

## Esmya (ullipristal acetate) for fibroids

---

This information leaflet is for women who have been offered treatment with Esmya for fibroids.

---

### What is Esmya?

Esmya is a tablet taken orally once a day for a course of 3 months. It is a very effective treatment for women who have symptoms caused by fibroids. Fibroids are non-cancerous growths in the uterus. Symptoms from fibroids can include heavy menstrual bleeding (heavy periods), pelvic pain, and pressure on other organs. Esmya can reduce the size of your fibroids and can also stop or reduce bleeding.

### What are the risks of taking Esmya?

Rare but serious cases of liver injury, including cases of hepatic failure requiring liver transplantation, have been reported worldwide in women treated with Esmya for the symptoms of uterine fibroids. For this reason, you should not take Esmya if you have an existing liver condition.

Esmya makes hormonal contraception (such as the pill, the implant, the depo injection or the Mirena IUS) less effective. It is therefore advised that you use additional reliable barrier method such as condoms to prevent pregnancy whilst you take Esmya. You should discuss this with your doctor before starting treatment.

You should not take Esmya if you are pregnant or breastfeeding

### Am I eligible for treatment with Esmya?

More than one course of Esmya can be taken by women of reproductive age with moderate to severe symptoms of fibroids who are not eligible for surgery. A single 3 month course of treatment can be taken by women of reproductive age before they have surgery for fibroids.

### Will I need monitoring whilst I take Esmya?

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

#### **Before the course**

Before you start treatment with Esmya you will have a blood test to confirm your liver is functioning normally. You should not start taking Esmya until your doctor has confirmed the results with you.

### **During the course**

Blood tests to check your liver function will be repeated monthly during the first 2 treatment courses. If you take more than 2 courses, blood tests will be taken before you start each course. Your doctor will discuss the results with you. If, in the unlikely event that there are any abnormalities we may advise that you stop taking Esmya.

### **At the end of the course**

Blood tests to check your liver function will be taken 2 to 4 weeks after you complete a course of Esmya.

### When to stop Esmya

You should stop taking Esmya and contact your doctor immediately if you experience any signs which may be caused by liver damage such as feeling of being sick (nausea or vomiting), fatigue, severe tiredness, jaundice (yellowing of the eyes or skin), dark urine, itching or upper stomach ache.

### Further information

More information is available at:

[www.nhs.uk/conditions/fibroids/treatment/](http://www.nhs.uk/conditions/fibroids/treatment/)

[www.gov.uk/drug-safety-update/esmya-ulipristal-acetate-and-risk-of-serious-liver-injury-new-restrictions-to-use-and-requirements-for-liver-function-monitoring-before-during-and-after-treatment](http://www.gov.uk/drug-safety-update/esmya-ulipristal-acetate-and-risk-of-serious-liver-injury-new-restrictions-to-use-and-requirements-for-liver-function-monitoring-before-during-and-after-treatment)

[www.rcog.org.uk/en/guidelines-research-services/guidelines/esmya-ulipristal-acetate---mhra-safety-alert/](http://www.rcog.org.uk/en/guidelines-research-services/guidelines/esmya-ulipristal-acetate---mhra-safety-alert/)

For more information about the Trust, visit our website at [www.royalberkshire.nhs.uk](http://www.royalberkshire.nhs.uk)

This document can be made available in other languages and formats upon request.

Department of Gynaecology, March 2019

Review due: March 2021