



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Benefits of medicines containing combination of methocarbamol and paracetamol continue to outweigh risks

On 26 March 2020, EMA concluded that the benefits of medicines containing methocarbamol and paracetamol continue to outweigh their risks in the short-term treatment of painful muscle spasms.

EMA's review was started because recent publications^{1,2} had raised questions about the effectiveness of the combination of these substances at treating conditions such as low back pain in the doses at which they are present in these medicines.

EMA's human medicines committee (CHMP) considered all available data on medicines containing methocarbamol 380 mg and paracetamol 300 mg and concluded that the available evidence was not enough to question their effectiveness in the treatment of painful muscle spasms.

In addition, the Committee considered that the safety profile of each substance contained in these medicines is well known, and no new significant safety concerns were identified for the fixed dose combination. However, a few cases of dry mouth and diarrhoea have been reported and may be caused by methocarbamol. The Committee therefore recommended including these as side effects in the product information.

Information for patients

- You can continue using medicines containing 380 mg of methocarbamol and 300 mg of paracetamol to relieve painful muscle spasms such as spasms in the lower back.
- As for all medicines, the recommended dose and duration of treatment mentioned in the package leaflet should be followed.
- If you have any questions you should talk to your doctor or pharmacist.

Information for healthcare professionals

- EMA's CHMP considered all available data on the fixed dose combination medicine from clinical trials, scientific literature and post marketing reports. The Committee concluded that the data

¹ Saragiotto BT, Machado GC, Ferreira ML, Pinheiro MB, Abdel Shaheed C, Maher CG. Paracetamol for low back pain. Cochrane Database Syst Rev. 2016 Jun 7;(6):CD012230.

² Emrich OM, Milachowski KA, Strohmeier M. Methocarbamol in acute low back pain. A randomized double-blind controlled study. MMW Fortschr Med. 2015 Jul;157 Suppl 5:9-16



available do not constitute sufficient evidence to question the efficacy of methocarbamol/paracetamol 380 mg/300 mg in the short-term, symptomatic treatment of painful muscle spasms associated with acute musculoskeletal disorders.

- In addition, no new significant information was identified on the overall safety profile of the fixed dose combination medicine. Although both active substances are metabolised in the liver, there is no evidence of a possible interaction between the 2 substances that may lead to hepatotoxicity.
- Cases of dry mouth and diarrhoea were considered at least possibly related to methocarbamol, and the CHMP recommended including them as side effects in the product information with a frequency unknown.

More about the medicine

Robaxisal compuesto is currently the only medicine authorised in the EU containing methocarbamol and paracetamol. Methocarbamol is a medicine that relieves muscle spasms, and paracetamol a painkiller. Robaxisal compuesto is available as tablets and is used to treat painful muscle spasms associated with short-term muscle disorders, such as spasms in the lower back.

Both active substances in the medicine are authorised as separate medicines in other EU countries.

More about the procedure

The review of medicines containing methocarbamol and paracetamol was initiated on 29 May 2019 at the request of Germany under [Article 31 of Directive 2001/83/EC](#).

The review was carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which has adopted the Agency's opinion. The CHMP opinion was forwarded to the European Commission, which issued a final legally binding decision applicable in all EU Member States on 9 June 2020.