LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Mifepristone Linepharma
mifepristone

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Summary Public Assessment Report

Mifepristone Linepharma
(mifepristone)

Tablets, 200 mg

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

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

What is Mifepristone Linepharma and what is it used for?

Mifepristone Linepharma is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but Mifepristone Linepharma has a different indication. The company has provided additional own data to demonstrate the safety and efficacy of Mifepristone Linepharma regarding this difference from the reference medicine.

The reference medicine for Mifepristone Linepharma is Mifegyne. Mifepristone Linepharma is used for termination of pregnancy:

- no later than 63 days after the first day of your last period,
- in combination with another treatment called prostaglandin (a substance that increases contraction of the womb) which you take 36 to 48 hours after taking Mifepristone Linepharma.

How does Mifepristone Linepharma work?

Mifepristone Linepharma is an anti-hormone that acts by blocking the effects of progesterone, a hormone which is needed for pregnancy to continue.

How is Mifepristone Linepharma used?

The pharmaceutical form of Mifepristone Linepharma is tablets for oral 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 Mifepristone Linepharma have been shown in studies?

Because Mifepristone Linepharma is a hybrid application of Mifegyne, clinical studies have been provided for Mifepristone Linepharma to show efficacy for the difference of Mifepristone Linepharma from the reference product Mifegyne.

What are the possible side effects of Mifepristone Linepharma?

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

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

Why is Mifepristone Linepharma approved?

This medicine is similar to a reference medicine containing the same active substance, but Mifepristone Linepharma has a different indication. The company has provided additional own data to demonstrate the safety and efficacy of Mifepristone Linepharma regarding this difference from the reference medicine.

No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Mifepristone Linepharma'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 Mifepristone Linepharma?

A risk management plan has been developed to ensure that Mifepristone Linepharma 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 Mifepristone Linepharma, 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 Mifepristone Linepharma

The marketing authorisation for Mifepristone Linepharma was granted on 2011-01-28 in Sweden.

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

This summary was last updated in 2015-01.