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INSIDE...

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Emergency contraception: towards a multidisciplinary consensus

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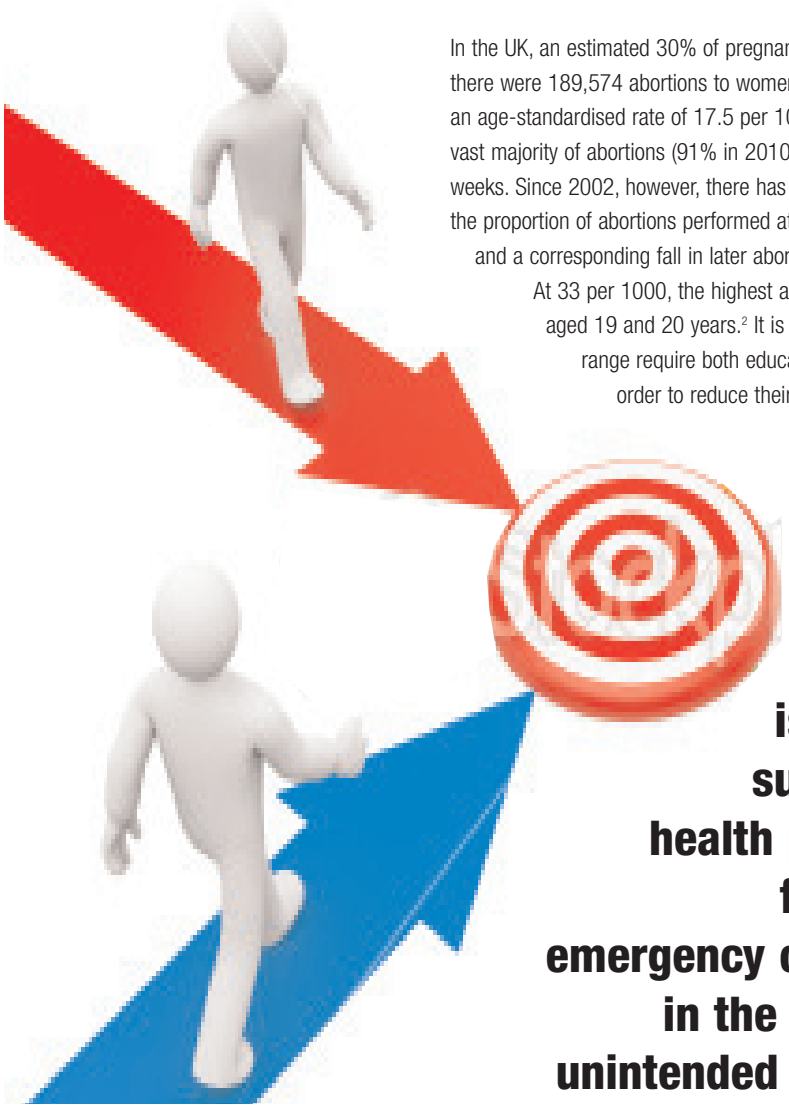
EMERGENCY CONTRACEPTION: TOWARDS A MULTIDISCIPLINARY CONSENSUS

The recent publication of the Faculty of Sexual and Reproductive Healthcare (FSRH) evidence-based guidance on emergency contraception (EC) was very welcome. However, some practitioners may have found the guidance difficult to interpret and apply in clinical practice. This article presents practical recommendations for implementation of the guidance, based on pragmatic discussions among a consensus expert group of multidisciplinary professionals involved in the management of women requesting EC.

Key points

- The availability of emergency contraception (EC) services is a key part of evidence-based contraceptive advice and practice
- Variations in geography and demographics between localities are key challenges in ensuring a national service standard for EC
- In future, commissioners of services must address geographical variations in practice and improve patient access to EC services
- There is strong consensus among healthcare professionals in their understanding of EC and support for its provision
- Support for the implementation of current guidance represents a significant opportunity to reduce variation in EC services and the impact of unwanted pregnancy



In the UK, an estimated 30% of pregnancies are unplanned.[1] In 2010 there were 189,574 abortions to women living in England and Wales, an age-standardised rate of 17.5 per 1000 women aged 15-44.[2] The vast majority of abortions (91% in 2010) are performed at < 15 weeks. Since 2002, however, there has been a continuing increase in the proportion of abortions performed at < 10 weeks of gestation and a corresponding fall in later abortions.[2]

At 33 per 1000, the highest abortion rate is among women aged 19 and 20 years.[2] It is clear that women in this age range require both educational and clinical support in order to reduce their relatively high incidence of unintended pregnancy.

