

Secufem

Levonorgestrel 0.75 mg

Formula:

Each tablet contains: 0.75 mg Levonorgestrel and excipients q.s.

Therapeutic action:

Emergency oral contraceptive.

Indications:

Prevention of pregnancy following unprotected intercourse.

Pharmacological action:

Inhibits or delays ovulation. Modifies the condition of the endometrium.

Dosage and method of administration:

The following indications must be followed to ensure treatment effectiveness: Take the first tablet with a glass of water as soon as possible within 72 hours of unprotected intercourse. Take the second tablet 12 hours after the first one.

Another effective method of administration is to take both tablets together within 72 hours of unprotected intercourse.

This drug can be administered at any time of the menstrual cycle.

After using this emergency method, a barrier contraceptive method (condom or diaphragm) must be used until the next menstrual period.

If the patient is taking oral contraceptives at the time of **Secufem** administration, the remainder of the tablets in the current pack must be taken as usual.

Contraindications:

Confirmed or suspected pregnancy.

Previous history of thromboembolism and thrombophlebitis.

Cardiovascular or cerebrovascular disease.

Dyslipidemia.

Known or suspected genital or mammary cancer and other hormone-dependent tumours.

Vaginal bleeding of unknown etiology.

Jaundice.

Generalized pruritus.

Herpes or otosclerosis occurring or aggravated during pregnancy.

Dubin-Johnson or Rotor syndromes.

Serious hepatic disease or a previous history of liver disease.

Porphyria.

Precautions and Warnings:

A physician's advice should be sought before taking emergency contraception. The following situations must be considered:

- It is undesirable to take high dose emergency oral contraceptives as a usual treatment.

- This method cannot be used to replace conventional oral contraception.

Menstrual bleeding after administration of **Secufem** will normally occur on the expected day, although it may be a few days early or late. In the event of abnormal bleeding prior to the expected date of menstruation following **Secufem** administration, or a delay of more than five days, a pregnancy test must be carried out to rule out the possibility of pregnancy.

Using **Secufem** does not protect against HIV (AIDS) or any other sexually transmitted disease. Condom or diaphragm use is necessary if this protection is required.

Secufem must not be administered in the presence of ectopic pregnancy or salpingitis. If vomiting occurs within two hours of the time of administration, it is recommended to take another tablet without delay.

Repeated administration within the same menstrual cycle is not recommended due to the possibility of cycle alterations.

Lactation:

Small amounts of progestogens are found in maternal milk of patients who have taken progestogen-only oral contraceptives for prolonged periods. However, no adverse effects related to maternal milk quality and quantity have been associated with this drug, so infant development and growth are not affected.

Consult your physician before using this product.

Driving or operating machinery:

This drug does not affect driving or machine operation skills. However, patients who experience any of the specified adverse reactions must refrain from driving or operating machinery.

Forgotten or missed tablets:

Failing to take one tablet of **Secufem** seriously affects treatment effectiveness.

Drug interactions:

Use of **Secufem** in combination with retinoids is contraindicated, as it leads to a reduction of contraceptive effectiveness.

Secufem must not be administered concomitantly with enzyme inducers, such as anticonvulsants (Carbamazepine, Phenobarbital, Phenytoin, Primidone), Griseofulvin, Rifabutin, Rifampicin.

What is emergency contraception?

It is a method used immediately after unprotected intercourse for the prevention of pregnancy.

When should emergency contraception be used?

It should be used as soon as possible within 72 hours (3 days) of unprotected intercourse, especially if:

- The patient and her partner did not use a contraceptive method.
- The patient failed to take her contraceptive tablets for more than the maximum time permitted: if so, refer to the pack insert of your oral contraceptives.
- The patient's partner did not use a condom or the condom was broken.
- The patient thinks that her intrauterine device (IUD) was expelled.
- The patient's diaphragm moved out of place or was removed too soon.
- Coitus interruptus or other natural contraceptive method used by the patient and her partner failed.
- The patient was raped.

In any of the above cases consult your physician before taking **Secufem**.

Side effects:

The following adverse reactions have been reported:

- Nausea, vomiting, vertigo, fatigue, headaches, abdominal pain, breast tenderness, genital bleeding following administration.
- In any of the above cases, or in the event of other symptoms, consult your physician.

Overdose:

No cases of untreated overdose have been reported. In the event of overdose, go to the nearest hospital.

Presentation:

Blister pack containing 2 tablets.

Store at room temperature (15 -30°C).

Keep out of the reach of children.