

YOU AND ESMYA[®]

A GUIDE FOR WOMEN WHO HAVE
BEEN PRESCRIBED ESMYA[®]

For more information please refer to
the Package Information Leaflet (PIL),
it contains important information for you.

esmya[®]
Ulipristal acetate

INTRODUCTION

You have been prescribed ESMYA® for the treatment of uterine fibroids. This guide provides important information for you before you start taking the tablets. It will help you to understand your condition and your treatment, and should be referred to alongside the PIL. Please speak to your doctor or pharmacist if you have any concerns.

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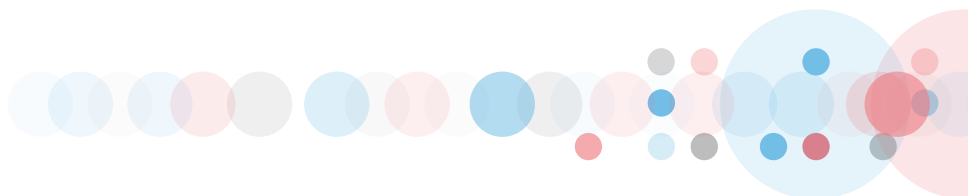
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WHAT ARE UTERINE FIBROIDS?

Uterine fibroids are unusual growths found in the muscle of the uterus (the medical term for your womb). They grow very slowly and over time can become very large. When this happens, they can cause pain and discomfort and (unsurprisingly) have a negative impact on your day-to-day life. Sometimes you may hear them referred to as 'tumours', which may sound alarming, but rest assured uterine fibroids are not a type of cancer. 'Tumour' simply means an unexpected growth.

HOW COMMON ARE THEY?

Uterine fibroids are very common: more than 40% of women will develop them at some point in their lives. Typically, they affect women of childbearing age (usually over the age of 35). However, the causes of uterine fibroids are not fully understood. What we do know is that they respond to changes in progesterone levels in your body – a naturally occurring hormone. Treatments that target progesterone, like ESMYA®, can help control the growth of uterine fibroids and the symptoms that they can cause.

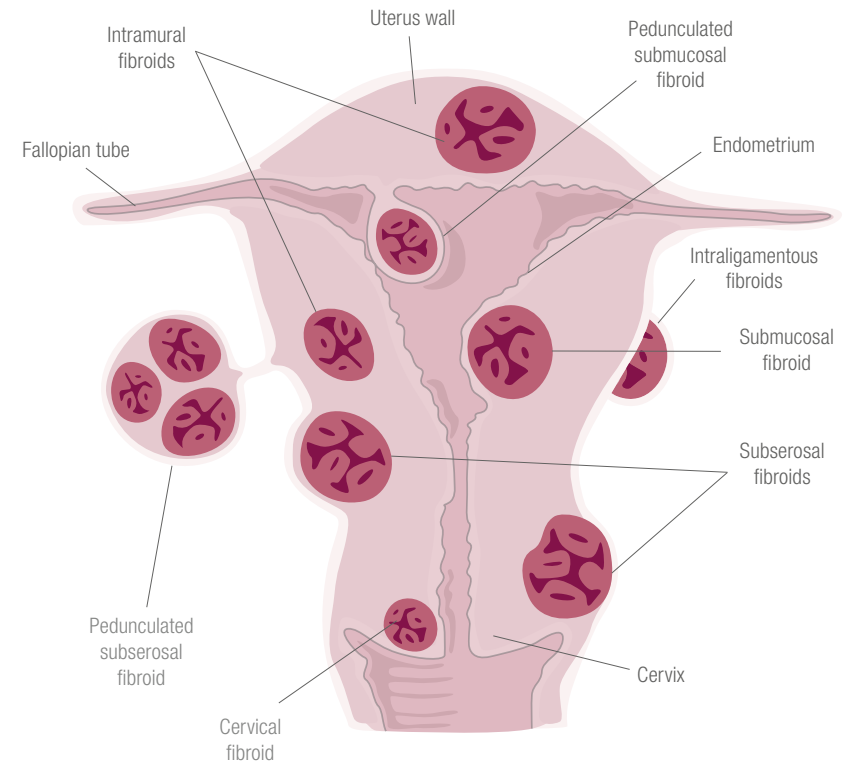


ARE THERE DIFFERENT TYPES OF UTERINE FIBROIDS?

There are many different types of uterine fibroids. Each type is found in a different location in the uterus, and a combination of different types can also occur:

- **Intramural fibroids** are found within the wall of the uterus and are the most common type
- **Subserosal fibroids** are found on the outer wall of the uterus. Sometimes they are attached by a thin stalk called a peduncle. These types are called 'pedunculated subserosal fibroids' and can cause a lot of pain because they can twist around or compress other organs in the stomach
- **Submucosal fibroids** grow on the inner wall of the uterus (endometrium). Because they push into the uterus, they can cause it to change in shape and size. Submucosal fibroids can also be pedunculated
- **Cervical fibroids** are found in the 'neck' (cervix) of the uterus
- **Intraligamentous fibroids** grow on the ligaments that hold the uterus in place

Illustration shows different types of uterine fibroids



WHAT ARE THE SYMPTOMS?

Uterine fibroids don't always cause symptoms, but you may experience:

- Heavy, painful periods that last a long time
- Anaemia (a lack of red blood cells) due to heavy periods, causing extreme tiredness
- Bleeding between periods
- A feeling of pressure in the bladder and stomach
- Needing to go to the toilet more often than usual
- Discomfort while going to the toilet
- A visible increase in the size of the stomach
- Constipation
- Pain during sex
- Complications during pregnancy, such as an increased risk of miscarriage and/or problems during labour
- Difficulty getting pregnant
- General fatigue

WHAT IS ESMYA®?

