

 **yselty**[®]
linzagolix

 **Theramex**
For Women. For Health

yselty[®]
& endometriosis



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Intended for patients who have been prescribed Yselty[®].

This guide is a summary only and does not replace the patient information leaflet provided in the Yselty[®] box. Please ensure you read the patient information leaflet in full before using Yselty[®].

If you have any queries or concerns, speak to your doctor or pharmacist.

yselty[®] is indicated in adult women (over 18 years) of childbearing age for the symptomatic treatment of endometriosis in women with a history of previous medical or surgical treatment for their endometriosis.

▼ 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.

Reporting of side effects: If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this brochure or in the package leaflet. You can also report side effects at yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects, you can help provide more information on the safety of this medicine.

If you would like to contact Theramex, please do so via:

Email: medinfo.uk@theramex.com

Telephone: **033 3009 6795**

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Although endometriosis is a common condition, we know the symptoms associated with it can have a big impact on daily life, and not just when you're having your period. Your doctor has prescribed Yselty® to help decrease the symptoms you are experiencing.

What is endometriosis?

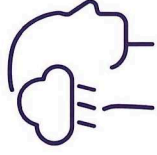
Endometriosis is a common condition, affecting up to 10 in 100 women. You're more likely to develop endometriosis if your mum or sister has had it.

Endometriosis happens when tissue similar to the womb lining grows in other places in the body. When these patches of endometriosis break down and bleed, they cannot leave your body, and this causes a range of symptoms.



Symptoms can include:

- Severe period pain
- Heavy periods
- Pain in your lower tummy and back (pelvic area)
- Pain when you go to the toilet
- Pain during or after sex
- Extreme tiredness (fatigue)



Are there side effects of Yselty®?

Like all medicines, Yselty® can cause side effects, although not everybody gets them. You could experience:

Very common (may affect >1 in 10)

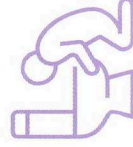
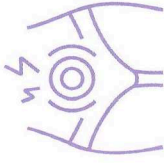
- Hot flush

Common (may affect up to 1 in 10)

- Mood disorders, such as mood swings, rapid changes in emotions, anxiety, depression, irritability, emotional disorder
- Excessive, irregular, or prolonged bleeding from the womb
- Vaginal dryness
- Pelvic pain
- Joint pain
- Headache
- Reduction in bone mineral density or bone strength
- Increased liver enzyme blood levels
- Nausea (feeling sick), vomiting, tummy pain
- Constipation
- Decreased interest in sex (libido)
- Weakness
- Increased sweating
- Night sweats

Uncommon (may affect up to 1 in 100)

- High blood pressure



Always talk to your doctor, pharmacist or nurse if you experience any side effects. They can help you to manage them. This includes any possible side effects not listed in this brochure or the patient leaflet.

See front cover for how to report side effects.

How should I take Yseltly®?

For endometriosis, you will have been prescribed 200mg once daily with ABT. The hormonal ABT you have been prescribed will be in a separate packet to your Yseltly®.

You should ideally start taking Yseltly® in the first week of your menstrual cycle, which is the week you start bleeding.

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 missed tablet.

If you think you have taken too much Yseltly®, tell your doctor. There have been no reports of serious harmful effects from taking several doses of this medicine at once. When Yseltly® is used together with ABT, overdose of the hormones may cause nausea and vomiting, breast tenderness, stomach pain, drowsiness, fatigue and withdrawal bleeding.

Your doctor will work out how long to continue treatment, based on the risk of bone mineral density loss. Your doctor will arrange a scan after the first 12 months of Yseltly® treatment to see if treatment with estradiol and norethisterone acetate can continue. If you continue Yseltly® treatment beyond one year, your doctor will keep checking your bone mineral density at regular intervals.

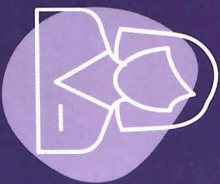
Yseltly® should be taken:

- Orally
- Once daily
- With a glass of water
- With or without food

Stop taking Yseltly® and get urgent medical attention if:

- **You become pregnant.** Because Yseltly® reduces or stops your periods, it may be difficult to recognise pregnancy
- **You notice signs of liver disease**, including 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 wish to stop taking Yseltly® it is important to talk to your doctor first. Your doctor will explain the effects of stopping treatment and discuss other possibilities with you.



