29 May 2019
EMA/271110/2019

# EMA begins review of the effectiveness of medicines containing methocarbamol and paracetamol

EMA has started a review of the effectiveness of medicines containing a combination of methocarbamol and paracetamol for the treatment of painful muscle spasms. The review is being carried out at the request of the German medicines agency, BfArM, which has been asked to evaluate a marketing application for a generic medicine based on Robaxisal compuesto, a medicine authorised in Spain for painful muscle spasms associated with various short-term muscle disorders, such as low back pain.

Robaxisal compuesto, which has been authorised for many years, contains methocarbamol, a medicine that reduces muscle spasm and paracetamol, which is a painkiller. However, more recent evidence suggests that these two substances, in the doses in which they are combined in the medicine, might not be effective in the conditions such as low back pain for which it is currently used. Therefore the German agency has asked EMA to review the effectiveness of the combination.

## More about the medicine

Robaxisal compuesto is a medicine authorised in Spain since 1968. It is available as tablets containing 380 mg of methocarbamol, a medicine that relieves muscle spasms, and 300 mg of the painkiller paracetamol, and is authorised for painful muscle spasms associated with short-term muscle disorders, such as low back pain.

Both the 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 will be carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

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