

## Package leaflet: Information for the user

Famenita 100 mg soft capsules  
Famenita 200 mg soft capsules  
Progesterone (micronized)

Read the entire package leaflet carefully before you start taking this medicine because it contains important information.

- Keep the package leaflet. You may want to read it again later.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. See section 4.

## What is in this leaflet

1. What is FAMENITA and what is it used for?
2. What should you consider before taking FAMENITA?
3. How to take FAMENITA?
4. What side effects are possible?
5. How to store FAMENITA?
6. Contents of the pack and other information

### 1. What is Famenita and what is it used for?

This medicine contains progesterone, a natural sex hormone produced in the female body. This medicine helps to regulate the hormonal balance in the body. This medicine is a treatment with a corpus luteum hormone (progestogen).

#### What is it used for

It is used for complaints caused by a lack of progesterone in the body. Your doctor may recommend taking this medicine in the following situations:

#### a) in case of progesterone deficiency

When progesterone, produced by the ovaries (in the luteal phase in the second half of the cycle), is below the normal value. This medicine should be used in this case:  
to treat irregularities in your menstrual cycle

#### b) if your menstrual period is permanently absent (after menopause)

Additional therapy as part of estrogen treatment during menopause in women with a functional uterus

### 2. What should you consider before taking Famenita?

Famenita must not be taken

if you have unexplained vaginal bleeding,  
if you are allergic to progesterone or any of the other ingredients of this medicine listed in section 6,  
if you have severe liver dysfunction,  
if you have a liver tumor,  
if you have or are suspected to have a malignant tumor of the breast or reproductive organs,  
if you have or have had a blood clot in a vein (thrombosis), e.g., in the legs (deep vein thrombosis) or in the lungs (pulmonary embolism),  
in case of cerebral hemorrhages,  
if you suffer from a rare, hereditary blood disorder called "porphyria".

#### Warnings and precautions

Please talk to your doctor or pharmacist before taking this medicine.

This medicine is not a contraceptive under the recommended conditions.

Before starting hormone therapy during menopause (and at regular intervals during therapy), you should discuss with your doctor whether a medical examination of the breast and abdomen is necessary.

If you start taking Famenita too early in the menstrual cycle (especially before the 15th day of the cycle), your menstrual cycle may shorten or bleeding may occur.

#### Consult your doctor if:

- o you have had a bloodclot (venous thrombosis) in the past
- o you have vaginal bleeding

#### You should stop taking this medicine if:

- o you experience visual disturbances (e.g., reduced vision, double vision, injuries to the blood vessels in the retina)
- o you have a blood clot (venous thrombotic or thromboembolic complications)
- o you have severe headaches

If your menstrual period is absent during treatment, you should ensure that you are not pregnant.

During treatment, excessive growth of the uterine lining (endometrial hyperplasia) may occur or worsen.

If unexpected bleeding or spotting persists, occurs at the end of treatment, or after the treatment period, you should consult your doctor for advice.

#### Children

The efficacy and safety of Famenita have not been established in children.

#### Taking Famenita with other medicines

Inform your doctor or pharmacist if you are taking, have recently taken, or intend to take other medicines.

Certain medicines can affect the action of Famenita.

- Older medicines, called barbiturates, used to treat sleep disorders or anxiety,
- Medicines for epilepsy (phenytoin, carbamazepine),
- Certain antibiotics (ampicillin, tetracyclines, rifampicin),

- Phenylbutazone (anti-inflammatory medicine),
- Spironolactone (diuretic medicine),
- Certain medicines for fungal infections (ketoconazole, griseofulvin).

Taking Famenita can affect the action of some medicines for diabetes.

Herbal preparations containing St. John's Wort (*Hypericum perforatum*) can

weaken the effect of Famenita.

Taking Famenita with food and drink

You should take this medicine regardless of meals and preferably in the evening before bedtime.

Pregnancy, breastfeeding, and fertility Pregnancy

If you are pregnant or breastfeeding, or if you suspect you are pregnant or intend to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

Breastfeeding

If you are breastfeeding, you should not take this medicine

Consult your doctor or pharmacist before you start taking this medicine.

Reproductive ability

This medication can be taken by women who have difficulty becoming pregnant.

Therefore, no harmful effects on reproductive ability are known.

Consult your doctor before starting any medication.

Driving ability and use of machines

You should avoid driving and operating machinery if you experience drowsiness or dizziness.

### 3. How should Famenita be taken?

Always take this medication exactly as agreed with your doctor. Ask your doctor or pharmacist if you are unsure.

Taking for irregular menstrual bleeding

You should take this medication for a period of 10 days per cycle; usually from the 17th day to the 26th day inclusive.

The recommended daily dose is 200 mg to 300 mg of progesterone. This dose can be taken as a single dose or as two separate doses, e.g., 200 mg in the evening before bedtime and, if necessary, an additional 100 mg in the morning.

