NHS
Royal Berkshire
NHS Foundation Trust

Ulipristal acetate (Esmya) for fibroids

This information is for women who have been offered treatment with ulipristal acetate for fibroids. Fibroids are non-cancerous growths that develop in or around the womb (uterus). The growths are made up of muscle and fibrous tissue and vary in size.

What is ulipristal acetate?

Ulipristal acetate may also be called Esmya. It is a tablet taken orally once a day for a course of three months. It can reduce the size of your fibroids and can also stop or reduce bleeding.

Restrictions

The use of ulipristal acetate was temporarily suspended in 2020 due to the risk of severe liver injury. The suspension has now been lifted but the indications for its use have been restricted. The risk of severe liver injury does not justify its use for the pre-operative treatment of fibroids. However, the benefits of 5mg ulipristal acetate in controlling fibroids may outweigh this risk in women who have no other treatment options.

Am I eligible for treatment with ulipristal acetate?

Ulipristal acetate should only be used for intermittent treatment of moderate to severe symptoms of uterine fibroids before menopause and when surgical procedures (including uterine fibroid embolisation) are not suitable or have failed.

What are the risks of taking ulipristal acetate?

Rare but serious cases of liver injury, including cases of liver failure requiring liver transplantation have been reported in women treated with ulipristal acetate. **You should not take it if you have an existing liver condition.**

Ulipristal acetate makes hormonal contraception (such as the pill, the implant, the depo injection or the Mirena IUS) **less effective**. You should use an additional reliable barrier method, such as condoms, to prevent pregnancy while you take ulipristal acetate. **You should not take it if you are pregnant or breastfeeding.**

Will I be monitored whilst I take ulipristal acetate?

We will arrange close monitoring of your liver function whilst you take ulipristal acetate.

- **Before the course:** You will have a blood test to confirm your liver is functioning normally. You should not start treatment with ulipristal acetate until your doctor has confirmed the results with you. You should not take it if your transaminase level (known as ‘AST’ or ‘ALT’ level is two times the upper limit of normal.

- **During the course:** Blood tests to check your liver function will be repeated monthly during the first two treatment courses. If you take more than two courses, blood tests will be taken before you start each course. Your doctor will discuss the results with you.
- **At the end of the course:** Blood tests to check your liver function will be taken two to four weeks after you complete a course of ulipristal acetate.

When to stop ulipristal acetate

You should treatment and contact your doctor immediately if you experience any signs that may be caused by liver damage. These include:

- feeling or being sick (nausea or vomiting)
- fatigue, severe tiredness
- jaundice (yellowing of the eyes or skin)
- dark urine
- itching
- upper stomach ache.

You will be also be advised to stop treatment if your transaminase levels (ALT or AST) are greater than three times the upper limit of normal.

Further information

More information is available at:

- www.nhs.uk/conditions/fibroids/treatment/
- https://www.gov.uk/drug-safety-update/ulipristal-acetate-5mg-esmya-further-restrictions-due-to-risk-of-serious-liver-injury

To find out more about our Trust visit www.royalberkshire.nhs.uk

Please ask if you need this information in another language or format.

S Phillip, Consultant Obstetrician, March 2019
Reviewed: October 2023
Next review due: October 2025