21 November 2014
EMA/710568/2014
Press Office

Press release

EMA recommends availability of ellaOne emergency contraceptive without prescription

Change in status to facilitate access for women in the European Union

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended a change in classification status from prescription to non-prescription for the emergency contraceptive ellaOne (ulipristal acetate). This means that the medicine could be obtained without a prescription in the European Union (EU).

ellaOne is an emergency contraceptive used to prevent unintended pregnancy if taken within 120 hours (five days) of unprotected intercourse or if a contraceptive method has failed. It works by preventing or delaying ovulation. ellaOne works best if taken within 24 hours. Removing the need to obtain a prescription for this medicine should speed up women's access to the medicine and therefore increase its effectiveness.

Based on the assessment of available information, the CHMP found that ellaOne can be used safely and effectively without medical prescription. ellaOne has been authorised in the EU since 2009 and extensive information on its risks and benefits has been collected and studied. Its safety profile is comparable to levonorgestrel-containing emergency contraceptives, which are the most frequently used emergency contraceptives in the EU. Levonorgestrel-containing emergency contraceptives are already available without prescription in most EU countries and are registered for use up to 72 hours after unprotected intercourse or contraceptive failure.

This CHMP recommendation will now be sent to the European Commission for a legally binding decision.

Notes

1. This press release, together with related documents, is available on the Agency's website.
2. The marketing authorisation holder for ellaOne is Laboratoire HRA Pharma.
3. This is a type II procedure where the marketing authorisation holder is requesting a change of legal status for ellaOne, i.e. a change of classification for its supply from 'medicinal product subject to medical prescription' to 'medicinal product not subject to medical prescription' in the EU.

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4. The full European Public Assessment Report (EPAR) for ellaOne can be found here.

5. Levonorgestrel-containing emergency contraceptives, for example Norlevo, Levonelle, Postinor, have a non-prescription status in 23 European countries. Exceptions are Malta, in which levonorgestrel-containing emergency contraceptives are not marketed, and the following countries in which levonorgestrel-containing emergency contraceptives are only available on prescription: Croatia, Germany, Greece, Hungary, Italy, Liechtenstein and Poland.

6. When assessing a switch from prescription-only to non-prescription status for a medicine, EMA's role is to assess whether it can be used in a safe and effective manner without prescription and make a recommendation to the European Commission on the re-classification of this medicine. If granted by the European Commission, such a re-classification to non-prescription status would in principle need to be implemented by all Member States. Any exception regarding the non-prescription status of this medicine falls within the responsibilities of the Member States.

7. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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