

Etonogestrel / Ethinyl Estradiol

Product:

ETONOGESTREL/ETHINYL ESTRADIOL (NuvaRing®) 11.4mg/2.6mg slow release vaginal ring

Class of drugs:

Contraceptive vaginal ring

Indication:

Prevention of pregnancy

Manufacturer:

Organon Canada Ltd

CED Recommendation

The CED recommended that etonogestrel/ethinyl estradiol (NuvaRing) not be funded through Ontario Public Drug Programs, on the basis that the drug does not provide any added value in terms of efficacy, safety or patient adherence compared to existing alternatives on the Formulary.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer decided not to fund etonogestrel/ethinyl estradiol (NuvaRing) through Ontario Public Drug Programs.

Status

No funding through Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Etonogestrel/ethinyl estradiol is a contraceptive vaginal ring used for birth control.
- ◆ Evidence indicates that compared to the birth control pills (oral contraceptives), etonogestrel/ethinyl estradiol vaginal ring is equally effective in preventing pregnancy.
- ◆ In clinical studies versus birth control pills, etonogestrel/ethinyl estradiol vaginal ring was associated with higher rates of vaginitis (vaginal inflammation) and leucorrhea (vaginal discharge).
- ◆ Whereas birth control pills are to be taken on a daily basis, etonogestrel/ethinyl estradiol is a vaginal ring that is inserted once a month. It has not been proven that this added convenience improves treatment adherence or provides better birth control.
- ◆ There have been reported cases where the vaginal ring was expelled from the body without the patient being aware, resulting in accidental pregnancies.
- ◆ Etonogestrel/ethinyl estradiol vaginal ring costs \$14 per month. Birth control pills cost approximately \$10 to \$13 per month. The cost premium is not justified given that there is no evidence of improved efficacy, safety or patient adherence.
- ◆ **Overall, the Committee noted that etonogestrel/ethinyl estradiol vaginal ring provides no added value in terms of efficacy or patient adherence compared with currently funded alternatives to justify the price premium.**

Background:

Etonogestrel/ethinyl estradiol vaginal ring is a combination product containing two hormones used for birth control. The product is a vaginal ring device that is inserted once a month. The ring releases two hormones into the body. After 21 days, the ring is removed, and the patient has a 7 day hormone-free period during which menstruation occurs.

Hormonal birth control products work by preventing the reproductive system from producing a mature egg. They also thicken the mucous produced by the cervix, thereby preventing the sperm from reaching the egg and making the lining of the uterus unreceptive to the implantation of a fertilized egg.

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Detailed Discussion:

- ◆ The Committee reviewed the funding of etonogestrel/ethinyl estradiol vaginal ring on two occasions, initially in November 2006 and again in June 2007.
- ◆ The focus of the review was two randomized controlled studies which compared etonogestrel/ethinyl estradiol vaginal ring to combination oral contraceptives. The two studies (Oddsson et al, 2005 and C-1757, 2005) found no significant differences in pregnancy rates between etonogestrel/ethinyl estradiol vaginal ring and oral contraceptives.
- ◆ The studies also found no significant differences in rates of total adverse events or serious adverse events. Etonogestrel/ethinyl estradiol vaginal ring was associated with slightly higher rates of vaginitis and leucorrhea in both studies and less nausea and vomiting in one study.
- ◆ One of the studies reported a higher rate of reproductive disorders with etonogestrel/ethinyl estradiol vaginal ring.
- ◆ The Committee also noted that one of the component medications, etonogestrel, is the end product of desogestrel, a drug that is associated with increased rates of venous thromboembolism (blood clots). There is currently inadequate information to reliably determine the magnitude of the risk of venous thromboembolism with etonogestrel/ethinyl estradiol.
- ◆ Expulsion of the device in over 5% of patients was reported in one study. This increases the risk of accidental pregnancies particularly if the expulsion is not apparent to the user.
- ◆ Treatment adherence was not reported in the studies. There is no evidence that etonogestrel/ethinyl estradiol vaginal ring is associated with improved patient adherence.
- ◆ Etonogestrel/ethinyl estradiol vaginal ring costs \$14 per month. Birth control pills cost approximately \$10 to \$13 per month. The cost premium is not justified given that there is no evidence of improved efficacy, safety or patient adherence. Furthermore, additional costs due to device expulsion and breakage as well as costs related to vaginitis and leucorrhea need to be considered.
- ◆ Overall, the Committee noted that etonogestrel/ethinyl estradiol vaginal ring provides no added value in terms of efficacy or patient adherence compared with currently funded alternatives. Moreover, the price premium is not justified.

CEDAC Recommendation:

(<http://www.cadth.ca/index.php/en/cdr/recommendations>)

The Canadian Expert Drug Advisory Committee (CEDAC) recommended that etonogestrel/ethinyl estradiol (NuvaRing) be listed on the condition that the amount paid by drug plans do not exceed the maximum paid for oral contraceptives.



Ministry of
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