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**EPAR summary for the public**

# Zoely

nomegestrol acetate / estradiol

This is a summary of the European public assessment report (EPAR) for Zoely. 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 Zoely.

## What is Zoely?

Zoely 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 Zoely used for?

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

## How is Zoely 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. Zoely 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 Zoely work?

Zoely 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. Zoely works by changing

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Send a question via our website** www.ema.europa.eu/contact

the body's hormonal balance to prevent ovulation, by altering the cervical mucus and by thinning the endometrium (the lining of the womb).

## How has Zoely been studied?

Zoely was investigated in two main studies involving a total of 4,433 women aged 18 to 50 years old. The participants were given either Zoely 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 Zoely are available in adolescents under 18 years old.

## What benefit has Zoely shown during the studies?

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

## What is the risk associated with Zoely?

The most frequent side effects with Zoely (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 Zoely, see the package leaflet.

Zoely must not be used when a woman has, or has had, blood clots in the veins or arteries or when a woman has some of the risk factors for blood clots. It should not be used in women who have pancreatitis (inflammation of the pancreas), severe liver problems, liver tumours or a history of liver tumours, 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 Zoely been approved?

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

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

A risk management plan has been developed to ensure that Zoely is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Zoely, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company will perform a study to further investigate the risk of blood clots.

## Other information about Zoely

The European Commission granted a marketing authorisation valid throughout the European Union for Zoely on 27 July 2011.

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

This summary was last updated in 04-2016.