LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Slinda
(drospirenone)

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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@lakemedelsverket.se

Summary Public Assessment Report

Slinda
(drospirenone)

Film-coated tablet, 4 mg.

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

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

What is Slinda and what is it used for?

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

How does Slinda work?

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

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

How is Slinda used?

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

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

What are the possible side effects of Slinda?

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

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

Why is Slinda approved?

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

Slinda 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 Slinda?"

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

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

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

This summary was last updated in 2020-01.