"There is widespread support among health professionals for the role of emergency contraception in the prevention of unintended pregnancy"

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Table 1: Key issues concerning provision of emergency contraception services in the UK

- Support for the implementation of current guidance
- Definitions of what to do in clinical practice
- Reduce variation in the availability of products from area to area
- Increase public awareness of the choices available for EC
- Address the anxiety that women have regarding EC
- The need to define the best way to inform and empower women in order to change behaviour
- Impact of unprotected sex may be a low priority in many women's lives
- Support access to appropriate resources for EC
- Support evidence-based practice

EC = emergency contraception

Effective, evidence-based contraception advice and practice therefore remains high on the healthcare and public health agenda. The availability of EC services is a key part of this provision.

Three types of EC are now available in the UK: the copper-bearing intrauterine device (Cu-IUD), ulipristal acetate (UPA) and levonorgestrel (LNG). Evidence-based guidance from the Clinical Effectiveness Unit (CEU) of the FSRH on the use of these methods was published in August 2011, and subsequently updated in January 2012.[3]

By focusing on the appropriate choice of EC according to current evidence, the CEU guidance provided a welcome addition to the literature. However, some practitioners may have found the recommendations insufficiently prescriptive and difficult to apply in clinical practice, especially as some formularies may not include all three therapeutic options.

ACHIEVING A CONSENSUS

A small, multidisciplinary group of professionals involved in the provision of EC services across primary and secondary care met in autumn 2011, with the objective of defining themes for future service development and implementation of EC clinical guidance. The group considered that the CEU guidance did not go far enough, that some unanswered questions remained (*ie* there was a lack of evidence in some areas), and that a pragmatic approach was therefore required. Table 1 lists key issues identified by the multidisciplinary group concerning EC services in the UK.

More widespread adoption of all EC options following unprotected sexual intercourse (UPSI) is desirable. Support for the implementation of current guidance represents a significant opportunity to reduce the overall impact on health resources presented by unwanted pregnancy. One of the key challenges in achieving this aim is to ensure that women have access to EC in their community setting. Currently, there is widespread variation across the UK according to geography and local policy. The Department of Health recognised this issue, and the National Institute for Health and Clinical Excellence (NICE) developed guidance to address the challenges.[4]

During a full-day meeting, the group discussed and debated EC services, and produced a list of 48 initial consensus statements (see online version of this article). The group recognised that it was essential to involve a wider audience in order to develop a robust consensus that would reflect the views of every key group within the multidisciplinary team. In order to build this wider consensus, the 48 initial statements were collated into a questionnaire and circulated to other professionals working with EC.

One hundred and sixty-three UK professionals (Table 2) involved in the provision of EC completed the questionnaire at professional meetings held in several locations around the UK. Respondents were representative of England and Scotland. Although there were no professionals from Wales and Northern Ireland, the 163 respondents were a mixed social and ethnic demographic sample, and were considered to be representative of healthcare professionals working with EC across the UK.

Table 2: Professional roles of respondents to the questionnaire

Consultant gynaecologist	2
Associate specialist	8
Emergency care practitioner	1
Advanced practitioner	13
Nurse	27
Student	4
General practitioner	63
Other staff	45
Total	**163**

To achieve a final consensus, the group used a Delphi methodology, informed by comments and amendments suggested by the respondents to the questionnaire. The Delphi method is a systematic, iterative consensus method that relies on a panel of experts involved in two or more rounds of discussion. After each round, a facilitator provides an anonymous summary of the experts' forecasts, as well as the reasons for their judgments.

