

Consumer Medicine Information**What is in this leaflet**

This leaflet answers some common questions about Esmya®. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you being given Esmya® against the expected benefits it will have for you.

If you have any concerns about being given this medicine, ask your doctor.

Keep this leaflet.

You may need to read it again.

What Esmya® is used for

Esmya® contains the active substance ulipristal acetate. It is used to treat moderate to severe symptoms of uterine fibroids (commonly known as myomas), which are non-cancerous tumours of the uterus (womb).

Esmya® is used in adult women (over 18 years of age) before they reach menopause.

In some women, uterine fibroids may cause heavy menstrual bleeding (your 'period'), pelvic pain (discomfort in the belly) and create pressure on other organs.

This medicine acts by modifying the activity of progesterone, a naturally occurring hormone in the body. It is used either before an operation on your fibroids or for long term treatment of your fibroids to reduce their size, to stop or reduce bleeding and to increase your red blood cell count.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you take Esmya®

You should know that most women have no menstrual bleeding (period) during the treatment and for a few weeks afterwards.

When you must not take it

- if you are allergic to ulipristal acetate or any of the ingredients listed at the end of this leaflet.
- if you are pregnant or if you are breastfeeding.
- if you have vaginal bleeding not caused by uterine fibroids.
- if you have cancer of the uterus (womb), cervix (the neck of the womb), ovary or breast.

You should not use this medicine after the expiry date printed on the Esmya® pack or if the packaging is torn or shows signs of tampering.

Before you start to take Esmya®**Tell your doctor or pharmacist:**

- **If you have allergies to any other medicines, foods, preservatives or dyes.**
- If you are currently taking hormonal contraception (for example birth control pills) (see "Taking other medicines") you should use an alternative reliable

barrier contraceptive method (such as a condom) while taking Esmya®.

- If you have liver or kidney disease.
- If you suffer from severe asthma.

Treatment with Esmya® may not be suitable for you.

Treatment with Esmya® usually leads to a significant reduction or may even stop your menstrual bleeding (your 'period') within the first 10 days of treatment. However, if you continue to experience excessive bleeding tell your doctor.

Your period should generally return within 4 weeks after treatment with Esmya® is stopped. The lining of the uterus may thicken or change as a result of taking Esmya®.

These changes return to normal after treatment is stopped and your periods restart.

If you have not told your doctor about any of the above, tell him/her before you take Esmya®.

Children and adolescents

Esmya® should not be taken by children under 18 years of age.

Pregnancy and breast-feeding

Do not take Esmya® if you are pregnant. Treatment while pregnant might affect your pregnancy (it is not known if Esmya® might harm your baby or whether it can cause miscarriage). If you do become pregnant during Esmya® treatment, you should stop taking Esmya® immediately and contact your doctor or pharmacist.

Esmya® passes into the breast milk. Therefore, do not breast-feed your baby while taking Esmya®.

Ask your doctor or pharmacist for advice before taking any medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket, health food shop, naturopath, herbalist or internet.

Tell your doctor or pharmacist if you are taking any of the medicines listed below, as these medicines can affect Esmya® or be affected by Esmya®:

- Certain medicines which are used to treat the heart (e.g. digoxin).
- Certain medicines used to prevent strokes and blood clots (e.g. dabigatran etexilate).
- Certain medicines used to treat epilepsy (e.g. phenytoin, fosphenytoin, phenobarbital, carbamazepine, oxcarbazepine, primidone).
- Certain medicines used to treat HIV infection (e.g. ritonavir, efavirenz, nevirapine).
- Medicines used to treat certain bacterial infections (e.g. rifampicin, telithromycin, clarithromycin, erythromycin, rifabutin).
- Certain medicines to treat fungal infections (e.g. ketoconazole (except shampoo), itraconazole).

- Herbal remedies containing St John's wort (*Hypericum perforatum*) used for depression or anxiety.
- Certain medicines used to treat depression (e.g. nefazodone).
- Certain medicines used to treat hypertension (e.g. verapamil).

