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Summary report on authorisation dated 4 June 2026

Yselty® (active substance: linzagolix)

Authorisation in Switzerland: 19 January 2026

Film-coated tablets for the treatment of heavy menstrual bleeding associated with fibroids in adult premenopausal women

About the medicinal product

Yselty contains the active substance linzagolix.

Yselty is a medicinal product for the treatment of heavy menstrual bleeding (hypermenorrhoea) caused by uterine fibroids in premenopausal women.

Uterine fibroids are benign, hormone-sensitive tumours of the uterus that frequently occur in premenopausal women, potentially leading to heavy menstrual bleeding and, consequently, anaemia.

Mode of action

Yselty works by lowering the production of female hormones in the body that promote the growth of uterine fibroids,

thereby reducing the severity of the menstrual bleeding.

Administration

Yselty is a prescription-only medicine.

Yselty is available as a film-coated tablet in dosage strengths of 100 mg and 200 mg.

The recommended dose is 100 mg once daily together with an add-back therapy (ABT) consisting of 1 mg oestradiol and 0.5 mg norethisterone acetate. If this dosage is not effective enough, the dose can be increased to 200 mg once daily, also with ABT.

If additional hormone therapy (ABT) cannot be used or needs to be avoided for medical reasons, a dosage of 100 mg once daily is recommended. If this dosage is insufficient, 200 mg once daily without add-back therapy may be used for a short treatment period of up to 6 months.

The treatment should be initiated and supervised by a doctor experienced in the diagnosis and treatment of fibroids.

Efficacy

The efficacy of Yselty in the treatment of heavy menstrual bleeding associated with uterine fibroids was evaluated in two studies (PRIMROSE 1 and 2). Over a treatment period of 52 weeks, patients received either a placebo (dummy drug), 100 mg or 200 mg Yselty as monotherapy or combined with an add-back therapy (ABT) consisting of oestrogen and progestogen. The studies showed a significant and rapid reduction in blood loss with all 4 investigated dosages.

Precautions, undesirable effects, & risks

Yselty must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effects (affecting more than 1 in 10 users) are hot flushes and headache.

Yselty can adversely affect bone density, particularly if it is taken without concomitant hormonal add-back therapy (ABT).

Pregnancy must be ruled out prior to starting treatment.

Yselty must not be used in combination with hormonal contraceptives.

Contraceptive efficacy has not been demonstrated for Yselty.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Fibroids can lead to heavy menstrual bleeding in the affected women. The studies showed that treatment with Yselty significantly reduced blood loss in patients with uterine fibroids and heavy menstrual bleeding.

Taking all the risks and precautions into account, and based on the available data, the benefits of Yselty outweigh the risks. Swissmedic has therefore authorised the medicinal product Yselty, containing the active substance linzagolix, in Switzerland for the treatment of heavy menstrual bleeding associated with fibroids in adult premenopausal women.

Further information on the medicinal product

At the time of publication of the Summary report on authorisation for Yselty, the Information for healthcare professionals and the Patient information were not yet available. As soon as the medicinal product becomes available in Switzerland, the product information will be made available on the following website: www.swissmedicinfo.ch

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.