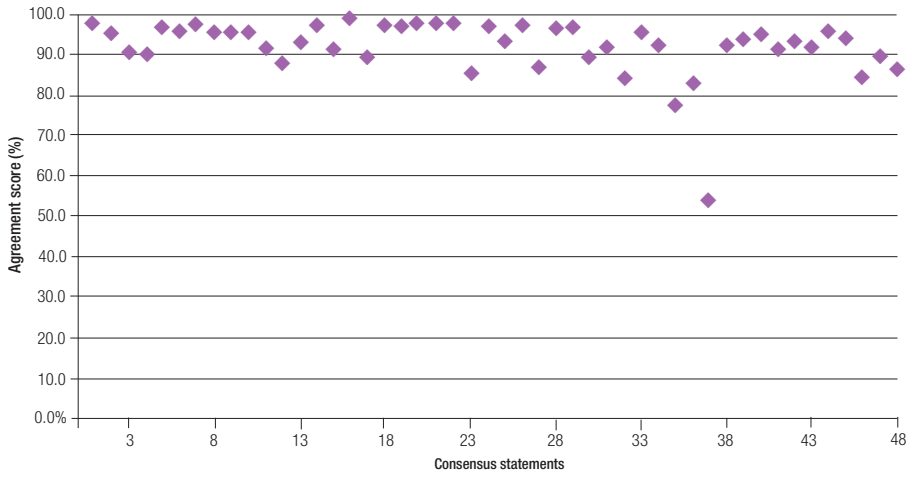
To measure consensus or agreement where differing opinions may exist, the Delphi method operates through written feedback. The level of individual agreement is measured using a four-point Likert scale: strongly disagree; disagree; agree; strongly agree. This allows respondents to record levels of agreement with each statement and to suggest changes.

Using the Delphi method encourages experts to revise earlier answers in light of the views of other members of their panel. During this process, the range of answers tends to narrow and the group converges towards the 'correct' answer; *ie* consensus. The process ends according to a pre-defined criterion (*eg* number of rounds, achievement of consensus, stability of results), and the mean or median scores of the final rounds determine the results.

OUTCOMES

Of the 48 statements initially produced by the consensus group, 36 scored > 90% agreement in the questionnaires (Figure 1). Overall, all but one statement achieved agreement of > 77.8%, indicating very strong consensus among respondents to the questionnaire. The one statement (number 37) with a low agreement of 54.1% related to the use of UPA more than once in the same menstrual cycle: 'Where UPA is given as an emergency contraceptive and further provision is needed when an IUD is unacceptable, UPA could be used twice in the same cycle.'

Figure 1: Total consensus agreement scores

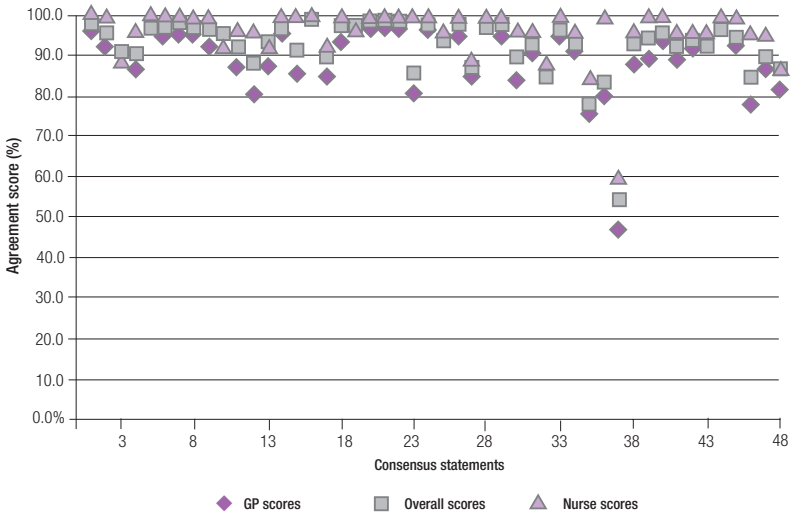


As shown in Figure 2, healthcare professionals involved in EC services are strongly aligned in their understanding of EC and its provision, and demonstrate robust group consensus. However, given the sample sizes, we performed subanalyses on two of the respondent subgroups: nurses (27 respondents) and GPs (63 respondents). Detailed results of these subanalyses are given in the online version of this article.

