

<INVENTED NAME> 100 mg, soft capsules

<INVENTED NAME> 200 mg, soft capsules

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 or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What <INVENTED NAME> 100 mg/200mg is and what it is used for
2. What you need to know before you take <INVENTED NAME> 100mg
3. How to take <INVENTED NAME> 100 mg/200 mg
4. Possible side effects
5. How to store <INVENTED NAME> 100 mg/200 mg
6. Contents of the pack and other information

1. What <INVENTED NAME> 100 mg/200 mg is and what it is used for

This medicine is a progesterone hormone treatment.

It is indicated in disorders related to progesterone deficiency :

- in cases of irregular cycles due to ovulation disorders,
- pain and disorders prior to menstruation,
- bleeding (bleeding due to fibroma,...)
- in treatment of the menopause (in association with oestrogen therapy).

2. What you need to know before you take <INVENTED NAME> 100 mg/200 mg

Do not take <INVENTED NAME> 100 mg/200 mg if:

- you are allergic (hypersensitive) to progesterone or to any of the other ingredients of this medicine (listed in section 6.)
- you suffer from a serious liver disease
- you have any unexplained vaginal bleeding
- you have an active or suspected breast or genital cancer
- if you have an active or history of blood clot in a vein (thrombosis), such as in the legs (deep venous thrombosis) or in the lungs (pulmonary embolism)
- if you have an active or on-going disease caused by blood clots in the arteries, such as a heart attack, stroke or angina
- if you have a bleeding in the brain
- you have a rare blood problem called “porphyria” which is passed down in families (inherited).

Warnings and precautions

Talk to your doctor before taking <INVENTED NAME> 100 mg/200 mg.

Warnings

If you have any of the following situations : myocardial infarction, cerebrovascular disorders, sudden severe headache, vision impairments and if you have a blot clot in your vein or arteries, the drug should be discontinued and you should contact your doctor.

[INVENTED NAME] Capsules could be co-prescribed with an estrogen product as Hormonal Replacement Therapy. With combined treatment occurred an increased risk of developing deep vein thrombosis (DVT) or pulmonary embolism.

There is suggestive evidence of a small increased risk of breast cancer with estrogen replacement therapy. It is not known whether concurrent progesterone influences the risk of cancer in post-menopausal women taking hormone replacement therapy.

This medicine is not a treatment of all the causes of spontaneous early abortion. It has no effect on those due to genetic accidents (i.e more than half of abortions),
The treatment used in the recommended conditions is not contraceptive.

Precautions

You should take this product away from mealtimes and preferably in the evening at bedtime.

- Prior to taking hormone replacement therapy (and at regular intervals thereafter) each woman should have a medical consult, where clinical examination of the breasts and pelvic examination could be performed;
- [INVENTED NAME] Capsules should not be taken with food and should be taken at bedtime.
- [INVENTED NAME] Capsules should be used cautiously in patients with :
 - conditions that might be aggravated by fluid retention (e.g. hypertension, cardiac disease, renal disease, epilepsy, migraine, asthma);
 - a history of depression, diabetes, mild to moderate hepatic dysfunction, migraine or photosensitivity and in breast-feeding mothers.

Other medicines and <INVENTED NAME> 100 mg/200 mg

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

Some medicines may interfere with the effect of <INVENTED NAME> 100 mg/200 mg. This applies to the following medicines:

- Medicines for epilepsy (such as phenobarbital, phenytoin and carbamazepin)
- Medicines for tuberculosis (such as rifampicin, rifabutin)
- Herbal remedies containing St John's Wort (*Hypericum perforatum*)
- Bromocriptine,
- ciclosporine
- ketoconazole

Smoking and alcohol intake may also interfere with <INVENTED NAME> 100 mg/200 mg.

Pregnancy, breast-feeding and fertility

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

Pregnancy

A large amount of data on pregnant women indicate no malformative nor feto/neonatal toxicity of Progesterone. Talk to your doctor or pharmacist before taking any medicine.

Breast-feeding

Detectable amounts of progesterone enter the breast milk. There is no indication for prescribing progesterone during lactation. However, progesterone intake during lactation does not seem to have deleterious effect on the baby growth.

