

NEW DRUGS

Ulipristal acetate

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Approved indication: emergency contraception

EllaOne (MS Health)

30 mg tablets

Australian Medicines Handbook section 17.1

Ulipristal acetate is another option for preventing pregnancy after unprotected sex. Levonorgestrel is effective for emergency contraception if it is taken within 72 hours. If a women presents after this time the only option is a copper intrauterine device (IUD). This can be used up to five days after unprotected intercourse. As IUD insertion is a medical procedure there has been research into an alternative option for presentations after 72 hours.

Ulipristal is a progesterone receptor modulator. By binding to the progesterone receptor it stops the surge in luteinising hormone which occurs before ovulation. Ulipristal will therefore either inhibit or delay ovulation.

The 30 mg tablet is rapidly absorbed. A second tablet is only needed if vomiting occurs within three hours. Ulipristal has a terminal half-life of 32 hours. Its metabolism involves cytochrome P450 3A4. The concomitant use of inducers of this enzyme, such as phenytoin and carbamazepine, is not recommended as these drugs will reduce the plasma concentration of ulipristal and may reduce its efficacy.

A double-blind trial compared ulipristal and levonorgestrel in women presenting within 72 hours of unprotected intercourse. Efficacy was assessed in 775 women who took ulipristal 50 mg and in 774 who took two doses of levonorgestrel 0.75 mg. Pregnancy occurred in 0.9% of the ulipristal group and 1.7% of the levonorgestrel group. The difference

was not statistically significant and met the criteria for non-inferiority.¹

This trial used a formulation which differs from what will be used in Australia. However a 30 mg dose of ulipristal has been compared with levonorgestrel in women presenting within five days. Efficacy was assessed in 941 women given ulipristal and 958 given levonorgestrel. The pregnancy rates in women who presented within 72 hours were 1.8% with ulipristal and 2.6% with levonorgestrel. There were 203 women who took emergency contraception between 72 and 120 hours after unprotected sex. The three pregnancies that occurred were in the levonorgestrel group.²

Both trials showed that ulipristal was non-inferior to levonorgestrel. Combining the results of the two trials seems to show an advantage for ulipristal (see Table).²

Another study reported on the efficacy of ulipristal 30 mg in 1241 women who took it 48-120 hours after unprotected sex. The pregnancy rate was 2.1%. There were 548 women who were treated 72-120 hours after sex. Their pregnancy rate was 1.8%.³

The most frequent adverse effects of ulipristal and levonorgestrel are nausea, headache and dysmenorrhoea. There may be intermenstrual bleeding and the next period may be earlier or later than expected. When ulipristal was not effective few women continued with the pregnancy. Data are only available on two women who continued to term. One had a normal live birth and the other had a baby with optic nerve hypoplasia. Ulipristal is excreted in breast milk.

While the evidence shows that ulipristal reduces the risk of pregnancy after unprotected sex, its efficacy will depend on the menstrual cycle. It will be less effective if ovulation has already occurred. If the woman has symptoms of pregnancy or her period is late, pregnancy should be excluded before prescribing ulipristal. After treatment, women are recommended to use a barrier method of contraception until their next period.

Table Efficacy of ulipristal and levonorgestrel for emergency contraception

Time after unprotected sex	Pregnancies per patient population	
	Ulipristal	Levonorgestrel
0-24 hours	5/584 (0.9%)	15/600 (2.5%)
0-72 hours	22/1617 (1.4%)	35/1625 (2.2%)
0-120 hours	22/1714 (1.3%)	38/1731 (2.2%)

Source: Reference 2

T T manufacturer provided additional useful information

REFERENCES

1. Creinin MD, Schlaff W, Archer DF, Wan L, Frezieres R, Thomas M, et al. Progesterone receptor modulator for emergency contraception: a randomized controlled trial. *Obstet Gynecol* 2006;108:1089-97. <http://dx.doi.org/10.1097/01.AOG.0000239440.02284.45>
2. Glasier AF, Cameron ST, Fine PM, Logan SJ, Casale W, Van Horn J, et al. Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis. *Lancet* 2010;375:555-62. [http://dx.doi.org/10.1016/S0140-6736\(10\)60101-8](http://dx.doi.org/10.1016/S0140-6736(10)60101-8)
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The Transparency Score (**T**) is explained in New drugs: transparency, Vol 37 No 1, Aust Prescr 2014;37:27.

At the time the comment was prepared, information about this drug was available on the websites of the European Medicines Agency (www.ema.europa.eu) and the Therapeutic Goods Administration (www.tga.gov.au/industry/pm-austpar.htm).