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 old⁴ (unless supplied through prescription or PGD).

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

2. Check if the woman has severe liver problems, a severe malabsorption syndrome or any other allergies.¹ ³ ⁴

3. Check if the woman has any medical conditions or other factors to consider e.g. pregnancy, allergies, breastfeeding.

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

5. Check to see if she has received and understands all relevant information on which to base her choice.

6. Explain the difference in efficacy between the options available, and their ability to prevent ovulation.

7. The risk of pregnancy is highest immediately before ovulation.⁵

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

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

- 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 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.
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. **DOSE:** one 30 mg 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 of 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 fatigue. 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

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**References**

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?
- When did you have unprotected sex, or when did this contraceptive mishap happen?
- Are you taking any other medicines (including any herbal medicines)?
- Do you have any medical conditions?
- Do you have any allergies?
- Are you breastfeeding?
- Could you be pregnant?
- Is your period late?
- Do you have any other signs of pregnancy?

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.

Sexually active women of all ages have contraceptive mishaps.
How to re-order more of these pads

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