LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Kyleena
(levonorgestrel)

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Summary Public Assessment Report

Kyleena
(levonorgestrel)

Intrauterine delivery system, 19.5 mg

This is a summary of the public assessment report (PAR) for Kyleena. It explains how Kyleena 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 Kyleena.

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

What is Kyleena and what is it used for?

Kyleena is used for the prevention of pregnancy (contraception) for up to five years.

How does Kyleena work?

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

Kyleena 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 Kyleena used?

The pharmaceutical form of Kyleena is intrauterine delivery system for intrauterine use.

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 Kyleena have been shown in studies?

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

What are the possible side effects of Kyleena?

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

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

Why is Kyleena approved?

The effect of Kyleena for the use to prevent pregnancy (contraception) for up to five 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 Kyleena's benefits are greater than its risks and recommended that it be approved for use.

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

A risk management plan has been developed to ensure that Kyleena 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 Kyleena, 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.

Other information about Kyleena

The marketing authorisation for Kyleena was granted on 2016-11-11 in Sweden.

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

This summary was last updated in 2016-11.