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EPAR summary for the public

Evra

norelgestromin / ethinylestradiol

This is a summary of the European public assessment report (EPAR) for Evra. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Evra.

For practical information about using Evra, patients should read the package leaflet or contact their doctor or pharmacist.

What is Evra and what is it used for?

Evra is a contraceptive used to prevent pregnancy. Its safety and effectiveness have been studied in women aged 18 to 45 years.

It contains two active substances: norelgestromin (6 mg) and ethinylestradiol (600 micrograms).

How is Evra used?

Evra is a transdermal patch (a patch that delivers a medicine across the skin). For the first three weeks of the menstrual cycle a new patch should be applied every week, followed by a fourth week, which is patch-free. The patch-free interval must not be longer than seven days; otherwise, additional non-hormonal contraceptive methods must be used, such as condoms. Transdermal patches must always be applied on the same day of the week to the buttock, abdomen (belly), upper arm or upper back. The same area of skin should not be used for two consecutive patches. Evra may work less well in women weighing 90 kg or more.

For full instructions on how to use Evra, see the package leaflet.

The medicine can only be obtained with a prescription.

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How does Evra work?

Evra is a transdermal patch version of 'the pill' (combined oral contraceptive tablet). Using a weekly transdermal patch instead of a daily pill may help the woman to stick to using her contraception appropriately. The active substances in Evra are two hormones, ethinylestradiol (an oestrogen) and norelgestromin (a progestogen). Ethinylestradiol has been in use extensively in oral contraceptives for many years, and norelgestromin is very similar to another progestogen, which is also used in some oral contraceptives. Evra works like the pill by changing the body's hormonal balance to prevent ovulation, by altering the cervical mucus and by thinning the endometrium (the lining of the womb).

What benefit of Evra has been shown in studies?

Evra has been shown to be an effective contraceptive. It was studied in three main studies in over 3,000 women, which determined the number of women who became pregnant while taking the medicine. In two studies, Evra was compared with combined oral contraceptives: in one study, the comparator was a 'monophasic' contraceptive (pill containing the same amounts of active substances over the first three weeks of the treatment cycle) and in the other study, they were 'triphasic' (with the amount of the active substances in the pills varying through the treatment cycle). The third study did not compare Evra with any other medicine. All of the studies lasted for a year (13 four-week cycles).

Overall in the three studies, 15 pregnancies occurred in women taking Evra, 12 of which were the result of a 'method failure' (when a pregnancy occurs despite the contraceptive being used correctly). Five of the pregnancies were in women weighing over 90 kg. This gives Evra a 'Pearl Index' of 0.90. The Pearl Index is a standard way of measuring the effectiveness of contraceptives, which measures how many unwanted pregnancies occur in 100 woman-years (corresponding to 1,300 cycles), with lower values indicating more effective contraception. The Pearl Indices for the oral contraceptives were 0.57 (monophasic) and 1.28 (triphasic).

What are the risks associated with Evra?

The most common side effects with Evra (seen in more than 1 patient in 10) were headache, nausea (feeling sick) and breast tenderness.

Evra must not be used when a woman has, or has had blood clots in the veins or arteries including a stroke or a heart attack or when a woman has risk factors for blood clots (such as severe high blood pressure, diabetes with damage to the blood vessels, high cholesterol levels, or a family history of thrombosis). It must not be used in women who have migraine with aura (unusual visual or other sensory experiences), severe liver problems, liver tumours or a history of liver tumours, some types of cancer or abnormal bleeding from the genital area whose cause has not been diagnosed. It must also not be used together with certain antiviral medicines containing the active substances ombitasvir, paritaprevir, ritonavir and dasabuvir. For the full list of all side effects and restrictions, see the package leaflet.

Why is Evra approved?

The European Medicines Agency decided that Evra's benefits are greater than its risks for female contraception and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Evra?

The company that markets Evra will perform a study to further investigate the risk of blood clots.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Evra have also been included in the summary of product characteristics and the package leaflet.

Other information about Evra

The European Commission granted a marketing authorisation valid throughout the European Union for Evra on 22 August 2002.

The full EPAR for Evra can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Evra, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 06-2017.