Fertility

The product does not have deleterious effect on fertility.

Driving and using machines

For those driving or using machines, you should note that there is a risk of drowsiness and/or dizzy spells associated with the use of this medicine.

<INVENTED NAME> 100 mg/200 mg contains soya lecithin

If you are allergic to peanut or soya, do not use this medicinal product.

3. How to take <INVENTED NAME> 100 mg/200 mg

Method of administration

This product is intended for oral use only.

<INVENTED NAME> 100 mg/200 mg should be taken away from mealtimes, preferably in the evening at bedtime.

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

Dose

On average, in cases of progesterone deficiency, the recommended dose is 200 to 300 mg per day, divided into one or two intakes: 100 mg in the morning and 100 or 200 mg in the evening at bedtime.

In any event, the dose must not exceed 200 mg per single intake. If you feel that the <INVENTED NAME> 100 mg/200 mg dose is too strong or too weak, please ask your doctor or pharmacist.

Frequency of administration

Depending on your case, the treatment can be prescribed continuously or in cycles of a few days per month, and it can be associated with an oestrogen treatment.

Swallow the capsule with a glass of water, away from mealtimes, in one or two intakes depending on the therapeutic regimen prescribed by your doctor.

Duration of treatment

The duration of treatment will be specified by your doctor depending on your case.

Depending on the nature of the indication and the efficacy of the treatment, your doctor may have to change the duration of treatment.

If you take more <INVENTED NAME> 100 mg/200 mg than you should

Immediately contact your doctor or pharmacist.

You could experiment symptoms of overdosage which include somnolence, dizziness, euphoria or dysmenorrhoea.

If you forget to take <INVENTED NAME> 100 mg/200 mg

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

4. Possible side effects

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

The following side effects have been observed :

- **Common side effects** (may affect up to 1 in 10 people):
 - change in menstruation, interruption of the menses, bleeding between the menses.
 - headache
- **Uncommon side effects** (may affect up to 1 in 100 people):
 - breast painful,
 - drowsiness or fleeting dizzy spells occurring 1 to 3 hours after taking the product,
 - gastro-intestinal disturbances,
 - rash, acne
 - fluid retention
- **Rare side effects** (may affect up to 1 in 1,000 people):
 - nausea,
 - jaundice,
 - change in weight
- **Very rare side effects** (may affect up to 1 in 10,000 people):
 - Changes in libido,
 - depression,
 - urticaria,
 - chloasma
 - fever
 - loss of hair

- excessive hairiness

These effects are generally due to overdosing.

In these cases, your Doctor would suggest :

- either decrease the quantity of medicine per intake
- or change the rhythm of the intakes

In any event, do not exceed the maximum dose of 200 mg per intake.

If you suffer from signs of overdosing, consult your doctor who will re-adapt your treatment.

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 national reporting system listed in [Appendix V](#)*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <INVENTED NAME> 100 mg/200 mg

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. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original carton in order to protect from light.

Do not use this medicine if you notice signs of deterioration. Return the medicine to your pharmacist.

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 <INVENTED NAME> 100 mg/200 mg contains

The active substance is progesterone. Each capsule contains 100 mg / 200 mg of progesterone.

The other ingredient is safflower oil, refined (type II).

The capsule itself is made of gelatin, glycerol and titanium dioxide.

External manufacturing intermediates : medium chain triglycerides and soya lecithin (see section 2. “<INVENTED NAME> 100 mg/200 mg contains soya lecithin”).

What <INVENTED NAME> 100 mg/200 mg looks like and contents of the pack

Each blister contains 15 capsules.

Each box contains 30 or 90 soft capsules

Each box contains 15 or 45 soft capsules

Marketing Authorisation Holder

< [To be completed nationally] >

Manufacturer

EFFIK

Bâtiment «Le Newton»
9-11 rue Jeanne Braconnier
92366 MEUDON LA FORET
FRANCE

Or

Laboratorios LEON FARMA SA

C/ La Vallina s/n
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This leaflet was last reviewed in (date)