LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Jaydess
(levonorgestrel)

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Summary Public Assessment Report

Jaydess
(levonorgestrel)

intrauterine delivery system, 13.5 mg

This is a summary of the public assessment report (PAR) for Jaydess. It explains how Jaydess was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Jaydess.

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

What is Jaydess and what is it used for?

Jaydess is used for the prevention of pregnancy (contraception) for up to three years.

How does Jaydess work?

Jaydess is a T-shaped intrauterine delivery system (IUS) which after placement inside the womb slowly releases a small amount of the hormone levonorgestrel.

Jaydess works by reducing the monthly growth of the lining of the womb and thickening the cervical mucus. These actions prevent the sperm and egg from coming into contact and so prevent fertilization of an egg by sperm.

How is Jaydess used?

Jaydess is a T-shaped intrauterine delivery system (IUS) which after placement inside the womb slowly releases a small amount of the hormone levonorgestrel.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Jaydess have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Jaydess is effective for the prevention of pregnancy (contraception) for up to three years.

What are the possible side effects of Jaydess?

For the full list of all side effects reported with Jaydess, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Jaydess approved?

The effect of Jaydess for the use to prevent pregnancy (contraception) for up to three years has been demonstrated via two clinical studies (one phase 2 and one phase 3 pivotal efficacy and safety study). Therefore, the Medical Products Agency in Sweden decided that Jaydess's benefits are greater than its risks and recommended that it be approved for use.

Jaydess has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below "What measures are being taken to ensure the safe and effective use of Jaydess?"

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

A risk management plan has been developed to ensure that Jaydess 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 Jaydess, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

The marketing authorisation holder is obliged to provide educational materials for healthcare professionals. The marketing authorisation holder is also obliged to carry out post-approval safety studies to investigate difficulties with inserting the intrauterine delivery system and to investigate treatments for dysplasia as an outcome of interest in the treatment groups in the study.

Other information about Jaydess

The marketing authorisation for Jaydess was granted on 2013-01-10 in Sweden.

The full PAR for Jaydess can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Jaydess, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2015-09.