LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Stelista
(drospirenone)

SE/H/1810/01/DC

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@lakemedelsverket.se

Summary Public Assessment Report

Stelista
(drospirenone)

Film-coated tablet, 4 mg.

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

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

What is Stelista and what is it used for?

Stelista is a contraceptive pill and is used to prevent pregnancy.

How does Stelista work?

Each blister of Stelista 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 Stelista 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, Stelista can be used by women who do not tolerate oestrogens.

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

How is Stelista used?

The pharmaceutical form of Stelista 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 Stelista have been shown in studies?

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

What are the possible side effects of Stelista?

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

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

Why is Stelista approved?

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

Stelista 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 Stelista?"

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

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

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

This summary was last updated in 2020-01.