Esmya® is likely to make some hormonal contraceptives less effective. In addition, hormonal contraceptives and progestagens (e.g. norethindrone or levonorgestrel) are also likely to make Esmya® less effective. Therefore, hormonal contraceptives are not recommended and you should use an alternative reliable barrier contraceptive method, such as a condom, during treatment with Esmya®.

Esmya® with food and drink

You should avoid drinking grapefruit juice while on treatment with Esmya®.

How to take Esmya®

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one 5 mg tablet per day, for treatment courses of up to 3 months each. If you have been prescribed several courses of Esmya® 3-month treatment, you should start each course at the earliest during the first week of the second menstrual period following the previous treatment completion.

You should always start taking Esmya® within the first week of your menstrual period.

How to take Esmya®

The tablet should be swallowed with water and may be taken with or without food.

If you forget to take it

If you miss a dose by less than 12 hours, take it as soon as you remember. If you miss a dose by more than 12 hours, skip the missed tablet and take only a single tablet as usual. Do not take a double dose to make up for the missed dose.

If you stop taking it

Esmya® is to be taken daily during treatment courses of up to 3 months continuously. During each course of treatment, do not stop taking your tablets without the advice of your doctor even if you feel better, as symptoms may re-occur later.

If you take too much (overdose)

Experience with Esmya® when several doses are taken at once is limited. There have been no reports of serious harmful effects from taking several doses of this medicine at once. You should nonetheless ask your doctor or pharmacist, or telephone the Poisons Information Centre in Australia (telephone 13 11 26) or National Poisons Centre in New Zealand (telephone 0800 POISON or 0800 764 766), for advice if you take more Esmya® than you should.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Esmya®.

Do not be alarmed by the following list of side effects, you may not experience any of them.

Tell your doctor if you notice any of the following common side effects and they worry you:

- reduction or absence of menstrual bleeding (amenorrhoea)
- thickening of the lining of the womb (endometrial thickening)
- headache
- spinning sensation (vertigo)
- stomach ache, feeling sick (nausea)
- acne
- muscle and bone (musculoskeletal) pain
- sac of fluid within the ovaries (ovarian cyst), breast tenderness/pain, lower abdominal (pelvic) pain, hot flushes
- tiredness (fatigue)
- weight increase.

Other uncommon or rare side effects include:

- anxiety
- mood swings
- dizziness
- dry mouth, constipation
- hair loss, dry skin, increased sweating
- back pain
- leakage of urine
- bleeding from the womb (uterine bleeding), vaginal discharge, abnormal vaginal bleeding
- breast discomfort
- swelling due to fluid retention (oedema)
- extreme tiredness (asthenia)
- increase in blood cholesterol seen in blood tests, increase in blood fats (triglycerides) seen in blood tests.
- nosebleed
- indigestion, bloating
- break of sac of fluid within the ovaries (ovarian cyst ruptured)
- breast swelling.

Tell your doctor if you notice anything that is making you feel generally unwell.

Other side effects not listed above are rare and may also occur in some people.

Esmya® may cause mild dizziness. Do not drive or use machines if you experience these symptoms.

Storage

Store below 30°C. Keep the blister in the outer carton to protect from light.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Keep Esmya® out of the sight and reach of children.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Esmya® is white to off-white, round curved tablet of 7 mm engraved with code "ES5" on one face.

Esmya® is available in Alu/PVC/PE/PVDC blisters or Alu/PVC/PVDC blisters in cartons containing 28 tablets.

Ingredients

- The active ingredient is ulipristal acetate. One tablet contains 5 mg of ulipristal acetate.
- The inactive ingredients are microcrystalline cellulose, mannitol, croscarmellose sodium, talc and magnesium stearate.

Supplier

Esmya® is supplied in Australia by:

Vifor Pharma Pty Ltd

Level 8, 80 Dorcas Street
Southbank, Melbourne VIC 3006
Australia

Tel: 1800 202 674

Esmya® is supplied in New Zealand by:

Pharmacy Retailing (NZ) Limited (trading as Healthcare Logistics)

58 Richard Pearse Drive
Airport Oaks, Mangere, 2022
New Zealand

Tel: 0800 996 312

Australian registration number:
AUST R 237700

This leaflet was prepared in December 2017