linzagolix

Yselty 200 mg film-coated tablets

Package leaflet: Information for the patient

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▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Yselty is and what it is used for

Yselty contains the active substance linzagolix. It is used to treat moderate to severe symptoms of uterine fibroids (commonly known as myomas), which are noncancerous tumours of the uterus (womb). Yselty is used in adult women (over 18 years of age) of childbearing age. In some women, uterine fibroids may cause heavy menstrual bleeding (your 'period') and pelvic pain (pain below the belly button).

Linzagolix blocks the action of a hormone, gonadotropin releasing hormone, that helps to regulate the release of female sex hormones estradiol and progesterone. These hormones trigger women's periods (menstruation). When blocked, the levels of the hormones estrogen and progesterone circulating in the body are reduced. By decreasing their levels, linzagolix stops or reduces menstrual bleeding and decreases pain and pelvic discomfort and other symptoms associated with uterine fibroids.

2. What you need to know before you take Yselty

Do not take Yselty
If you have any of the conditions listed below:

- if you are allergic to linzagolix or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant or if you think you might be pregnant or if you are breast-feeding
- if you have osteoporosis (a condition that makes bones fragile)
- if you have any genital bleeding of unknown origin.

If you are taking Yselty together with additional hormonal therapy of estradiol and norethisterone acetate (also known as add back therapy), follow the instructions in the "Do not take…" section of the package leaflets for estradiol and norethisterone acetate.

Warnings and precautions
Talk to your doctor or pharmacist before taking Yselty.

Before you start treatment with Yselty, your doctor will discuss your medical and family history and relevant risk factors with you. Your doctor will also need to check your blood pressure and make sure you are not pregnant. You may also need a physical examination and additional checks before you start treatment, such as a scan to measure how strong your bones are, that will be specific to your medical needs and/or concerns.

Stop taking Yselty and get urgent medical attention if you notice:
- signs of liver disease:
  – yellowing of your skin or the whites of your eyes (jaundice).
  – nausea or vomiting, fever, severe tiredness.
  – dark urine, itching or upper abdominal pain.
- if you become pregnant.

Talk to your doctor or pharmacist before taking Yselty if you have:
- reduced liver or kidney function.
  Yselty is not recommended in women with severely reduced liver or moderately or severely reduced kidney function as the linzagolix blood level may become too high.
- increased levels of liver enzymes in the blood.
  Temporary increased levels of liver enzymes in the blood without symptoms may occur during treatment with Yselty.
- heart or blood circulation problems, a family history of changes in the electrical activity of the heart known as "QT prolongation" or you are taking a medicine that changes the electrical activity in the heart.
- increased blood fat levels (cholesterol). These levels should be monitored during treatment as Yselty may lead to further increases.
- had a fracture that was not caused by a major trauma, or other risks of bone mineral loss or reduced bone density. Yselty can lower bone mineral density, so your doctor may want to check it beforehand in this case.
- previously suffered from depression, mood changes, thoughts about suicide or any depressive symptoms as these have been reported with medications that work in the same way as Yselty does.
- if you think you might be pregnant. Yselty usually leads to a significant reduction or may even stop your menstrual bleeding (your 'period') during treatment and for a few weeks afterwards, making it difficult to recognise pregnancy. See under "Pregnancy and breast-feeding.

Yselty has not been shown to provide contraception. See under "Pregnancy and breast-feeding".

Yselty can be used together with another tablet containing the hormones estradiol and norethisterone acetate (also known as hormonal add-back therapy). If prescribed to you, read the leaflet of the tablet containing these hormones carefully as well as this leaflet.

Children and adolescents
Yselty is not recommended for children and adolescents under 18 years as it has not been studied in this age group.

Other medicines and Yselty
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including hormonal contraception.

Particularly inform your doctor or pharmacist if you are taking:
- repaglinide (a medicine used to treat diabetes)
- paclitaxel, sorafenib (medicines used to treat cancer)

Yselty is not recommended if you are using one of these medicines.

