

Package leaflet: Information for the user

Progesterone 400 mg pessaries

Progesterone

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Progesterone is and what it is used for
2. What you need to know before you use Progesterone
3. How to use Progesterone
4. Possible side effects
5. How to store Progesterone
6. Contents of the pack and other information

1. What Progesterone is and what it is used for

Progesterone contains progesterone which is a natural, female sex hormone, produced in the body.

Progesterone is for women who need extra progesterone while undergoing treatment in an Assisted Reproductive Technology (ART) programme.

Progesterone acts on the lining of the womb and it helps you to become and to stay pregnant when you are treated for infertility.

2. What you need to know before you use Progesterone

Do not use Progesterone:

- if you are allergic to progesterone or any of the other ingredients of this medicine (listed in section 6),
- have unusual vaginal bleeding that has not been evaluated by the doctor,
- have known or suspected tumour that is hormone sensitive,
- have porphyria disorders (a group of inherited or acquired disorders of certain enzymes),
- have or have had blood clots in the legs, lungs, eyes or elsewhere in the body,
- currently have or have had severe liver problems,
- have a miscarriage and your physician suspects some tissue is still in the uterus or pregnancy outside of the womb.

Warnings and precautions

Take special care and tell your doctor straight away if you experience any of these symptoms during treatment or even few days after the last dosage:

- pains in the calves or chest, a sudden shortness of breath or coughing blood indicating possible clots in the legs, heart, or lungs
- severe headache or vomiting, dizziness, faintness, or changes in vision or speech, weakness or numbness of an arm or leg indicating possible clots in the brain or eye
- worsening of depression

Check with your doctor or pharmacist before using Progesterone if you have or ever have had:

- liver problems
- epilepsy
- migraine
- asthma
- cardiac or renal dysfunction
- diabetes

Children and adolescents

There is no relevant use of Progesterone in children.

Other medicines and Progesterone

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

This is especially important in case you are taking carbamazepine (e.g. to prevent fits, treat certain type of pain or mood disorders), rifampicin (to treat infections) or phenytoin (e.g. to prevent fits or treat certain type of pain) as they may decrease the effectiveness of progesterone.

Using other vaginal products at the same time as Progesterone is used vaginally is not recommended as it is not known if it affects the treatment.

Pregnancy and breast-feeding

Progesterone can be used during the first trimester of pregnancy for women who need extra progesterone while undergoing treatment in an Assisted Reproductive Technology (ART) programme.

The risks of congenital (conditions present at birth) anomalies, including genital abnormalities in male or female infants, from exposure to exogenous progesterone during pregnancy have not been fully established.

This medicine should not be used during breast feeding.

Driving and using machines

Progesterone has minor or moderate influence on the ability to drive and use machines. It may cause dizziness; therefore caution is advised in drivers and users of machines.

3. How to use Progesterone

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

The recommended dose is 400 mg twice a day by vaginal insertion. Start using Progesterone on the day of egg retrieval. If pregnancy has been confirmed, the administration of Progesterone should be continued for 38 days from the start of therapy .

How to insert Progesterone

Always wash your hands before and after inserting the pessary.

To insert into the vagina, place the pessary between the lips of the vagina and push the pessary upwards and backwards. You may find it easier to do this if you are lying down or squatting.

If you use more Progesterone than you should

If you (or someone else) has accidentally swallowed any of the pessaries or you use too many, contact your nearest hospital casualty department or your doctor immediately for advice.

If you forget to use Progesterone

If you forget to insert a pessary, do so as soon as you remember, unless it is nearly time for the next dose. Never use two doses together. Remember to use the remaining doses at the correct time.

If you stop using Progesterone

Please consult your doctor or pharmacist for advice if you intend to stop or have stopped using Progesterone. Abrupt discontinuation of progesterone dosing may cause increased anxiety, moodiness, and increased sensibility to seizures.

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.

Adverse reactions in patients undergoing ART treatment is presented below:

The following common side effects (may affect up to 1 in 10 people):

- Abdominal distension (swelling in the abdomen), abdominal pain, constipation
- Sleepiness
- Tiredness
- Hot flush
- Breast pain

The following uncommon side effects (may affect up to 1 in 100 people):

- Headache, dizziness, mood changes
- Change in taste, vomiting, flatulence (wind), diarrhoea, bloat (gastric dilatation)
- Night sweats, skin rash or itching
- Joint pain
- Pelvic pain, ovarian enlargement, vaginal bleeding
- Frequent urination, involuntary excretion of urine
- Weight increase
- Bleeding
- Itching at the application site, feeling cold or body temperature change or general discomfort

After using Progesterone you may notice some leakage after the pessary has dissolved. Do not worry, this is quite normal when using medicines that are inserted into the vagina or rectum.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Progesterone

Keep this medicine out of the sight and reach of children.

Do not store above 30 °C.

Do not use this medicine after the expiry date which is stated on the strip and carton after EXP. The expiry date refers to the last day of that month.

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 Progesterone contains

- The active substance is progesterone. Each pessary contains 400 mg progesterone
- The other ingredient is hard fat

What Progesterone looks like and contents of the pack

Off-white, approximately 10mm x 30mm, torpedo shaped pessary packed in PVC/PE strip packs.

Pack size: 12, 15, 30, 45 pessaries
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Gedeon Richter Plc.
Gyömrői út 19-21.
1103 Budapest
Hungary

Manufacturer

FULTON MEDICINALI S.P.A
Via Marconi, 28/9 – 20044
Arese (MI)
Italy

Gedeon Richter Plc.
Gyömrői út 19-21.
1103 Budapest
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This medicinal product is authorised in the Member States of the EEA under the following names:

UK	Progesterone 400 mg pessaries
AT	Cyclogest 400 mg Vaginalzäpfchen
BE	Amelgen 400 mg ovules/Vaginalzäpfchen
BG	Cyclogest 400 mg pessaries
CY	Cyclogest
CZ	Amelgen
DE	Cyclogest
DK	Cyclogest
EE	Amelgen
EL	Cyclogest
ES	Cyclogest
FI	Cyclogest
FR	Amelgen
HR	Cyclogest 400 mg vagitoriji
HU	Cyclogest 400 mg hüvelykúp
IE	Progesterone 400 mg pessaries
IS	Cyclogest
IT	Amelgen
LU	Amelgen
LV	Amelgen
MT	Cyclogest
NL	Cyclogest
NO	Cyclogest
PL	Cyclogest

PT	Cyclogest
RO	CYCLOVITA
SE	Cyclogest
SI	Amelgen 400 mg vaginalne globule
SK	Amelgen

This leaflet was last revised in November 2022