LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Propess
(dinoprostone)

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Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@mpa.se

Summary Public Assessment Report

Propess
(dinoprostone)

Vaginal delivery system, 10 mg

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

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

What is Propess and what is it used for?

Propess is a medicine with 'well-established use'. This means that the medicinal use of the active substance of Propess is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Propess is used to help start the birth process provided that 37 weeks of pregnancy have been completed.

How does Propess work?

The active substance in Propess, dinoprostone, opens the part of the birth canal known as the cervix, to allow the baby through.

How is Propess used?

The pharmaceutical form of Propess is vaginal delivery system for vaginal 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 Propess have been shown in studies?

As dinoprostone is a well-known substance, and its use to help start the birth process provided that 37 weeks of pregnancy have been completed is well established, the applicant presented data from the scientific literature. The literature, which has been provided, confirmed the efficacy and safety of dinoprostone in the use to help start the birth process provided that 37 weeks of pregnancy have been completed.

What are the possible side effects of Propess?

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

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

Why is Propess approved?

The use of Propess to help start the birth process provided that 37 weeks of pregnancy have been completed is well-established in medical practice and documented in the scientific literature. No new or unexpected safety concerns arose from these applications. Therefore, the Medical Products Agency in Sweden decided that Propess'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 Propess?

A risk management plan has been developed to ensure that Propess 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 Propess, 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 Propess

The marketing authorisation for Propess was granted on 1996-12-13 in Sweden.

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

This summary was last updated in 2018-08.