PROFESSIONAL INFORMATION

SCHEDULING STATUS

S2

1 NAME OF MEDICINE

Lornestin 1,50 mg tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1,50 mg levonorgestrel.

Contains sugar (lactose monohydrate): 120,00 mg per tablet.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablets.

Lornestin is white to off white, round bevel edged, flat faced tablets, debossed with ‘‘J06’’ on one side and plain on the other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method.

4.2 Posology and method of administration

Posology

The tablet should be taken, no later than 72 hours after unprotected intercourse.

If the patient vomits within three to four hours of taking the tablet, another tablet

should be taken immediately.

Lornestin can be used at any time during the menstrual cycle unless menstrual bleeding is overdue.

After using emergency contraception, it is recommended to use a local barrier method (e.g., condom) until the next menstrual period starts. The use of Lornestin does not contraindicate the continuation of regular hormonal contraception.

Paediatric population

Lornestin is not recommended in children.

Very limited data are available in women under 16 years of age.

Method of administration

For oral administration.

4.3 Contraindications

Lornestin is contraindicated in:

- hypersensitivity to levonorgestrel or to any of the excipients listed in section 6.1;
- severe hepatic insufficiency;
- pregnancy or suspected pregnancy (see section 4.6);
- depression not well controlled with treatment;
- a history of depression with the use of hormonal contraceptives.

4.4 Special warnings and precautions for use

Emergency contraception is an occasional method to be used in an "emergency situation" only. It should in no instance replace a regular contraceptive method. Lornestin does not prevent a pregnancy in every

instance.

If there is uncertainty about the timing of the unprotected intercourse or if the woman has had unprotected intercourse more than 72 hours earlier in the same menstrual cycle, conception may have occurred.

Treatment with Lornestin following the second act of intercourse may therefore be ineffective in preventing pregnancy. If menstrual periods are delayed by more than 5 days or abnormal bleeding occurs at the expected date of menstrual periods or pregnancy is suspected for any other reason, pregnancy should be excluded.

If pregnancy occurs after treatment with Lornestin, the possibility of an ectopic pregnancy should be considered, especially in those women who present with abdominal/pelvic pain or collapse and those with a history of ectopic pregnancy, fallopian tube surgery or pelvic inflammatory disease.

The absolute risk of ectopic pregnancy is likely to be low, as Lornestin prevents ovulation and fertilization. Ectopic pregnancy may continue, despite the occurrence of uterine bleeding. Therefore, Lornestin is not recommended for patients who are at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy).

Lornestin is not recommended in patients with severe hepatic dysfunction (see section 4.3).

Severe malabsorption syndromes, such as Crohn's disease, might impair the efficacy of Lornestin.

After Lornestin intake, menstrual periods are usually normal and occur at the expected date. They can sometimes occur earlier or later than expected by a few days. It is recommended to make a medical appointment to initiate or adopt a

method of regular contraception. In case no menstrual period occurs in the next pill-free period following the use of Lornestin after regular hormonal contraception, pregnancy should be ruled out.

Repeated administration within a menstrual cycle is not advisable because of the possibility of disturbance of the cycle.

Limited and inconclusive data suggest that there may be reduced efficacy of Lornestin with increasing body weight or body mass index (BMI). In all women, emergency contraception should be taken as soon as possible after unprotected intercourse, regardless of the woman's body weight or BMI.

Lornestin is not as effective as a conventional regular method of contraception and is suitable only as an emergency measure. Women who present for repeated courses of emergency contraception should be advised to consider long-term methods of contraception.

Use of emergency contraception does not replace the necessary precautions against sexually transmitted diseases.

Mood changes and depression are side effects reported with the use of hormonal contraceptives including Lornestin. There is some evidence that hormonal contraceptive use may be associated with severe depression and a higher risk of suicidal thoughts/behaviour (e.g., talking about suicide, withdrawing from social contact, having mood swings, being preoccupied with death or violence, feeling hopeless about a situation, increasing use of alcohol/drugs, doing self-destructive things, personality changes) and suicide.

Prescribers should inform their patients to contact their doctor for advice if they experience mood changes and depression whilst on treatment with Lornestin.

Lornestin contains lactose

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

The metabolism of Lornestin is enhanced by concomitant use of liver enzyme inducers, mainly CYP3A4 enzyme inducers.

Concomitant administration of efavirenz has been found to reduce plasma levels of levonorgestrel (AUC) by around 50 %.

Medicines suspected of having the capacity to reduce the efficacy of levonorgestrel containing medication include barbiturates (including primidone), phenytoin, carbamazepine, herbal medicines containing *Hypericum perforatum* (St. John's Wort), rifampicin, ritonavir, rifabutin, griseofulvin, ampicillin and other antibiotics, including medicines used to treat tuberculosis, ciclosporin (see below).

