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EPAR summary for the public

Ioa

nomegestrol acetate / estradiol

This is a summary of the European public assessment report (EPAR) for Ioa. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Ioa.

What is Ioa?

Ioa is a medicine available as 24 white 'active' tablets that contain the active substances nomegestrol acetate (2.5 mg) and estradiol (1.5 mg), and four yellow 'inactive' (placebo) tablets that do not contain any active substance.

What is Ioa used for?

Ioa is a contraceptive pill. The medicine can only be obtained with a prescription.

How is Ioa used?

One tablet a day is taken for as long as contraception is required, starting with an active tablet on the first day of the cycle. Ioa comes in blisters containing 28 tablets (24 white tablets followed by 4 yellow tablets), which are taken in sequence using stickers to identify the days of the week for each tablet.

How does Ioa work?

Ioa is a combined contraceptive pill that contains two active substances, nomegestrol acetate (a progestogen) and estradiol (an oestrogen). Estradiol is the same as a hormone naturally produced by the ovaries during a menstrual cycle. Nomegestrol acetate is derived from the hormone called progesterone which is also produced by the ovaries during a menstrual cycle. Ioa works 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).

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How has Ioa been studied?

The effects of Ioa were first tested in experimental models before being studied in humans.

Ioa was investigated in two main studies involving a total of 4,433 women aged 18 to 50 years old. The participants were given either Ioa or another contraceptive pill containing drospirenone and ethinyl estradiol for one year (13 menstrual cycles). The main measure of effectiveness was the number of women aged 18 to 35 who became pregnant during or shortly after treatment, expressed in terms of a pregnancy rate using the 'Pearl Index'. The Pearl Index is a standard way of measuring the effectiveness of contraceptives, which measures how many unwanted pregnancies occur in 100 women-years (corresponding to 1,300 menstrual cycles). A lower Pearl Index represents a lower chance of getting pregnant.

No clinical study data on Ioa are available in adolescents under 18 years old.

What benefit has Ioa shown during the studies?

In women aged 18 to 35, the Pearl Index was around 0.4 with Ioa and 0.8 with the comparator medicine in the first study, and around 1.2 with Ioa and 1.9 with the comparator medicine in the second study.

What is the risk associated with Ioa?

The most frequent side effects with Ioa (seen in more than 1 user in 10) are acne and changes to menstrual periods (e.g. absence or irregularity). For the full list of all side effects reported with Ioa, see the package leaflet.

Ioa should not be used in women who are hypersensitive (allergic) to nomegestrol acetate, estradiol or any of the other ingredients. It must not be used when a woman has, or has had, venous or arterial thrombosis (blood clots in the veins or arteries) including a stroke or a heart attack or when a woman has some of the risk factors for thrombosis (severe high blood pressure, diabetes with damage to the blood vessels or high cholesterol levels). It should not be used in women who have a disorder affecting blood clotting (such as protein C deficiency), migraine with aura (visual or other symptoms), severe liver problems with the liver still not functioning normally, certain types of cancer, or abnormal bleeding from the genital area whose cause has not been diagnosed. For the full list of restrictions, see the package leaflet.

Why has Ioa been approved?

The CHMP decided that the benefits of Ioa are greater than its risks and recommended that it be given marketing authorisation.

Other information about Ioa

The European Commission granted a marketing authorisation valid throughout the European Union for Ioa on 16 November 2011.

The full EPAR for Ioa 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 Ioa, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2011.