swissmedic

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Drovelis® (active substances: drospirenone and estetrol)

First authorisation in Switzerland: 5 May 2022

Medicinal product (film-coated tablets) for oral contraception

About the medicine

The medicinal product Drovelis with the active substances drospirenone and estetrol is used for oral contraception in women over 18 years of age. Compared with the combined hormonal contraceptives (CHCs) already available, Drovelis contains a new oestrogen (estetrol) combined with a progestogen (drospirenone) that is already known and used in other CHCs. Estetrol is a naturally occurring hormone.

Mode of action

Oestrogens and the progestogen progesterone play a fundamental role in a woman's cycle. Oral CHCs are used for contraception. They contain a combination of an oestrogen and a progestogen. Their primary mechanism of action is inhibition of ovulation. The contraceptive action of Drovelis, as with other CHCs, is achieved primarily by the progestogen (drospirenone). The main purpose of the oestrogen (estetrol) is to stabilise the cycle, i.e. to achieve regular cycles and a low volume of blood loss. The oestrogen used in Drovelis (estetrol) is a hormone that is formed naturally by the fetus during pregnancy and passes into the mother's blood through the placenta.

Use

Drovelis with the active substances drospirenone and estetrol is a prescription-only medicine.

Drovelis is available as a monthly pack containing 28 tablets and as a pack containing tablets for several months. Each monthly pack contains 24 pink and 4 white film-coated tablets. The pink film-coated tablets each contain 3 mg drospirenone combined with 14.2 mg estetrol. The white film-coated tablets do not contain active substances; they make it easier to take the medicinal product regularly. The contraceptive is taken once daily starting on the first day of a menstrual period; it is taken continuously without a break. It should always be taken at the same time of day. Drovelis does not need to be taken with a meal.

Efficacy

The efficacy of Drovelis in preventing pregnancy was investigated in two studies involving adult women, each lasting 13 menstrual cycles, i.e. one year. Study C301 was performed in Europe and Russia, study C302 in America. Only study C301 was classified as the pivotal study for authorisation in Switzerland since American studies of hormonal contraceptives usually show substantially higher rates of pregnancy, and the results cannot therefore be applied in full to the situation in Switzerland.

The study investigated the risk of becoming pregnant and the bleeding pattern during the menstrual cycle.

The risk of pregnancy is described using the Pearl Index (PI). The lower the PI, the more reliable the method of contraception.

The PI is determined for the age group up to 35 since female fertility declines naturally after this age. In study 301 there were 1,373 women in this age group.

The study produced a Pearl Index of 0.47. This finding can be considered a demonstration of the contraceptive efficacy of Drovelis.

The bleeding pattern while taking Drovelis showed no abnormalities in comparison with other CHCs. Bleeding occurred on a median[1] of five days per menstrual cycle.

Precautions, undesirable effects & risks

Drovelis must not be used in those who are hypersensitive to the active substances or any of the excipients.

The commonest undesirable effects are headaches (6%), breakthrough bleeding (metrorrhagia) (5%), viral infections of the upper airways (4%) and acne (4%).

All precautions, risks and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

The efficacy of Drovelis containing the combination of a new oestrogen (estetrol) and a known progestogen (drospirenone) in the prevention of pregnancy was demonstrated. An acceptable bleeding pattern while using this combination was also demonstrated. The risks associated with Drovelis are largely the same as those associated with existing authorised CHCs.

Provided the precautions are adequately observed, based on the available data, the benefits of Drovelis outweigh the risks. Swissmedic has therefore authorised the medicinal product Drovelis, with the active substances estetrol and drospirenone, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Drovelis®

Information for patients (package leaflet): Information for patients Drovelis®

[1] Median: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always smaller than the median, the other half are always greater.

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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