

**PACKAGE LEAFLET**

## **Package leaflet: Information for the patient**

### **Yselty 100 mg film-coated tablets** linzagolix

▼ 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
2. What you need to know before you take Yselty
3. How to take Yselty
4. Possible side effects
5. How to store Yselty
6. Contents of the pack and other information

#### **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 non-cancerous tumours of the uterus (womb).
- symptoms associated with endometriosis in women with a history of previous medical or surgical treatment for their endometriosis (endometriosis is an often painful disorder in which tissue similar to the tissue that normally lines the inside of your uterus - the endometrium - grows outside your uterus).

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). Yselty is used for the treatment of your fibroids to stop or reduce bleeding and to decrease pain and pelvic discomfort associated with uterine fibroids.

Women with endometriosis can experience pelvic or lower abdominal pain, pain with menstrual periods and pain with intercourse. Yselty is used for the treatment of endometriosis to decrease the symptoms due to displaced tissue of the lining of the womb.

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, pelvic discomfort and other symptoms associated with uterine fibroids and endometriosis.

#### **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**

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

### **Other medicines and Ysely**

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)

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

### **Pregnancy and breast-feeding**

Do not use Ysely 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 Ysely and contact your doctor. Because Ysely 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 Ysely.

### **Driving and using machines**

Ysely has no influence on the ability to drive and use machines.

### **Ysely 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 Ysely**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### Uterine Fibroids:

Your doctor will work out the right dose of Ysely for you. **The following dose options are possible:**

- Either 100 mg Ysely (one tablet) or 200 mg Ysely (two tablets of 100 mg), 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 Ysely tablets as this will help to reduce side effects including the risk and extent of bone mineral density loss.
- For women for whom estradiol and norethisterone acetate are not suitable, Ysely can be taken in a dose of one tablet of 100 mg daily alone, i.e. without estradiol and norethisterone acetate.
- For short-term use (up to 6 months only), Ysely 200 mg daily (two tablets of 100 mg) can be given without estradiol and norethisterone acetate to treat symptoms associated with large fibroid or uterine size.

### Endometriosis:

- Two tablets of 100 mg Yselty taken once daily together with a medication containing the hormones oestrogen and progestogen (also known as add-back therapy). The add-back therapy is important to be taken with your Yselty tablets as this will help to reduce side effects including the risk and extent of bone mineral density loss.

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(s) 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. For the Uterine Fibroids, the 200 mg dose (two tablets of 100 mg) 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 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

**Uncommon** (may affect up to 1 in 100 people)

- 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)**

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://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](http://www.hpra.ie)

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

## **5. How to store Ysely**

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 Ysely contains**

- The active substance is linzagolix.  
One tablet of Ysely 100 mg contains 100 mg linzagolix.
- The other ingredients are:  
Tablet core: lactose monohydrate, microcrystalline cellulose, low-substituted hydroxypropylcellulose, hydroxypropylcellulose, croscarmellose sodium and magnesium stearate. See section 2 “Ysely contains lactose and sodium”.  
Film-coating: macrogol poly(vinyl alcohol) grafted copolymer (E1209), talc (E553b), titanium dioxide (E171) and iron oxide yellow (E172).

### **What Ysely looks like and contents of the pack**

Ysely 100 mg film-coated tablets are round shaped of 10 mm diameter, pale yellow, engraved with “100” on one side and plain on the other side.

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

Pack size: 28 or 84 film-coated tablets.

Not all pack sizes may be marketed.

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