Compared with scores in the total group, there were fewer statements scoring < 90% among the nurses. The exception was Statement 3 – 'For most women, unwanted pregnancy is a negative life event'– which scored lower among nurses than among other respondents. Otherwise, the level of agreement was higher within the nurse subgroup than among respondents overall.

In general, GPs scored slightly lower levels of agreement and hence several statements fell below the nominal 90% threshold. Despite this slightly lower mean level of agreement, however, agreement was still high among GPs, with only Statement 37 scoring low with < 50% of GPs in agreement.

Figure 2: Comparison of subgroup consensus scores



RECOMMENDATIONS

The Delphi method described above established consensus around the CEU Guidance and the themes deemed most relevant to EC clinical practice. Levels of agreement with the 48 initial consensus statements were unusually high from the outset of the project, so these remain unchanged. The expert group's general consensus recommendations on EC provision are shown in Table 3.

The expert group's initial advice concerning EC treatment options was amended following review of the responses to the questionnaire. The intention was to reflect concerns that many women presenting for EC are clearly not intending to progress with the pregnancy and will therefore opt for abortion if EC fails. The final recommendations are shown in Table 4 and as an algorithm on pages 6-7.

Table 3: Consensus recommendations on the provision of emergency contraception in the UK

1. The principles supporting EC provision in the UK should be driven by the 48 consensus statements*
2. Clear integrated care pathways for optimal patient management and therapy selection are needed for EC provision
3. Clarity is needed to define best practice in EC at a local level
4. There needs to be an EC clinical lead in each locality
5. Practice policies (pathways) for EC should be developed locally and implemented in shared practice time
6. Practice policies should be reviewed and allowed to evolve over time according to a service improvement process
7. More effective media engagement is needed to enhance public awareness of all available EC options

EC = emergency contraception

*See online version of this article

Table 4: Recommendations for use of emergency contraception*

	Day 1	Day 2	Day 3	Day 4	Day 5	Breast feeding	Early in cycle	Mid-cycle	Late in cycle	BMI >30	Enzyme-inducing drugs	Previous use in this cycle
Cu-IUD	Y	Y	Y	Y	Y	Y	1st choice	1st choice	1st choice	1st choice	1st choice	1st choice
UPA	Y	Y	Y	Y	Y	Y	1st choice	2nd choice	2nd choice	2nd choice	N	Y†**¶
LNG	Y	Y	Y	Y†	N	Y	1st choice	3rd choice	2nd choice	3rd choice**	Y†§	Y

*Refer to prescribing information for all treatment options †Outside licence **Expert opinion §Double-dose LNG ¶Repeat if previous dose given < 7 days before in the same cycle
Cu-IUD = copper-bearing intrauterine device UPA = ulipristal acetate LNG = levonorgestrel BMI = body mass index (kg/m^2) Y = Yes: can be used N = No: should not be used

TOWARDS NATIONAL STANDARDS

One of the key challenges to a national service standard for EC is the variation in geography and demographics between localities, which makes provision of rapid access more challenging in some areas than in others. The need to deliver equity of service and informed choice may be expected to reduce variation over time. But the challenges are still to ensure that women are offered services appropriately, and are aware of the best route to access EC.

The high levels of agreement among GPs is important, since they will be responsible for directly commissioning services on behalf of their patients. In future, primary care services must address geographical variations in practice and improve patient access to EC services. In this context, a clear alignment with best practice in the provision of EC is an important milestone for service development and the minimalisation of clinical risk.

The burden of abortion in the UK, particularly in women aged 19 and 20 years, is significant and presents both financial and social problems to the NHS. While national guidance exists, awareness among the public and some healthcare professionals may still require support through education and wider understanding of the problems caused by unwanted pregnancy and the effective solutions that are available. Encouraging the media to promote the positive impacts of EC in addressing unwanted pregnancy in the UK could be seen as a positive step.

