

Secufem Plus

Levonorgestrel 1.5 mg.



LI-0000-00

Formula:

Each tablet contains: Levonorgestrel 1.50 mg and excipients (q.s.)

Therapeutic effect:

Emergency oral contraceptive

Indications:

Preventing pregnancy after unprotected sexual intercourse.

Pharmacological effect:

Ovulostatic. Alters the conditions at the endometrium.

Posology and method of administration:

Take the **SECUFEM PLUS** tablet (usually known as the "morning-after pill") with a glass of water as soon as possible, preferably within 12 hours and no later than 72 hours after having unprotected sexual intercourse.

This medicine can be taken during any stage of the sexual cycle.

Upon using this emergency method, you should use a barrier contraceptive (such as a condom) until your next menstrual bleeding.

If you used **SECUFEM PLUS** during treatment with oral contraceptives, you must continue the oral contraceptives as usual until finishing the pack.

If you vomit within three hours of taking the tablet, you must take another tablet immediately.

Women who have used enzyme-inducing drugs within last 4 weeks, and who need emergency contraception, are advised to use a non-hormonal emergency contraceptive, i.e., a copper IUD, or to take a double dose of levonorgestrel (i.e., 2 pills at a time) if they cannot or do not wish to use a copper IUD.

Contraindications:

Known or suspected pregnancy.

History of thromboembolism and thrombophlebitis.

Cardiovascular or encephalic vascular disease.

Dyslipidaemias.

Confirmed or suspected genital or breast cancer, and other hormone-dependent tumours. Vaginal bleeding of undetermined causation.

Jaundice.

Generalised itching.

Herpes or otosclerosis, arising or worsening at pregnancy.

Dubin-Johnson or Rotor syndrome.

Severe liver disease or a history of severe liver disease.

Porphyria.

Precautions and warnings:

Emergency contraception should be used when the doctor deems it necessary. The following situations should be considered:

- The high administered dose is not a desirable routine treatment.
- This method is not a replacement for traditional oral contraception.

SECUFEM PLUS should not be used together with emergency contraceptives containing ulipristal acetate.

This medicine should not be used in patients with severe liver failure.

Severe malabsorption syndromes, such as Crohn's disease, can decrease the efficacy of **SECUFEM PLUS**.

Menstrual bleeding after taking **SECUFEM PLUS** will occur on the expected date. However, this could occur a few days before or a few days later. If there is an abnormal bleeding after taking **SECUFEM PLUS** and before the expected date, or if bleeding is delayed more than 5 days, you should take a test to rule out pregnancy.

The use of **SECUFEM PLUS** does not protect against HIV infection or any other sexually transmitted disease, for which the use of a condom is this irreplaceable.

SECUFEM PLUS should not be taken in case of an extrauterine pregnancy (ectopic pregnancy) or salpingitis.

If you vomit within three hours of taking the pill, you must take another tablet immediately.

Repeated administration within a menstrual cycle is inadvisable due to the possibility of cycle disruption.

This medicine contains lactose. Patients with hereditary intolerance to galactose, Lapp lactase insufficiency, or malabsorption of glucose or galactose should not take this medicine.

Breastfeeding

In women taking long-term oral contraceptives containing only progestogens, small amounts of progestogens are found in breast milk. However, no medication-related adverse effects on breastfeeding in terms of quality and quantity of breast milk have been observed and, therefore, the development and growth of the infant is not affected.

Talk to your doctor before using this product.

Effect on driving vehicles and using machines:

This medicine does not affect the individual's capacity to drive vehicles or use machines. Nonetheless, this medicine should be avoided if case of any manifestation detailed in *Adverse reactions*.

Interactions:

Associations with enzyme inducers such as anticonvulsants (carbamazepine, phenobarbital, phenytoin, primidone), efavirenz, ritonavir, St. John's wort, ulipristal acetate, cyclosporine, griseofulvin, rifabutin, and rifampicin should be avoided.

What is emergency contraception?

It is a method used immediately after unprotected sexual intercourse to prevent getting pregnant.

When should I use an emergency contraceptive?

Use this medicine as quickly as possible, within 72 hours (3 days) at most, after unprotected sexual intercourse, especially if:

- You had sexual intercourse while you or your partner were not using a contraceptive method.
- If you forgot to take your birth control pill for longer than the maximum allowed time: in such case, read the leaflet of your oral contraceptive again.
- If your partner's condom broke or they forgot to use it.
- If you are under the impression that your intrauterine device (IUD) has been expelled.
- If your diaphragm has moved or you took it out too soon.
- In case of failure of the *coitus interruptus* method or other natural contraceptive methods.
- In case of rape.

In all cases, you should consult your doctor.

Adverse reactions:

Observed unwanted effects include:

- Nausea, vomiting, dizziness, fatigue, headache, abdominal pain, breast tenderness, and genital bleeding after taking the pills.
- In any case, if you experience these or other symptoms, you should talk to your doctor.

Presentation:

Pack containing 1 tablet.

Keep at room temperature (15 to 30°C).

In case of poisoning, seek medical assistance immediately.

Keep out of the reach of children.



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