How does Yseltly® work?

Yseltly® works by blocking the action of a hormone (gonadotropin releasing hormone) that helps with regulating the release of the female sex hormones estradiol and progesterone. These hormones trigger women's periods (menstruation).

When the gonadotropin releasing hormone action is blocked, the levels of oestrogen and progesterone circulating in the body are reduced. By decreasing their levels, Yseltly® stops or reduces menstrual bleeding and decreases pain and other symptoms associated with endometriosis.

Your doctor has prescribed a 200mg dose of Yseltly® that you need to take once daily. You should take this at the same time as the hormonal add back therapy (ABT) that you have also been prescribed. This is to help manage potential side effects. This will come in a separate packet to your Yseltly®.

Why do I need hormonal add back therapy with Yseltly®?

Hormonal ABT must be taken when Yseltly® is prescribed for the treatment of endometriosis. This is to help decrease side effects including the risk and extent of bone mineral density loss. There are different ways of taking hormonal ABT, your doctor will discuss these options with you.

It is important that you take ABT for the duration of your treatment with Yseltly®, and if you are using hormonal ABT in tablet form, ensure you take it at the same time as your Yseltly® medication.

ABT contains the hormones oestrogen and progesterone. When your doctor prescribes this to you, read the leaflet of the pack containing these hormones carefully.

Whilst no medication can cure endometriosis, your doctor has prescribed Yseltly® 200mg taken with ABT to help decrease pain and other symptoms that you may be experiencing.



Things to consider before taking Yselty®

Do not take Yselty® if you:

- Are **allergic** to linzagolix or any ingredients of this medicine. *See the package leaflet for a full list of ingredients*
- Are **pregnant** or think you may be pregnant
- Are **breastfeeding**
- Have **osteoporosis** (a condition that makes bones fragile)
- Have any **genital bleeding of unknown origin**

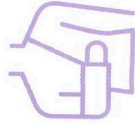
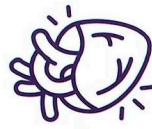


It's important to also read and follow the instructions in the "Do not take..." section of the package leaflet for the ABT.



Before taking Yselty®, tell your doctor if you have:

- Reduced **liver** or **kidney** function
- Increased levels of **liver enzymes** in the blood
- **Heart or blood circulation problems**, a family history of changes in the electrical activity of the heart or you are taking a medicine that changes the electrical activity in the heart
- Increased **blood fat levels** (cholesterol)
- Risks of **bone mineral loss**, reduced bone density, or had a fracture that was not caused by a major trauma
- Suffered from **depression, mood changes**, thoughts about suicide or any depressive symptoms
- Suspicions you might be **pregnant**
- **Intolerance to some sugars**



Please speak to your doctor or read the patient information leaflet found within the Yselty® box for further information on considerations while taking Yselty®.

Before you start treatment with Yselty®, your doctor will:

- Discuss your medical and family history and relevant risk factors with you
- Check your blood pressure and make sure you are not pregnant
- Assess whether you will need a physical examination and additional checks before you start treatment, such as a scan to measure how strong your bones are. Anything additional will be specific to your medical needs and/or concerns. **See the package leaflet in the Yselty® box for more information on this section**



It is also important to tell your doctor or pharmacist if you're taking, have recently taken or might take any other medications, including hormonal contraception. Yselty® has not been shown to provide contraception so **women who could become pregnant should use effective non-hormonal contraception when taking Yselty®**.

Yselty® is not recommended if you are taking:

- **Repaglinide** (a medicine used to treat diabetes)
- **Pacitaxel, sorafenib** (medicines to treat cancer)

It is important to always take Yselty® exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure before starting the treatment.



Your dose of Yselty®

Yselty® is made up of linzagolix (as choline salt) and lactose. If you have an intolerance to some sugars, speak to your doctor before taking this medicinal product.

You will receive a box containing blister packs of 28 tablets, which are 200mg each.

