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 [e.g. barbiturates (including primidone and phenobarbital), phenytoin, fosphenytoin, carbamazepine, oxcarbazepine, herbal medicines containing *Hypericum perforatum* (St. John's wort), rifampicin, rifabutin, griseofulvin, efavirenz, nevirapine] not recommended (may decrease efficacy of ellaOne). Long term use of ritonavir not recommended. Not recommended for women who have used enzyme-inducing drugs in the past 4 weeks. Non-hormonal emergency contraception (i.e. a copper intrauterine device (Cu-IUD)) should be considered. 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

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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