

Summary Public Assessment Report

Drospirenone Exeltis (drospirenone)

SE/H/1869/01/DC

Summary Public Assessment Report

Drospirenone Exeltis
(drospirenone)

Film-coated tablet, 4 mg.

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

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

What is Drospirenone Exeltis and what is it used for?

Drospirenone Exeltis is a contraceptive pill and is used to prevent pregnancy.

How does Drospirenone Exeltis work?

Each blister of Drospirenone Exeltis contains 24 white tablets, also called active tablets, and 4 green tablets, also called placebo tablets, that do not contain active substance. Each of the 24 white active tablets contains a small amount of one type of female sex hormone, the progestogen drospirenone. For this reason Drospirenone Exeltis is called a progestogen-only-pill (POP). Contrary to the combined pills, POPs don't contain any oestrogen hormone next to the progestogen. For this reason, Drospirenone Exeltis can be used by women who do not tolerate oestrogens.

Drospirenone Exeltis provides high contraceptive efficacy. The contraceptive effect of Drospirenone Exeltis is based on the inhibition of ovulation, changes in the cervical mucus and effects on the endometrium, which becomes thinner.

How is Drospirenone Exeltis used?

The pharmaceutical form of Drospirenone Exeltis is film-coated 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 in Sweden.

What benefits of Drospirenone Exeltis have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Drospirenone Exeltis is effective in contraception.

What are the possible side effects of Drospirenone Exeltis?

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

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

Why is Drospirenone Exeltis approved?

It was noted that the effect of Drospirenone Exeltis in contraception is comparable to other well-established contraceptives. Therefore, the Medical Products Agency in Sweden decided that Drospirenone Exeltis's benefits are greater than its risks and recommended that it be approved for use.

Drospirenone Exeltis 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 Drospirenone Exeltis?"

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

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

A need for more data on the risk of venous thromboembolism VTE in users of progestogen-only contraception in general and in users of drospirenone-only in particular was identified. The Applicant has committed to perform a post-authorization safety study (PASS) to monitor the risk of VTE in users of drospirenone-only contraception and compare the risk to that with an appropriate comparator.

Other information about Drospirenone Exeltis

The full PAR for Drospirenone Exeltis can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Drospirenone Exeltis, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2020-01.