Helping your customer choose the most appropriate emergency contraceptive pill for her

Information for pharmacists

ellaOne® is licensed for any woman of childbearing age, including adolescents.[1] Use the Fraser guidelines to assess competency to consent to ellaOne®.[2,3]

Levonorgestrel is licensed for women >16 years old[4] (unless supplied through prescription or PGD).

1 You may need to consider the woman's age

2 Check that unprotected sex / contraceptive failure was no more than 120 hours ago

ellaOne® can be used up to 120 hours after unprotected sexual intercourse (UPSI).[1]

Levonorgestrel is licensed for use within 72 hours of UPSI.[4]

3 Check if she is taking any medications, including OTC or herbal preparations

Efficacy may be affected by medications such as liver enzyme inducers, e.g. anticonvulsants and St John's Wort. Refer to the SmPC for details.[1,4]

4 Check to see if she has any medical conditions or other factors to consider e.g. pregnancy, allergies, breastfeeding

- Check if the woman has severe liver problems, a severe malabsorption syndrome or any other allergies.[1,4]
- ellaOne® is not recommended for women with severe asthma treated by oral corticosteroids.[1]
- Breastfeeding should be avoided for at least one week after ellaOne® intake[1] and at least 8 hours following levonorgestrel administration.[4]
- Check that she may not already be pregnant. Emergency contraception is not intended for use in established or suspected pregnancy.

5 If both EHC options are appropriate ensure that she has received and understands all relevant information on which to base her choice

- Explain the difference in efficacy between the options available, and their ability to prevent ovulation.
- The risk of pregnancy is highest immediately before ovulation.[5]

ellaOne®
30 mg tablet / ulipristal acetate
effective when it matters most

PRODUCT INFORMATION ellaOne® 30 mg tablet (ulipristal acetate). Refer to the SmPC for further information. **INDICATION:** Emergency contraception (EC) within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure. **DOSAGE:** one 30mg tablet taken orally as soon as possible, but no later than 120 hours (5 days) after unprotected intercourse or contraceptive failure. Another tablet should be taken if vomiting occurs within 3 hours of intake. Can be taken at any time during the menstrual cycle. Not recommended for women with severe hepatic impairment. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or excipients. **SPECIAL WARNINGS AND PRECAUTIONS:** Occasional use only. Use reliable barrier method after use until next menstrual period. If next menstrual period is delayed >7 days or is abnormal or suggestive symptoms occur then perform pregnancy test. Consider ectopic pregnancy. If pregnancy confirmed, woman should contact their doctor. Concomitant use with EC containing levonorgestrel not recommended. Does not contraindicate the continued use of regular hormonal contraception but reliable barrier method should be used until next menstrual period. Not recommended in severe asthma treated by oral corticosteroids. Concomitant use of CYP3A4 inducers not recommended. Contains lactose. **FERTILITY, PREGNANCY AND LACTATION:** Not intended for use during existing or suspected pregnancy. Limited human data does not suggest safety concern. Does not interrupt existing pregnancy. No teratogenic potential was observed; animal data insufficient with regard to reproduction toxicity. Marketing Authorisation Holder maintains a pregnancy registry (www.hra-pregnancy-registry.com) to monitor outcomes of pregnancy in women exposed to ellaOne®. Patients and health care providers are encouraged to report any exposure. Ulipristal acetate is excreted in human breast milk; breastfeeding is not recommended for one week after intake. Breast milk should be expressed and discarded. A rapid return of fertility is likely following ellaOne use; regular contraception should be continued or initiated as soon as possible; subsequent acts of intercourse should be protected by reliable barrier method until next menstrual period. **UNDESIRABLE EFFECTS:** Always consult the SmPC before prescribing. Only the most common side effects and those which are rare but may be serious are listed below. Most commonly reported adverse reactions: headache, nausea, abdominal pain and dysmenorrhea. Common (≥1/100 to <1/10): mood disorders, dizziness, abdominal pain upper, vomiting, abdominal discomfort, myalgia, back pain, dysmenorrhea, pelvic pain, breast tenderness and faitigue. Rare (≥1/10,000 to <1/1,000): ruptured ovarian cyst. **RETAIL PRICE:** ellaOne 30 mg single tablet blister pack; £34.95**.**

MARKETING AUTHORISATION HOLDER: Laboratoire HRA Pharma, 15, rue Béranger, F-75003 Paris, France. Marketed in the UK by: HRA Pharma UK & Ireland Limited, Haines House, 21 John Street, Bloomsbury, London, WC1N 2BF **MARKETING AUTHORISATION NUMBER(S):** EU/1/09/522/001**. LEGAL CATEGORY:** P

Adverse events should be reported. Reporting forms can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to HRA Pharma UK & Ireland limited on 0800 917 9548 or email med.info.uk@hra-pharma.com

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References

1. ellaOne® Summary of Product Characteristics. Available at https://www.medicines.org.uk/emc/medicine/22280. Accessed March 2015.
2. Cornock M. Journal of Children's and Young People's Nursing 2007; 1(3): 124.
3. FPA Under 16s Factsheet 2009. Available at http://www.fpa.org.uk/sites/default/files/under-16s-consent-and-confidentiality-factsheet-march-2009.pdf. Accessed March 2015.
4. Upostelle Summary of Product Characteristics. Available at https://www.medicines.org.uk/emc/medicine/28337. Accessed March 2015.
5. Brache V *et al.* Contraception 2013; 88(5): 611-618.

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- If you've had unprotected sex, and it is not the right time in your life to have a baby, you are right to consider emergency contraception
- There is no need to be embarrassed - unprotected sex, or contraceptive accidents can happen to anyone
- These questions will help you prepare for your consultation with the pharmacist, and make sure they can make a suitable recommendation for you.

You & your pharmacist

Choosing a morning after pill

1 Sexually active women of all ages have contraceptive mishaps

Your pharmacist will provide a private room or area and will ask you a few standard questions.
Under 16s can get EHC from a pharmacist but the pharmacist may ask a few additional questions.

2 When?

When did you have unprotected sex, or when did this contraceptive mishap happen?

3 Other medicines?

Are you taking any other medicines (including any herbal medicines)?

4 Anything else?

- Do you have any medical conditions?
- Do you have any allergies?
- Are you breastfeeding?
- Could you be pregnant?

Pregnancy happens 6-12 days after unprotected sex, but could you have fallen pregnant before the mishap we are talking about today?

- Is your period late?
- Do you have any other signs of pregnancy?

5 Your choice

Depending on your answers to these questions, there may be a choice of emergency contraceptive pills. The options will be explained to you.

How important is it for you not to be pregnant at this time?

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WOMEN'S HEALTH

How to re-order more of these pads

To order more copies of this pad, please phone 01284 715298 or email **ellaOnepharmacist@precision.email**

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