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Drovelis (drospirenone / estetrol)

An overview of Drovelis and why it is authorised in the EU

What is Drovelis and what is it used for?

Drovelis is a combined hormonal contraceptive. It contains the active substances drospirenone and estetrol monohydrate.

How is Drovelis used?

Drovelis can only be obtained with a prescription. It comes in blisters containing 28 tablets (24 'active' tablets and 4 'inactive' tablets that do not contain the active substances).

Tablets are taken by mouth in sequence, starting on the first day of the menstrual cycle with the active tablets, followed by the 4 inactive tablets. Each subsequent pack is started the day after finishing the previous pack, for as long as contraception is required. For more information about using Drovelis, see the package leaflet or contact your doctor, pharmacist or prescriber.

How does Drovelis work?

Drovelis is a combined contraceptive pill that contains two active substances, drospirenone (a progestogen) and estetrol (an oestrogen). Estetrol is a synthetic version of an oestrogen that is naturally present during pregnancy, and drospirenone is a hormone with similar effects to the progesterone produced during the menstrual cycle. Both these substances change the body's hormonal balance to prevent ovulation.

What benefits of Drovelis have been shown in studies?

Drovelis was found to be effective at preventing unwanted pregnancies in 2 main studies involving a total of around 3,400 women.

The main measure of effectiveness was the number of unwanted pregnancies in 100 women-years (corresponding to 100 women taking contraception for one year). This measure is known as the Pearl Index, and a lower Pearl Index represents a lower chance of getting pregnant.

In a first study conducted in 1,553 women between the ages of 18 and 50, the Pearl Index was 0.44 in the group aged 18 to 35 and 0.38 in the whole group. This was considered a sufficiently low value for an oral contraceptive.

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In a second study, conducted in 1,864 women aged 16 to 50 years old, where more pregnancies were reported, the Pearl Index was 2.42 in women aged 16 to 35 and 2.30 in the group aged 16 to 50.

What are the risks associated with Drovelis?

The most common side effects with Drovelis (which may affect up to 1 in 10 people) are irregular bleeding between periods (metrorrhagia), headache, acne, vaginal bleeding and painful periods (dysmenorrhoea). For the full list of side effects of Drovelis, see the package leaflet.

Drovelis should not be used by women with a history of blood clots in the veins or arteries, or by women with risk factors for blood clots. It should also not be used by women who have experienced severe liver and kidney problems, liver tumours, hormone-dependent cancers, or abnormal bleeding from the genital area of unknown cause. For the full list of restrictions, see the package leaflet.

Why is Drovelis authorised in the EU?

Overall, Drovelis was considered effective at preventing unwanted pregnancies. In terms of safety, the side effects of Drovelis are similar to those of other combined hormonal contraceptives and are in line with what would be expected with an oestrogen and a progestogen pill. The European Medicines Agency therefore decided that Drovelis's benefits are greater than its risks and it can be authorised for use in the EU.

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

The company that markets Drovelis will provide a checklist for healthcare professionals and an information card for women to help manage the risk of thromboembolic events.

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

As for all medicines, data on the use of Drovelis are continuously monitored. Side effects reported with Drovelis are carefully evaluated and any necessary action taken to protect patients.

Other information about Drovelis

Further information on Drovelis can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/drovelis.

This overview was last updated in 05-2021.