The attitudes of young women to EC and the wider issues of contraception and sexual health suggest that the role of EC is currently understated within the national curriculum. This again indicates the need for improvement both in standardisation and delivery across the UK. Further education is also required for healthcare professionals. The importance of including EC in continuing professional development (CPD) programmes is underlined by the strong consensus regarding this issue among questionnaire respondents.

CONCLUSION

The high levels of agreement shown by respondents to the majority of consensus statements suggest that there is widespread support among health professionals for the role of EC in the prevention of unintended pregnancy. Encouragingly, while the NHS is fragmented across the UK, high levels of agreement also suggest convergence around the role of EC and the evidence base surrounding treatment choice, indicating a desire and opportunity to standardise care.

Further education will ensure that services develop over time and become more accessible to the women who require them. In addition, improved guidance and structure regarding the availability of services and the treatments offered will ensure that EC is included in initiatives for local service development.

more information

- A longer version of this article will be available in June 2012 at **www.pcwhj.com**
- FSRH clinical guidance on emergency contraception (updated January 2012): **www.fsrh.org**
- Glasier A *et al.* Can we identify women at risk of pregnancy despite using emergency contraception? *Contraception* 2011;**84**:363-7

References

1. National Institute for Health and Clinical Excellence. Long-acting reversible contraception: the effective and appropriate use of long-acting reversible contraception (CG30). October 2005
2. Department of Health/National Statistics. Abortion statistics, England and Wales: 2010. May 2011
3. Faculty of Sexual and Reproductive Healthcare. Clinical Guidance. Emergency Contraception. August 2011, updated January 2012
4. National Institute for Health and Clinical Excellence. Press release: NICE seeks to reduce unwanted pregnancies by improving contraceptive services. Last updated 24 May 2010 (last accessed 6 April 2012) **http://www.nice.org.uk/newsroom/pressreleases/2010053ImprovingContraceptiveServices.jsp**

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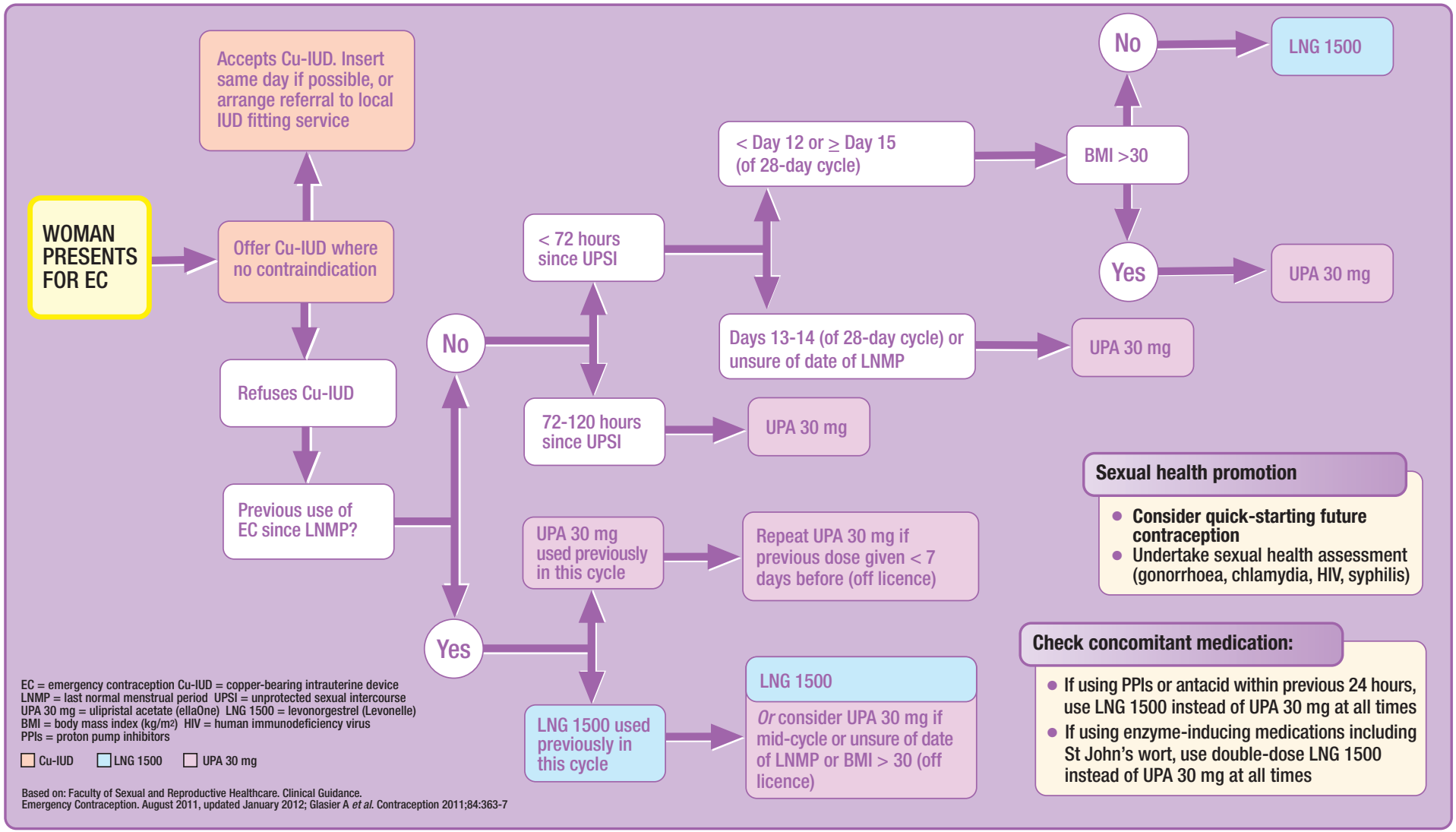
BACK TO BASICS: EMERGENCY CONTRACEPTION

