1 June 2018
EMA/338589/2018

EMA begins review of medicines containing metamizole

Review of painkiller prompted by inconsistent doses and contraindications

The European Medicines Agency (EMA) has started a review of medicines containing the painkiller metamizole, which is used in a number of EU member states to treat severe pain and fever that cannot be controlled with other treatments.

The review was started at the request of the Polish medicines authority because of substantial differences between member states in the recommended maximum daily doses of the medicine and the contraindications on its use during pregnancy or in women who are breast feeding.

EMA's Committee for Medicinal Products for Human Use (CHMP) will therefore consider the available evidence and make recommendations as to whether the marketing authorisations for metamizole-containing medicines should be amended across the EU.

More about the medicine

Metamizole (also known as dipyrone) is an analgesic medicine (painkiller) that can also relieve fever and muscle spasm. It has been used for many decades in the EU by mouth, as suppositories or by injection, to treat severe pain and fever that cannot be controlled with other treatments.

Metamizole-containing medicines are available in Bulgaria, Croatia, Germany, Hungary, Italy, Lithuania, Poland, Romania, Slovenia and Spain under a variety of names including Algifen, Algifen Neo, Algi-Mabo, Algoblock, Algocalmin, Algopyrin, Algozone, Alindor, Alkagin, Alvotor, Amizolmet, Analgin, Benalgin, Benlek, Berlosin, Buscapina Compositum, Dialgin, Dolocalma, Flamborin, Freshalgin, Gardan, Generalgin, Hexalgin, Litalgin, Locamin, Metagelan, Metalgial, Metamilan, Metamistad, Metapyrin, Metarapid, Nevralgin, Nodoryl, Nolotil, Novalgin, Novalgina, Novalgine, Novaminsulfon, Novocalmin, Panalgorin, Parakofdal, Piafen, Piralgin, Proalgin, Pyralgin, Pyralgina, Quarelin, Scopolan Compositum, Spasmalgon, Spasmoblok, Tempalgin and Tempimet.

More about the procedure

The review of metamizole was initiated on 31 May 2018 at the request of Poland, under Article 31 of Directive 2001/83/EC.

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The review is being 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.