review of carisoprodol-containing medicinal products was initiated in September 2007 following plans made for its withdrawal from the Norwegian market (scheduled to take effect as of May 2008), due to new information relating to an increased risk of abuse or addiction as well as intoxication and events related to psychomotor impairment. The CHMP reviewed the safety of these medicines to assess whether the regulatory actions taken by Norway should be implemented throughout the EU countries.

Following the assessment of the available information on the safety of carisoprodol-containing medicinal products, the CHMP concluded that there is evidence for carisoprodol-associated risk of abuse and addiction, intoxication and psychomotor impairment. In the light of these findings the CHMP considered that the risks of these medicines outweigh their benefits. The CHMP therefore recommended the suspension of the marketing authorisations of all carisoprodol-containing medicinal products.

Due to the risk of withdrawal symptoms, patients should not stop carisoprodol treatment before seeking advice from their doctor on other therapeutic options. Any switch to new medication should be made gradually and under medical supervision.

The CHMP opinion will now be sent to the European Commission for the adoption of a decision, applicable in all EU countries.

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Notes:

1. More information about the review is available in a separate [question-and-answer-document](#).
2. Carisoprodol-containing medicinal products are available in Europe in the Czech Republic, Denmark, Finland, Greece, Hungary, Iceland, Italy, Norway, the Slovak Republic, Spain, Sweden and the United Kingdom.
3. Carisoprodol-containing medicinal products include Somadril, Somadril comp, Carisoma, Soma Complex, Scutamil C, Relacton-C, Mio Relax and Relaxibys.
4. The review of carisoprodol was conducted under Article 107 of the Community code relating to medicinal products for human use (Directive 2001/83/EC). This type of procedure is initiated in cases where a Member State withdraws, suspends or changes the marketing authorisation of a nationally authorised medicine as a result of the evaluation of safety data. It provides for a harmonised European approach because the CHMP is asked to prepare an opinion on whether or not the regulatory actions should be implemented throughout the European Union.

5. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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