Taking for treatment after menopause

In postmenopausal women who still have their uterus, it is not recommended to take estrogens alone.

A single dose of 200 mg of progesterone should be taken additionally in the evening before bedtime for at least 12 to 14 days per month (in the last two weeks of each treatment cycle).

This is followed by approximately one week without hormone replacement therapy, during which withdrawal bleeding may occur.

How should you take the capsules?

Swallow the capsules with some water.

Do not take the capsules with food.

Preferably take this medication in the evening before bedtime. Take the second dose in the morning.

If you take larger amounts of Famenita taken more than you should have, contact your doctor immediately.

In case of an overdose, you may experience symptoms such as dizziness, fatigue, malaise or painful menstrual bleeding. In this case, the dose can be reduced. Consult your doctor for advice.

If you forget to take Famenita

Take the next dose as soon as you remember. However, if it is almost time for your next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Famenita

Your doctor will tell you how long to take this medication. Do not stop your treatment prematurely.

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

#### 4. What side effects are possible?

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

Stop taking Famenita immediately if any of the following conditions/situations occur:

- Stroke, blood clots, or bleeding in the brain,
- Blood clots in a vein, e.g., in the legs or pelvis,
- Sudden, severe headaches,
- Visual disturbances,
- Yellowing of the skin or the whites of your eyes (jaundice).

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

- Headaches,
- Changes in the frequency of your menstrual bleeding or bleeding at times other than withdrawal bleeding. In this case, your doctor may change the dosing schedule.

Occasionally occurring side effects (may affect up to 1 in 100 treated):

- Pain and tenderness in the breasts,
- Fatigue, dizziness,
- Vomiting, diarrhea, constipation,
- Yellowing of the skin or the whites of your eyes (jaundice),
- Itchy skin, acne.

Rare side effects (may affect up to 1 in 1000 treated):

- Nausea.

Very rare side effects (may affect up to 1 in 10000 treated):

- Depression,

Rash (possibly itchy),  
Brown or dark discoloration of the skin (the so-called pregnancy mask).

Other adverse drug reactions have been reported in connection with estrogen/progestogen hormone replacement therapy:

Estrogen-dependent benign growths as well as malignant tumors, e.g., cancer of the Endometrium,  
Blood clots in the veins (venous thromboembolism), i.e., blockages of the deep leg or

Pelvic veins by blood clots (thromboses) as well as pulmonary embolisms. These occur more frequently in users of hormone replacement therapy drugs than in non-users,

Heart attack and stroke,  
Diseases of the gallbladder,  
Brownish skin pigmentation (chloasma), various skin diseases with blister and nodule formation of the skin (erythema multiforme, erythema nodosum, vascular purpura),  
Cognitive impairment,  
Famenita can very rarely cause allergic reactions.

If the treatment cycle is started too early in the month (especially before the 15th day of the cycle)

The cycle may shorten and bleeding may occur at times other than withdrawal bleeding.

#### Reporting side effects

If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects directly to the Federal Institute for Drugs and Medical Devices, Dept. Pharmacovigilance, Kurt-Georg-Kiesinger Allee 3, 53175 Bonn, website: <http://www.bfarm.de>. By reporting side effects, you can help provide more information on the safety of this medicine.

#### 5. How to store Famenita?

Keep this medicine out of the reach of children.

Do not store above 30°C.

Store in the original package to protect the contents from light.

Do not use this medicine after the expiry date stated on the carton and blister after 'Use by'. The expiry date refers to the last day of that month.

Do not use the medicine if you notice visible signs of damage. You can return the medicine to the pharmacy.

Never dispose of medicines via wastewater (e.g., do not dispose of via the toilet or sink). Ask your pharmacist how to dispose of the medicine if you no longer use it. This helps protect the environment. For more information, visit [www.bfarm.de/arzneimittelentsorgung](http://www.bfarm.de/arzneimittelentsorgung).

## 6. Contents of the pack and other information

### What Famenita contains

- The active substance is progesterone. Each soft capsule contains 100 mg or 200 mg of micronized progesterone.
- The other ingredients are: refined safflower oil, gelatin, glycerol, and titanium dioxide.

### What Famenita looks like and contents of the package

FAMENITA soft capsules are almost white, ovoid, soft capsules filled with a whitish suspension.

- Famenita 100mg soft capsules are available in packs of 30 or 90 soft capsules.
- Famenita 200mg soft capsules are available in packs of 15, 30, 45, or 90 soft capsules.

Not all pack sizes may be marketed.

### Pharmaceutical entrepreneur and manufacturer

Pharmaceutical entrepreneur

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This medicinal product is authorized in the Member States of the European Economic Area (EEA) under the following names:

Germany:	FAMENITA 100 mg soft capsules
	FAMENITA 200 mg soft capsules
Austria:	Arefam 100 mg soft capsules
	Arefam 200 mg soft capsules

This package leaflet was last revised in May 2019.