Primary Care Women's Health Forum



Based on: Faculty of Sexual and Reproductive Healthcare. Clinical Guidance. Emergency Contraception. August 2011, updated January 2012; Glasier A *et al.* Contraception 2011;84:363-7

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 occurs within 3 hours of intake. Can be taken at any point during the 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 the 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 is not recommended. Emergency contraception only; women should be advised to adopt a regular method of contraception. May reduce contraceptive action of regular hormonal contraception; 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, possibility of an ectopic pregnancy should be considered. 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.

Drug interactions: Ulipristal acetate is metabolized by CYP3A4 *in vitro*. No specific drug interaction studies have been performed *in vivo*.

Potential for other medicinal products to affect ulipristal acetate: CYP3A4 inducers (e.g. rifampicin, phenytoin, phenobarbital, carbamazepine, St John's wort/Hypericum perforatum) may reduce plasma concentrations of ulipristal acetate and decrease efficacy, even if stopped enzyme inducer within last 2-3 weeks. Ritonavir can have an inducing effect on CYP3A4 if used chronically. Concomitant use not recommended. Concomitant administration of medicinal products that increase gastric pH (e.g. proton pump inhibitors, antacids and H2-receptor antagonists) may reduce plasma concentrations of ulipristal acetate and decrease efficacy and therefore not recommended. Potent CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, ritonavir, telithromycin, clarithromycin, nefazodone) may increase exposure to ulipristal acetate. Clinical relevance unknown. ***Potential for ulipristal acetate to affect other medicinal products***: Ulipristal acetate may act as an inhibitor of P-gp. Co-administration with P-gp substrates (e.g. dabigatran etexilate, digoxin) is not recommended. Because ulipristal acetate binds to the progesterone receptor with high affinity, it may interfere with action of progestogen-containing medicinal products. Contraceptive action of combined hormonal contraceptives and progestogen-only contraception may be reduced. Concomitant use of ulipristal acetate and emergency contraception containing levonorgestrel not recommended.

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. HRA Pharma 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 to ellaOne® by contacting the Marketing Authorisation Holder. Unknown whether ulipristal acetate is excreted in human or animal breast milk. A risk to the breast-fed child cannot be excluded: breastfeeding not recommended for ≥36 hours after intake.

Undesirable effects: Always consult the SmPC before prescribing.

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. Uncommon (≥1/1,000 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 (≥1/10,000 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

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