Pregnancy and breast-feeding
Do not use Yselty if you are pregnant or breast-feeding as it might harm your baby. If you think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

If you become pregnant, stop taking Yselty and contact your doctor. Because Yselty reduces or stops your periods it might be difficult to recognise pregnancy. Carry out a pregnancy test if there is any chance you may be pregnant.

Women who could become pregnant should use effective non-hormonal contraception when taking Yselty.

Driving and using machines
Yselty has no influence on the ability to drive and use machines.

Yselty contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Yselty

Treatment with Yselty will be prescribed by a doctor who is experienced in the care of patients with uterine fibroids. Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will work out the right dose of Yselty for you. **The following dose options are possible for Yselty 200 mg tablets**:

- One tablet of 200 mg Yselty taken once daily together with another tablet once daily containing the hormones estradiol and norethisterone acetate (also known as add-back therapy). If your doctor prescribes this add-back therapy, it is important to always take it with your Yselty tablets as this will help to reduce side effects including the risk and extent of bone mineral density loss.

- For short-term use (up to 6 months only), one tablet of Yselty 200 mg once daily can be given without estradiol and norethisterone acetate to treat symptoms associated with large fibroid or uterine size.

It should be noted that a dose of 100 mg Yselty can be used if a lower dose is required.

Take the recommended dose **once daily**.
Start taking Yselty preferably in the first week of your menstrual cycle, which is the week you have bleeding.
Swallow the tablet with one glass of water, with or without food.

Duration of use
Your doctor will work out how long to continue treatment, based on the risk of bone mineral density loss. The 200 mg dose without add-back therapy should be prescribed for no longer than 6 months.
Your doctor will check your bone mineral density by arranging a scan after the first 12 months of Yselty treatment to see if treatment with estradiol and norethisterone acetate can continue. If you continue Yselty treatment beyond one year, your doctor will keep checking your bone mineral density at regular intervals.

If you take more Yselty than you should
Tell your doctor if you think you have taken too much Yselty.

There have been no reports of serious harmful effects from taking several doses of this medicine at once. If Yselty is used together with the additional hormonal therapy of estradiol and norethisterone acetate, overdose of the hormones may cause nausea and vomiting, breast tenderness, stomach pain, drowsiness, fatigue and withdrawal bleeding.

If you forget to take Yselty
If you miss a dose, take it as soon as you remember and then resume taking your tablet the next day as usual. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Yselty
If you would like to stop taking Yselty, talk to your doctor first. Your doctor will explain the effects of stopping treatment and discuss other possibilities with you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects can occur with the following frequencies:
Very common (may affect more than 1 in 10 people)
- hot flush

Common (may affect up to 1 in 10 people)
- mood disorders, such as mood swings, affect lability (i.e. rapid changes in emotions), anxiety, depression, irritability, emotional disorder
- excessive, irregular, or prolonged bleeding from the womb (uterine bleeding)
- vaginal dryness
- pelvic pain
- joint pain
- headache
- reduction in bone mineral density or bone strength
- increased liver enzyme blood levels
- nausea (feeling sick), vomiting, pain in stomach region
- constipation
- decreased interest in sex (libido)
- weakness
- increased sweating
- night sweats
- high blood pressure

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly:

for United Kingdom (Great Britain and Northern Ireland)
Scheme Card Yellow
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

for Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Yselty

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and cardboard box after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Yselty contains
- The active substance is linzagolix.
  One tablet of Yselty 200 mg contains 200 mg linzagolix.
- The other ingredients are:
  Tablet core: lactose monohydrate, microcrystalline cellulose, low-substituted hydroxypropylcellulose, hydroxypropylcellulose, croscarmellose sodium and magnesium stearate. See section 2 "Yselty contains lactose and sodium".
  Film-coating: macrogol poly(vinyl alcohol) grafted copolymer (E1209), talc (E553b), titanium dioxide (E171) and iron oxide yellow (E172).

What Yselty looks like and contents of the pack
Yselty 200 mg film-coated tablets are oblong (19 × 9 mm), pale yellow, engraved with "200" on one side and plain on the other side.

Yselty is provided in a cardboard box with 2 or 6 blisters containing 14 film-coated tablets (tablet) per blister.

Pack sizes: 28 or 84 film-coated tablets.

Not all pack sizes may be marketed.

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