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## Ulipristal acetate for uterine fibroids (Esmya)

**Clinical author's note: Michael Stewart 04/03/2021:** following a temporary licence suspension and review into liver safety, **additional restrictions and safety measures** are now in place for Esmya® (ulipristal).

- Rare cases of serious liver damage have occurred in people taking Esmya® (ulipristal) for uterine fibroids
- Blood tests are needed before, during and after treatment with Esmya® to check your liver is working normally
- If you notice any signs of liver damage, including yellowing of the skin or eyes, dark urine, or nausea or vomiting, stop taking Esmya® and contact your doctor immediately

Your doctor will discuss both the risks and benefits of your treatment. A patient alert card describing the risk of liver injury should be given to you with your packet of medicine.

**Clinical author's note: Michael Stewart 20/02/2018: temporary safety measures** have been put in place for Esmya® (ulipristal) following five reports of serious liver injury in women taking this medicine for uterine fibroids. Contact your doctor or pharmacist for advice if you have any concerns. This issue does not affect ulipristal when taken as a single one-off dose for **emergency contraception using EllaOne®**.

Ulipristal acetate is a female hormone treatment.

Take one tablet daily.

The most common side-effects are no periods, hot flushes, and headache.

# About ulipristal acetate for uterine fibroids

Type of medicine	A progesterone receptor modulator
Used for	Fibroids in the uterus
Also called	Esmya®
Available as	Tablets

Ulipristal acetate works by blocking the effects of the female hormone progesterone. There are two brands of ulipristal acetate tablets available. The two brands of tablet have different uses and contain different amounts of ulipristal acetate. Low-strength tablets (Esmya® brand containing 5 mg ulipristal acetate) are used to treat heavy or painful periods caused by [uterine fibroids](#). This leaflet discusses ulipristal acetate when it is prescribed for this purpose. More information is available about the higher strength of ulipristal acetate tablet (EllaOne® brand) in the medicine leaflet called [Emergency hormonal contraception](#).

Fibroids (which are also known as myomas) are non-cancerous growths in the womb (uterus). They can sometimes cause heavy or painful periods, tummy swelling and urinary problems. Surgery is the most common treatment for fibroids which cause symptoms. Ulipristal acetate is prescribed to reduce the size of the fibroids before the surgery.

The female hormone progesterone is thought to play a role in the development of fibroids. Ulipristal acetate works by blocking the effects of progesterone. This stops the fibroids from growing and they shrink in size.

## Before taking ulipristal acetate for uterine fibroids

Some medicines are not suitable for people with certain conditions, and sometimes a medicine may only be used if extra care is taken. For these reasons, before you start taking ulipristal acetate for uterine fibroids it is important that your doctor knows:

- If you are pregnant or breastfeeding.
- If you have severe asthma.
- If you have any problems with the way your liver works, or any problems with the way your kidneys work.
- If you have breast cancer, or cancer of the womb (uterus), neck of the womb (cervix), or ovaries.
- If you have ever had an allergic reaction to a medicine.
- If you are taking any other medicines. This includes any medicines you are taking which are available to buy without a prescription, as well as herbal and complementary medicines.

## **How to take ulipristal acetate for uterine fibroids**

- Before you start the treatment, read the manufacturer's printed information leaflet from inside the pack. It will give you more information about ulipristal acetate and will provide you with a full list of the side-effects which you may experience from taking it.
- Take ulipristal acetate exactly as your doctor tells you to. You will be asked to start taking the tablets during a week you are having a period. Continue to take one 5 mg tablet each day. You will be prescribed the tablets for a maximum of four months, possibly on two occasions.
- You can take ulipristal acetate tablets before or after food. Swallow the tablets with a drink of water.
- If you forget to take a dose, take it as soon as you remember unless you are more than 12 hours late. If you are more than 12 hours late, leave out the forgotten dose and take your next tablet at the usual time. Do not take two tablets together to make up for a missed dose.

## **Getting the most from your treatment**

- Try to keep your regular appointments with your doctor. This is so your doctor can check on your progress.

- You should avoid getting pregnant both while you are taking ulipristal acetate and for at least 12 days after stopping taking it. Please use a barrier method of contraception (such as a condom), as hormonal methods of contraception are not suitable with ulipristal acetate. If you need further contraceptive advice, please speak with your doctor.
- Do not drink grapefruit juice while you are on ulipristal acetate. This is because a chemical in grapefruit juice can increase the amount of ulipristal acetate in your bloodstream. This could make side-effects more likely.

## **Can ulipristal acetate tablets cause problems?**

Along with their useful effects, most medicines can cause unwanted side-effects although not everyone experiences them. The table below contains some of the most common ones associated with ulipristal acetate. You will find a full list in the manufacturer's information leaflet supplied with your medicine. The unwanted effects often improve as your body adjusts to the new medicine but speak with your doctor or pharmacist if any of the following continue or become troublesome.

<b>Very common ulipristal acetate side-effects (these affect more than 1 in 10 women)</b>	<b>What can I do if I experience this?</b>
No periods during the treatment and for a few weeks afterwards, thickening of the lining of the womb (uterus)	Your doctor will discuss these with you before you start the treatment
<b>Common ulipristal acetate side-effects (these affect fewer than 1 in 10 women)</b>	<b>What can I do if I experience this?</b>
Headache, other aches or pains	Drink plenty of water and ask your pharmacist to recommend a suitable painkiller. If the pain continues, let your doctor know
Feeling dizzy or tired	Do not drive and do not use tools or machines while affected
Feeling sick (nausea), tummy (abdominal) pain	Stick to simple meals - avoid rich and spicy foods
Acne, increased weight, breast tenderness, hot flushes	If any of these become troublesome, speak with your doctor

**Important:** rare cases of serious liver damage have occurred in people taking Esmya® (ulipristal) for uterine fibroids:

- Blood tests are needed before, during and after treatment with Esmya® to check your liver is working normally.
- If you notice any signs of liver damage, including yellowing of the skin or eyes, dark urine, or nausea or vomiting, stop taking Esmya® and contact your doctor immediately.

If you experience any other symptoms which you think may be due to the tablets, please speak with your doctor or pharmacist for further advice.

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## How to store ulipristal acetate

- Keep all medicines out of the reach and sight of children.
- Store in a cool, dry place, away from direct heat and light.

## Important information about all medicines

Never take more than the prescribed dose. If you suspect that you or someone else might have taken an overdose of this medicine, go to the accident and emergency department of your local hospital. Take the container with you, even if it is empty.

This medicine is for you. Never give it to other people even if their condition appears to be the same as yours.

If you are having an operation or dental treatment, please tell the person carrying out the treatment which medicines you are taking.

If you buy any medicines, check with a doctor or pharmacist that they are suitable for you to take with your other medicines.

Do not keep out-of-date or unwanted medicines. Take them to your local pharmacy which will dispose of them for you.

If you have any questions about this medicine ask your pharmacist.

If you experience side effects, you can report them online through the [Yellow Card website](#).

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## Further reading

- [Manufacturer's PIL, Esmya® 5 mg tablets \(ulipristal acetate\)](#); Gedeon Richter (UK) Ltd, The electronic Medicines Compendium. Dated January 2021.
- [Medicines Complete BNF 88th Edition](#); British Medical Association and Royal Pharmaceutical Society of Great Britain, London.

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