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Yselty (*linzagolix choline*)

An overview of Yselty and why it is authorised in the EU

What is Yselty and what is it used for?

Yselty is a medicine used in adult women of childbearing age to treat:

- moderate to severe symptoms of uterine fibroids, which are non-cancerous (benign) tumours of the womb (uterus);
- symptoms of endometriosis, a condition where tissue similar to the endometrium (the lining of the womb) grows outside the womb. It is used in women who have already had treatment for this condition.

Yselty contains the active substance linzagolix choline.

How is Yselty used?

Yselty can only be obtained with a prescription, and treatment should be started and supervised by a doctor experienced in the diagnosis and treatment of uterine fibroids or endometriosis.

Yselty is available as tablets to be taken by mouth once a day. Treatment should preferably start during the first week of the menstrual period.

The recommended dose of Yselty depends on the condition it is being used to treat and, for uterine fibroids, whether it is to be taken short-term or long-term and whether it is used with hormonal add-back therapy (ABT, which comprises estradiol and norethisterone acetate taken once daily).

For the treatment of endometriosis symptoms, Yselty is taken together with hormonal ABT.

Before starting treatment with Yselty, pregnancy must be ruled out. In patients with risk factors for osteoporosis or bone loss, a dual X-ray absorptiometry (DXA) scan is recommended before starting Yselty; a DXA scan is also recommended for all patients after 1 year of treatment with Yselty.

For more information about using Yselty, see the package leaflet or contact your doctor or pharmacist.

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How does Yselty work?

The active substance in Yselty, linzagolix choline, is a gonadotropin-releasing hormone (GnRH) receptor antagonist. Linzagolix choline attaches to GnRH receptors (targets) in the pituitary gland, thereby blocking the action of GnRH, a hormone that regulates the levels of oestrogen and progesterone. Both progesterone and oestrogen are hormones that are involved in fibroid growth, and oestrogen promotes growth of the endometrium and similar tissue outside the womb. By blocking the action of GnRH, linzagolix choline lowers the levels of oestrogen and progesterone, thereby decreasing pain and other symptoms associated with uterine fibroids and endometriosis.

What benefits of Yselty have been shown in studies?

Yselty reduced bleeding associated with uterine fibroids in two main studies involving a total of 1,109 women. Women took either placebo (a dummy treatment) or one of two different doses of Yselty (100 or 200 mg once a day), with or without ABT.

After 24 weeks of treatment, more women taking Yselty with or without ABT reported monthly menstrual blood loss of fewer than 80 mL and at least 50% less blood loss than before the treatment, compared with placebo (56-76% of women using Yselty versus 35% of women on placebo in the first study, 56-93% versus 29% in the second study). The highest number of patients who benefited from treatment in both studies was in the group of women treated with Yselty 200 mg plus ABT. The effect of Yselty was maintained until the end of the study (52 weeks).

Yselty given with ABT was also found to reduce pain associated with endometriosis in a study involving 486 women with endometriosis. The study compared Yselty given with or without ABT with placebo. Among the women given Yeselty, 73% of those treated with Yselty plus ABT reported a reduction in menstrual pain after 3 months, compared with 24% of women who received placebo. In addition, 47% of women using Yselty plus ABT reported a reduction in non-menstrual pain, compared with 31% of those receiving placebo. The effect on pain reduction was maintained until the end of the study (6 months).

What are the risks associated with Yselty?

For the full list of side effects and restrictions of Yselty, see the package leaflet.

When used to treat uterine fibroids, the most common side effects with Yselty include hot flushes (which may affect more than 1 in 10 people) and headache (which may affect up to 1 in 10 people). In the studies, these were more frequent with high doses of Yselty, and less frequent when Yselty was taken with ABT.

In women with endometriosis, the most common side effects with Yselty used with ABT (which may affect up to 1 in 10 people) include hot flushes and headache.

Yselty must not be used in women who are pregnant or breastfeeding, in women with known osteoporosis and in women who have genital bleeding of unknown cause; in women taking ABT, the contraindications for this therapy also apply.

Why is Yselty authorised in the EU?

Yselty was shown to improve bleeding associated with uterine fibroids when used with or without ABT. It was also found to reduce pain associated with endometriosis when used with ABT. Yselty may impact bone density, and the product information includes recommendations on how to monitor patients for bone loss, and how to manage those with additional risk factors for developing osteoporosis. Aside from this, Yselty was generally well tolerated, and its side effects are considered manageable.

The European Medicines Agency therefore decided that Yselty's benefits are greater than its risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Yselty have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Yselty are continuously monitored. Suspected side effects reported with Yselty are carefully evaluated and any necessary action taken to protect patients.

Other information about Yselty

Yselty received a marketing authorisation valid throughout the EU on 14 June 2022.

Further information on Yselty can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/yselty

This overview was last updated in 11-2024.