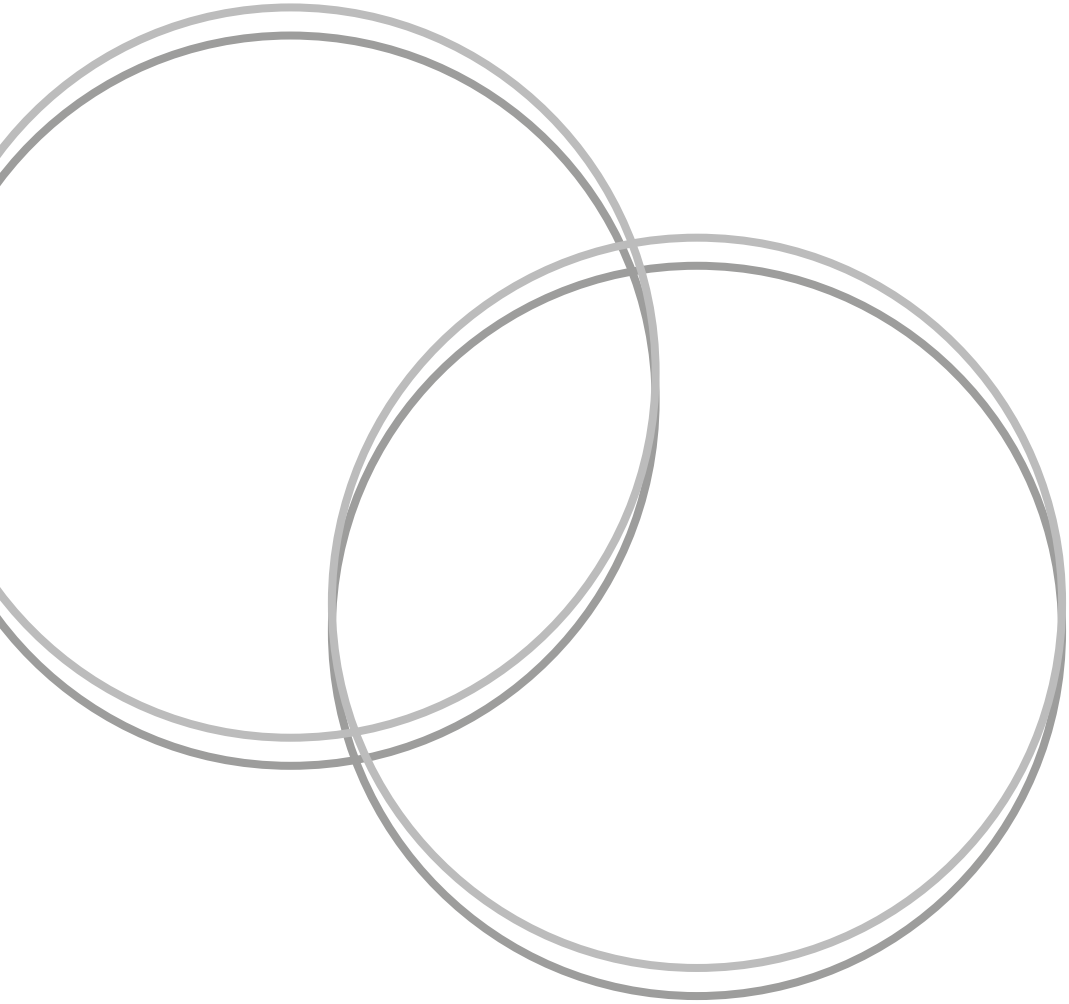
Oxford University Hospitals
NHS Foundation Trust

Linzagolix for symptoms of Endometriosis or Fibroids

Information for patients



This leaflet provides important information about Linzagolix and answers some common questions. Further information can be found in the manufacturer's patient information leaflet or please ask your Gynaecologist, Specialist Nurse or Pharmacist.

Why have I been started on this medication?

Your Gynaecologist has recommended that you take linzagolix to help you with symptoms caused by endometriosis or fibroids.

Endometriosis is when tissue similar to that lining the uterus (womb), grows outside the uterus, most commonly in the pelvis or abdomen. Because the tissue growing outside the uterus still responds to menstrual cycle hormones, it changes with your cycle and can cause pain and inflammation.

Fibroids, also called myomas or leiomyomas, are non-cancerous growths inside or around the uterus. Some people who have fibroids do not notice any problems, but others may experience symptoms such as heavy or painful periods, pain in the lower abdomen, lower back pain or constipation.

How does Linzagolix work?

- Linzagolix 100mg and 200mg tablets work by reducing how much oestrogen and progesterone is produced by your ovaries.
- Oestrogen and progesterone are the female hormones that regulate your menstrual cycle and help prepare your body for pregnancy if needed. Levels of these hormones reduce naturally at menopause.
- Although oestrogen has an important role in your body it can also make fibroids and endometriosis grow, which makes symptoms worse. By reducing oestrogen levels, Linzagolix can help to:
  - » ease pain caused by fibroids and endometriosis
  - » shrink fibroids
  - » reduce heavy bleeding
- Reducing oestrogen and progesterone helps symptoms of fibroids and endometriosis but causes side effects similar to the menopause. These include mood changes, hot flushes and loss of bone strength. To help prevent these side effects Linzagolix is usually taken alongside hormone replacement therapy (HRT) although the lower 100mg dose may sometimes be taken alone. Your doctor may ask you to start HRT at the same time as Linzagolix, or they may ask you to wait for up to 6 months before starting. The choice will depend on the reason you are taking Linzagolix and on future treatment plans. You should not take the 200mg dose for more than 6 months without HRT.
- Taking Linzagolix, with or without HRT keeps your hormonal levels low and steady, which helps control your symptoms.

