ABBREVIATED PRESCRIBING INFORMATION (UK)

ellaOne®(ulipristal acetate)

Please refer to the SmPC before prescribing ellaOne®

Presentation: White/off-white, round curved tablet engraved *"ella"* on both faces
Indications: Emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure.
Dosage: One 30mg tablet to be taken orally as soon as possible, but no later than 120 hours after unprotected intercourse or contraceptive failure, with or without food. Another tablet should be taken if vomiting within 3 hours of intake. Can be taken at any point in menstrual cycle. Pregnancy should be excluded. Renal or hepatic impairment: no specific dose recommendations. Severe hepatic impairment: not recommended. Children and adolescents: Limited safety and efficacy data in women under 18 years.
Contraindications: Hypersensitivity to active substance or excipients. Pregnancy.
Special warnings and precautions for use: Concomitant use with an emergency contraceptive containing levonorgestrel is not recommended. Use in severe asthma insufficiently controlled by oral glucocorticoid not recommended. Emergency contraception only; women should be advised to adopt a regular method of contraception. May reduce contraceptive action of regular hormonal contraception, when continued or initiated immediately after ellaOne use; subsequent acts of intercourse should be protected by reliable barrier method until next menstrual period. Repeated administration within the same menstrual cycle is not advisable. No data for unprotected intercourse more than 120 hours before intake. Does not prevent pregnancy in every case; delay of >7 days in next menstrual period, abnormal bleeding at menses, or symptoms of pregnancy, exclude pregnancy. If pregnancy occurs, consider possibility of ectopic pregnancy. Menstrual periods can sometimes occur earlier or later than expected by a few days. In ~ 7%, menstrual periods occurred > 7 days early. In ~ 18.5% a delay of > 7 days occurred, and in 4% the delay was > 20 days. Contains lactose monohydrate; patients with galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should avoid. CYP3A4 inducers (e.g. rifampicin, phenytoin, phenobarbital, carbamazepine, efavirenz, fosphenytoine, nevirapine, oxcarbazepine, primidone, rifabutine, St John's wort/Hypericum perforatum, long term use of ritonavir) may reduce plasma concentrations of ulipristal acetate and decrease efficacy, even if stopped enzyme inducer within last 2-3 weeks. Concomitant use not recommended.
Potential for other medicinal products to affect ulipristal acetate: *CYP3A4 inducers* - In vivo results using potent inducer show marked decreases of Cmax and AUC (>90%) and reduced half life (2.2-fold) corresponding to 10-fold decrease in exposure. *CYP3A4 Inhibitors* - In vivo results show administration of ulipristal acetate with a potent and a moderate CYP3A4 inhibitor increased Cmax and AUC of ulipristal acetate 2- and 5.9-fold, (max) respectively; clinical consequences unlikely. *Medicinal products affecting gastric pH* - Administration of ulipristal acetate (10 mg) together with esomeprazole (20 mg daily for 6 days) resulted in approx 65% lower mean Cmax, delayed tmax and 13% higher mean AUC; clinical relevance unknown. **Potential for ulipristal acetate to affect other medicinal products:** *P-gp substrates* - In vitro data indicate that ulipristal acetate may inhibit P-gp; in vivo results with fexofenadine inconclusive. *Hormonal contraceptives* - Ulipristal acetate binds to the progesterone receptor with high affinity and may interfere with contraceptive action of progestogen-containing products. **Fertility, pregnancy and lactation:** contra-indicated during existing or suspected pregnancy. Extremely limited data available on health of the foetus/new-born in pregnancy exposed to ulipristal acetate. No teratogenic potential was observed; animal data insufficient with regard to reproduction toxicity. Marketing Authorisation Holder maintains a pregnancy registry 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. Most commonly reported adverse reactions: headache, nausea, abdominal pain and dysmenorrhea. Common (U1/100 to <1/10): mood disorders, dizziness, abdominal pain upper, vomiting, abdominal discomfort, myalgia, back pain, dysmenorrhea, pelvic pain, breast tenderness and faitigue. Uncommon (U1/1,000 to <1/100): vaginitis, nasopharyngitis, influenza, UTI, appetite disorders, emotional disorder, anxiety, insomnia, hyperactivity disorder, libido changes, somnolence, migraine, visual disturbance, hot flush, abdominal pain lower, diarrhoea, dry mouth, dyspepsia, constipation, flatulence, acne, skin lesion, pruritus, menorrhagia, vaginal discharge, menstrual disorder, metorrhagia, vaginal haemorrhage, hot flush, premenstrual syndrome, pain, irritability, chills, malaise, pyrexia. Rare (U1/10,000 to <1/1,000): conjunctivitis, hordeolum, pelvic inflammatory disease, dehydration, disorientation, tremor, disturbance in attention, dysguesia, poor quality of sleep, parosmia, syncope, abnormal sensation in eye, ocular hyperaemia, photophobia, vertigo, haemorrhage, upper respiratory tract congestion, cough, dry throat, epistaxis, gastro-oesophageal reflux disease, toothache, urticaria, general pruritus, pain in extremity, arthralgia, urinary tract disorder, chromaturia nephrolithiasis, renal pain, bladder pain, genital pruritus, dysfunctional uterine bleeding, dyspareunia, ruptured ovarian cyst, vulvovaginal pain, menstrual discomfort, hypomenorrhea, chest discomfort, inflammation, and thirst.
Package quantities and basic NHS price: ellaOne® 30 mg Tablet Oral use 1 tablet blister pack: £16.95.
Marketing authorisation holder: Laboratoire HRA Pharma, 15, rue Béranger, F-75003 Paris, France. Marketed in the UK by: HRA Pharma UK & Ireland Limited, Unit 7, RB Building, 557 Harrow Rd Kensal Green London W10 4RH. Additional information is available on request, contact medical information on 0800 917 9548 or e mail med.info.uk@hra-Pharma.com.
Marketing authorisation number(s) EU/1/09/522/001
Legal category: POM.
Date of last revision of the API text: July 2013.

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

Any case of pregnancy exposed to ellaOne should be reported on www.hra-pregnancy-registry.com