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Package leaflet: Information for the patient

Ulipristal Acetate 5 mg tablets

Ulipristal acetate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ulipristal is and what it is used for

Ulipristal 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).
Ulipristal is used in adult women (over 18 years of age) before they reach the 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 occuring hormone in the body. It is used for long term treatment of your fibroids to reduce their size, to stop or reduce bleeding and to increase your red blood cell count.

2. What you need to know before you take Ulipristal

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

DO NOT take Ulipristal:
- if you are allergic to ulipristal acetate or any of the other ingredients of this medicine (listed in section 6).
- If you have an underlying hepatic disorder
- 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.

Warnings and precautions:
- Before you start treatment with Ulipristal blood tests will be undertaken to find out how well your liver is working. Depending on the result of these tests your doctor will decide if treatment with Ulipristal is suitable for you. These tests will be repeated monthly for the first 2 treatment courses. For further treatment courses, your liver will be checked once before each new treatment course and if you experience any of the symptons described below. Moreover, an additional check of your liver 2-4 weeks after your treatment has stopped should be done. If during the treatment you experience any liver related signs 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, you should stop treatment and immediately contact your doctor, who will check the functioning of your liver and decide if you can continue the treatment.
- If you are currently taking hormonal contraception (for example birth control pills) (see "Other medicines and Ulipristal") you should use an alternative reliable barrier contraceptive method (such as a condom) while taking Ulipristal.
- If you have liver or kidney disease tell your doctor or pharmacist before taking Ulipristal.
- If you suffer from severe asthma, treatment with Ulipristal may not be suitable for you. You should discuss this with your doctor.

Treatment with Ulipristal 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 Ulipristal is stopped. The lining of the uterus may thicken or change as a result of taking Ulipristal. These changes return to normal after treatment is stopped and your periods restart.

Children and adolescents
Ulipristal should not be taken by children under 18 years of age since safety and efficacy of ulipristal acetate has not been established in this age group.

Other medicines and Ulipristal
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

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

Ulipristal with food and drink
You should avoid drinking grapefruit juice while on treatment with Ulipristal.

Pregnancy, breast-feeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

Ulipristal is likely to make some hormonal contraceptives less effective (see "Other medicines and Ulipristal").

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

Driving and using machines
Ulipristal may cause mild dizziness (see section 4 "Possible side effects"). Do not drive or use machines if you experience these symptoms.

Ulipristal contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium free".

3. How to take Ulipristal

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 Ulipristal 3 month treatment, you should start each course at the earliest during the second menstrual period following the previous treatment completion.

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

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

If you take more Ulipristal than you should
Experience with ulipristal acetate 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 for advice if you take more Ulipristal than you should.

If you forget to take Ulipristal
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 a forgotten tablet.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Ulipristal and immediately contact a doctor if you experience any of the following symptoms:
- swelling of face, tongue or throat; difficulty swallowing; hives and breathing difficulties. These are possible symptoms of angioedema (frequency not known).
- nausea or vomiting, severe tiredness, jaundice (yellowing of the eyes or skin), dark urine, itching or upper stomach ache. These symptoms may be signs of liver injury (frequency not known), which in a small number of cases led to liver transplantation. See also section 2 Warnings and precautions.

Very common (may affect more than 1 in 10 people) side effects:
- reduction or absence of menstrual bleeding (amenorrhea)
- thickening of the lining of the womb (endometrial thickening).

Common (may affect up to 1 in 10 people) side effects:
- 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.

Uncommon (may affect up to 1 in 100 people) side effects:
- drug allergy
- 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.

Rare (may affect up to 1 in 1,000 people) side effects:
- nosebleed
- indigestion, bloating
- break of sac of fluid within the ovaries (ovarian cyst ruptured)
- breast swelling.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for the MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ulipristal

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and on the blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

Store the blister in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ulipristal contains
- The active substance is ulipristal acetate. One tablet contains 5 mg of ulipristal acetate.
- The other ingredients are povidone (K29/32)sodium starch glycolate (Type A), cellulose, microcrystalline , lactose monohydrate (see section 2) and magnesium stearate.

What Ulipristal looks like and contents of the pack
Ulipristal is white or almost white, round biconvex tablet of 7 mm, engraved with "149" on one side and "LP" on the other side.
It is available in PVC/PVDC Aluminium blisters of 14 tablets each, in cartons containing 28 and 84 tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Mercury Pharmaceuticals Limited
Dashwood House,
69 Old Broad Street,
London, EC2M 1QS,
United Kingdom

Manufacturer
Cyndea Pharma S.L
Polígono Industrial Emiliano
Revilla Sanz.,
Avenida de Ágreda, 31,
42110 Ólvega, Soria, Spain

SC Labormed Pharma SA
44B Theodor Pallady Blvd,
3rd District 032266
Bucharest, Romania

Alvogen Malta (Out-Licensing) Ltd
Malta Life Sciences Park, Building 1,
Level 4, Sir Temi Zammit Buildings,
San Gwann SGN 3000, Malta

This leaflet was last revised in March 2024.

MercuryPharma

AW-LF-0000360 (v0.4)

Área para sellado
Sealing area
(adhesivo / adhesivo)

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Sealing area
Área para sellado
(adhesive / adhesivo)

Sentido de lectura
Reading direction
DataMatrix

Sentido de lectura
Reading direction
DataMatrix

40 mm
40 mm
40 mm
40 mm

320 mm
10 mm
10 mm
10 mm
10 mm
510 mm
85 mm

This artwork is Not Technically Approved
and technical approval needs to be taken, from the CMO, before Implementation.

MercuryPharma

AMS Component No.:	**AW-LF-0000360 (v0.4)**
Product Description:	**Ulipristal Acetate 5mg x 28s UK**
Component:	LF
Product Code:	104382
Country:	UK
Vendor Name:	Alvogen Malta (Out-Licensing) Ltd
Proof Number:	**0.4**
Revision Date:	15-Feb-2024
Revised by:	DAJ

Dimension:	320 x 510 mm
Commodity No.:	N/A
Pharma Code:	N/A
Print Colours:	Black
Non-Print Colours:	Cutter & Varnish Free
Min. Font Size:	9 pt

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