LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

# Summary Public Assessment Report

# Dienogest/Ethinylestradiol Exeltis (ethinylestradiol, dienogest)

# SE/H/2380/01/DC

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# Summary Public Assessment Report

Dienogest/Ethinylestradiol Exeltis
Prolonged-release tablet, 2 mg/0,02 mg

This is a summary of the public assessment report (PAR) for Dienogest/Ethinylestradiol Exeltis. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

**What is Dienogest/Ethinylestradiol Exeltis and what is it used for?**

The product is used to prevent pregnancy and for treatment of hirsutism in women with Polycystic Ovary Syndrome (PCOS).

**How does Dienogest/Ethinylestradiol Exeltis work?**

Each of the 24 pale white tablets contains a small amount of two different female hormones, namely dienogest and ethinylestradiol. The 4 green tablets contain no active substances and are called placebo tablets.
Contraceptive pills that contain two hormones are called “combination pills”.

**How is Dienogest/Ethinylestradiol Exeltis used?**

The pharmaceutical form is prolonged-release tablet 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 in Sweden.

**What benefits of Dienogest/Ethinylestradiol Exeltis have been shown in studies?**

The company provided its own data on efficacy and safety studies. These studies have shown that the product is effective in preventing pregnancy and for treatment of hirsutism in women with Polycystic Ovary Syndrome (PCOS).

**What are the possible side effects from Dienogest/Ethinylestradiol Exeltis?**

For the full list of side effects, see section 4 of the package leaflet.

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

## Why is Dienogest/Ethinylestradiol Exeltis approved?

The Swedish Medical Products Agency decided that the benefits are greater than its risks and recommended that it can be approved for use.

## What measures are being taken to ensure the safe and effective use of Dienogest/Ethinylestradiol Exeltis?

A risk management plan has been developed to ensure that the product 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, 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 Dienogest/Ethinylestradiol Exeltis

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

This summary was last updated in 2026-04.