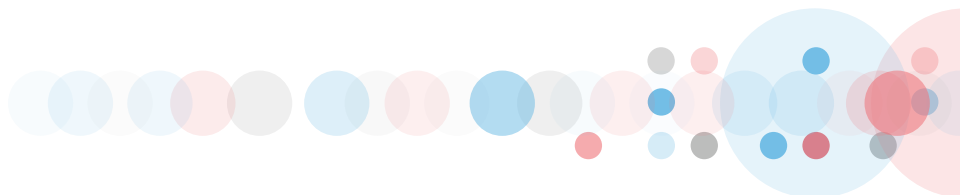
ESMYA® is a 5 mg pill taken by mouth. It contains the active substance ulipristal acetate and is used to treat moderate to severe symptoms of fibroids. Created especially for women with uterine fibroids, it stops certain organs (that is the uterus, cervix and ovaries) from reacting to the hormone progesterone. ESMYA® can stop fibroid cells growing and dividing, so eventually they die. By reducing the size of the fibroids it relieves the symptoms caused by them.

ESMYA® has now been used for treating uterine fibroids in over 193,000 women in 47 countries. (Data on file: IMS data for ESMYA®, end-May 2015)

WHY IS ESMYA® DIFFERENT?

ESMYA® doesn't just control the symptoms of uterine fibroids – it targets the cause of the condition (the first treatment to do this). By using an 'intermittent' therapy approach (3 months 'on' treatment followed by about 2 months 'off'), ESMYA® relieves the symptoms of uterine fibroids and shrinks them – effects that continue even when you're not taking ESMYA®.

ESMYA® is used either before an operation on your fibroids or for the long-term treatment of your fibroids in order to reduce their size, to stop or reduce bleeding, and to increase your red blood cell count.



WHAT TO EXPECT FROM ESMYA®

Benefits

ESMYA® improves a wide range of uterine fibroid symptoms:

- Brings bleeding under control quickly (normally within a week)
- Shrinks fibroids
- Reduces pain
- Improves women's quality of life

Side effects

Please refer to the PIL for a full list of side effects.

ESMYA® is well tolerated, even during long-term treatment. However, some people have experienced side effects, the most common being headaches and hot flushes. However, the vast majority of these are mild-to-moderate, temporary and go away on their own.

If you are worried about any side effects, please speak to your doctor or pharmacist.

HOW AND WHEN TO TAKE ESMYA®

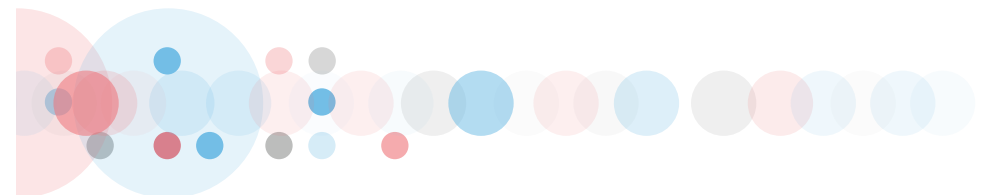
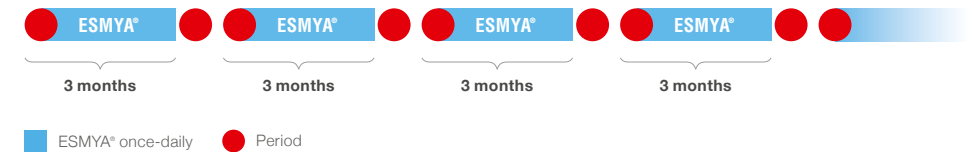
Always take ESMYA® exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

ESMYA® uses an 'intermittent' treatment schedule.

- Take one 5 mg pill once-daily for 3 months, then stop for about 2 months
- The first treatment course should start during the first week of your period (repeated courses start as early as you can during the first week of the second period, after the previous treatment course is completed)
- Choose the time of day you prefer to take your pill and stick to it

Dosing schedule



HOW AND WHEN TO TAKE ESMYA®

Facts to remember:

- It's important that each treatment course starts at the correct point during your period
- If a dose is missed, ESMYA® should be taken as soon as possible. If the dose was missed by more than 12 hours, the missed dose should not be taken – instead, the usual dosing schedule should be resumed
- You should avoid drinking grapefruit juice while on treatment with ESMYA®
- Please note that most women have little or no periods during the treatment and for a few weeks afterwards
- Keep the blister pack in its outer carton to protect from the sunlight

Again, if you are worried about any side effects or missing a dose, please speak to your doctor.

NOTES:

USEFUL RESOURCES

Women's Health

www.womens-health.co.uk/fibroids.asp

NHS Choices

www.nhs.uk/conditions/Fibroids/Pages/Introduction.aspx

British Fibroid Trust

www.britishfibroidtrust.org.uk

ESMYA® AND UTERINE FIBROIDS – IN BRIEF

Uterine fibroids

- Are unusual growths found in the muscle wall of the uterus (the medical term for your womb)
- Can cause heavy and painful periods and have a negative impact on your day-to-day life
- Respond particularly to changes in progesterone levels (a type of natural hormone)

ESMYA®

- Targets progesterone to control uterine fibroid growth and symptoms
- Is the first treatment specifically designed not only to control various symptoms of uterine fibroids but also to manage the condition
- Brings bleeding under control within 5-6 days, shrinks fibroids, improves quality of life and greatly reduces pain
- Is well tolerated and has now been used for treating uterine fibroids in over 193,000 women in 47 countries^{(Data on file: IMS data}

for ESMYA®, end-May 2015)