Is Linzagolix suitable for everyone?

To help your Gynaecologist decide if Linzagolix is right for you, tell them if you:

- Have:
  - » high blood pressure
  - » osteoporosis
  - » depression or have previously suffered from depression
  - » kidney or liver disease
  - » have been told you have high levels of liver enzymes (sometimes called LFTs) in your blood
- Could be pregnant or are breastfeeding

Also tell your doctor about any other medicines you take including any herbal supplements.

What are the side effects?

Very Common: hot flushes. One person in every ten who takes Linzagolix might get these.

Common: loss of libido (low sex drive), headache, nausea, constipation, excessive sweating, night sweats, joint pain, pelvic pain, mood changes, irregular, heavy or prolonged bleeding from the uterus vaginal dryness, loss of bone strength, and increases in liver enzymes. Between one and ten people out of every 100 people who take Linzagolix might get these.

The increase in liver enzymes is usually harmless and doesn't cause any symptoms, however if you notice yellowing of your skin or the whites of your eyes (jaundice), nausea or vomiting, fever, severe tiredness, dark urine, itching or upper abdominal pain see your doctor straight away as these could be signs of liver problems.

Uncommon: high blood pressure. One person in every 100 people who take Linzagolix might get this.

What do I do if I experience side effects?

You will have a review with a member of your hospital gynaecology team 3 months after starting Linzagolix, please discuss any side effects with them. If unwanted effects appear after your review please discuss them with your GP in the first instance.

How do I take Linzagolix?

The dose is either 100mg or 200mg taken as one tablet once daily at the same time every day, with or without food. To help you to remember to take your tablet choose a time of day that suits you.

How and where do I get the tablets?

The hospital Gynaecologist who starts you on Linzagolix will prescribe you a 3 month supply. You will have a review with a member of the Gynaecology team at around 3 months, which might be in person or over the phone. If you are both happy that Linzagolix is suitable for you the Gynaecologist will prescribe a further 2 months' supply and write to your GP who will then provide further prescriptions.

How long does it take to work?

It usually takes two to three months to see an improvement; some people continue to experience further improvement for a few months after that.

How long will I be taking it for?

If you and your Gynaecologist are both happy that Linzagolix is suitable for you then you can take it until your menopause.
At menopause your levels of oestrogen drop naturally and most people find that their symptoms improve at this point. Some people might need to stop taking Linzagolix earlier if they get side effects, or if you or your doctor decide it is not the best treatment for you. Talk to your doctor before stopping Linzagolix.

What if I forget a dose?

If you forget a tablet take it as soon as you remember. Take the next tablet at the usual time the following day. Do not take a double dose to make up for any missed tablets.

Do I need any special checks while I'm on Linzagolix?

When you have been taking Linzagolix for a year you should have a bone density scan (also called a DEXA) to check your bone strength. The scan is quick and painless and is to check that Linzagolix is not affecting your bones. The results from a bone density scan are usually used alongside a fracture risk assessment to assess your chances of osteoporosis and breaking a bone. Whilst you are taking Linzagolix you should have yearly reviews of your treatment which should include assessment of fracture risk.

Your Gynaecologist will talk to you about having a DEXA scan when you attend your 3-month review if you both agree you should continue with Linzagolix.

Linzagolix and contraception

Linzagolix has not been shown to provide contraception. If it is possible that you could become pregnant you must use effective non-hormonal methods of contraception (for example condoms) to prevent pregnancy.

Linzagolix should not be taken with hormonal contraception ('the pill').

Linzagolix and pregnancy

There is no information on the safety of Linzagolix during pregnancy and you should not take Linzagolix if you are pregnant.

If you would like to plan a pregnancy discuss this with your doctor before stopping Linzagolix and any HRT you are taking.

While you are taking Linzagolix you may have lighter, shorter periods or no periods at all. This can make it harder to recognise if you become pregnant. If you suspect you could be pregnant do a pregnancy test and if you get a positive result stop taking Linzagolix and any HRT straight away and contact your GP or specialist team.

Where can I get more information and support?

If you have any concerns about your treatment that cannot wait until your three-month review please contact the gynaecology department:

Telephone: 01865 231571 (Monday to Friday 9am-4pm)

Email: **Gynae.Secretaries@ouh.nhs.uk**

After this please speak to your GP in the first instance.

You can find more information in the manufacturer's patient information leaflet (PIL), in each pack of Linzagolix, or search for Linzagolix online at **www.medicines.org.uk/emc/browse-medicines**.

More about endometriosis and fibroids can be found on the NHS website under Health A to Z, conditions A to Z.

www.nhs.uk/health-a-to-z/

www.nhs.uk/conditions/endometriosis/

www.nhs.uk/conditions/fibroids/

More information about DEXA scans can be found on the NHS website under Health A to Z, tests and treatments A to Z.

Bone density scan (DEXA scan) - NHS
www.nhs.uk/tests-and-treatments/dexa-scan/

Further information

If you would like an interpreter, please speak to the department where you are being seen.

Please also tell them if you would like this information in another format, such as:

- Easy Read
- large print
- braille
- audio
- electronic
- another language.

We have tried to make the information in this leaflet meet your needs. If it does not meet your individual needs or situation, please speak to your healthcare team. They are happy to help.

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