



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Review of emergency contraceptives started

The European Medicines Agency has started a review of emergency contraceptives to assess whether increased bodyweight and body mass index (BMI) reduce the efficacy of these medicines in preventing an unintended pregnancy following unprotected sexual intercourse or contraceptive failure.

Emergency contraceptives act by blocking and/or delaying ovulation. Available emergency contraceptive medicines in the European Union contain levonorgestrel or ulipristal acetate.

The European Medicines Agency will evaluate the impact of new data suggesting that a high bodyweight could impair the effectiveness of emergency contraceptives. It will assess whether any changes should be made to the product information for all emergency contraceptive medicines containing levonorgestrel or ulipristal acetate.

More about the medicines

The emergency contraceptives being reviewed include a number of medicines authorised at the national level that contain the progestogen (hormone) levonorgestrel, such as Norlevo, Levonelle/Postinor and Levodonna. It also includes a centrally-authorised medicine, ellaOne, which contains ulipristal acetate and was granted a marketing authorisation in Europe in 2009.

Emergency contraceptives containing levonorgestrel can be used up to 72 hours after unprotected sexual intercourse or contraceptive failure while ulipristal acetate can be used up to 120 hours. Levonorgestrel-containing emergency contraceptives are available 'over the counter' in certain European countries. EllaOne can only be obtained with a prescription.

More about the procedure

The review of emergency contraceptives started at the request of the Swedish medicines regulatory agency, under Article 31 of Directive 2001/83/EC.

It follows a procedure finalised in November 2013 for Norlevo, an emergency contraceptive medicine containing levonorgestrel, to add the following information to the summary of product characteristics: 'In clinical trials, contraceptive efficacy was reduced in women weighing 75 kg or more, and



levonorgestrel was not effective in women who weighed more than 80 kg'. This information is currently not reflected in the product information for other emergency contraceptives containing levonorgestrel.

For ulipristal acetate, no information regarding the woman's weight or BMI is currently included in the product information.

The review is being conducted by the Committee for Medicinal Products for Human Use (CHMP), the Committee responsible for all questions concerning medicines for human use. The CHMP opinion will then be forwarded to the European Commission for a legally-binding decision.

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