For women who have used enzyme-inducing medicines in the past 4 weeks and need emergency contraception, the use of non-hormonal emergency contraception (i.e., a Cu-IUD) should be considered. Taking a double dose of levonorgestrel (i.e., 3,00 mg within 72 hours after the unprotected intercourse) is an option for women who are unable or unwilling to use a Cu-IUD, although this specific combination (a double dose of levonorgestrel during concomitant use of an enzyme inducer) has not been studied.

The requirement for oral antidiabetics and insulin can change as a result of an effect on glucose tolerance.

Medicines containing levonorgestrel as in Lornestin may increase the risk of ciclosporin toxicity due to possible inhibition of ciclosporin metabolism.

4.6 Fertility, pregnancy and lactation

Pregnancy

Lornestin should not be given to pregnant women and

will not interrupt the pregnancy. In case of failure of this emergency contraception with developing pregnancy, epidemiological studies indicate no adverse effects of progestogens on the foetus.

In case of unprotected coitus more than 72 hours earlier, the patient may be pregnant. In these cases, pregnancy should be excluded.

Breastfeeding

About 0,1 % of the maternal Lornestin dose can be transferred via milk to the nursed infant. Potential exposure of an infant to Lornestin can be reduced if the breastfeeding woman takes the tablet immediately after feeding and avoids nursing at least 8 hours following Lornestin administration.

Fertility

Levonorgestrel increases the possibility of cycle disturbances which can sometimes lead to earlier or later ovulation date. These changes can result in modified fertility date, however, there are no fertility data in the long term.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

a. Summary of the safety profile

The most frequently reported side effect is nausea.

b. Tabulated summary of adverse reactions

System Organ Class	Frequency	Undesirable effect
Nervous system disorders	*Frequent*	Headache, dizziness.
Gastrointestinal disorders	*Frequent*	Nausea, lower abdominal pain, diarrhoea, vomiting.
Reproductive system and breast disorders	*Frequent*	Bleeding not related to menses*, breast tenderness, delay of menses more than 7 days#, menstruation irregular.
General disorders	*Frequent*	Fatigue.

The following side effects have been reported with the post marketing use of hormonal contraceptives:

System Organ Class	Frequency	Undesirable effect
Psychiatric disorders	*Frequency unknown*	Severe depression with a higher risk of suicidal thoughts/behaviour and suicide.
Gastrointestinal disorders	*Less frequent*	Abdominal pain.
Skin and subcutaneous	*Less frequent*	Rash, urticaria, pruritus.

tissue disorders		
Reproductive system and breast disorders	*Less frequent*	Pelvic pain, dysmenorrhoea.
General disorders and administration site conditions	*Less frequent*	Face oedema.

c. Description of selected adverse reactions

*Bleeding patterns may be temporarily disturbed. 78 % of women will have their next menstrual period within 5 days of expected time. #If the next menstrual period is more than 5 days overdue pregnancy should be excluded.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

Serious undesirable effects have not been reported following acute ingestion of large doses of oral contraceptives. Overdose may cause nausea, and withdrawal bleeding may occur.

There are no specific antidotes and treatment should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 21.8.2 2 Progesterones with or without oestrogens.

Pharmacotherapeutic group: Sex hormones and modulators of the genital system, emergency contraceptives, ATC code: G03AD01.

Mechanism of action

The precise mode of action of Lornestin is not known. Emergency hormonal contraception is thought to work mainly by preventing fertilisation by altering tubal transport of sperm and/or ova. It may also cause endometrial changes that discourage implantation.

Levonorgestrel is not effective once the process of implantation has begun.

Results from a study on 1,50 mg levonorgestrel, taken within 72 hours of unprotected sex, prevents 84 % of expected pregnancies. At the recommended regimen, levonorgestrel is not expected to induce significant modification of blood clotting factors, and lipid and carbohydrate metabolism.

5.2 Pharmacokinetic properties

Absorption

Orally administered levonorgestrel is rapidly and almost completely absorbed.

The absolute bioavailability of levonorgestrel was determined to be almost 100 % of the dose administered.

The results of a pharmacokinetic study carried out with 16 healthy women showed that following ingestion of one tablet of Levonorgestrel 1,5 mg maximum medication serum levels of 18,5 ng/mL were found at 2 hours.

Distribution

Levonorgestrel is bound to serum albumin and sex hormone binding globulin (SHBG). Only about 1,5 % of the total serum levels are present as free steroid, but 65 % are specifically bound to SHBG.

About 0,1 % of the maternal dose can be transferred via milk to the nursed infant.

Biotransformation

The biotransformation follows the known pathways of steroid metabolism, the levonorgestrel is hydroxylated in the liver and the metabolites are excreted as glucuronide conjugates.

No pharmacologically active metabolites are known.

Elimination

After reaching maximum serum levels, the concentration of levonorgestrel decreased with a mean elimination half-life of about 26 hours.

Levonorgestrel is not excreted in unchanged form but as metabolites. Levonorgestrel metabolites are excreted in about equal proportions with urine and faeces.

Pharmacokinetics in obese women

A pharmacokinetic study showed that levonorgestrel concentrations are decreased in obese women (BMI ≥ 30 kg/m²) (approximately 50 % decrease in C_{max} and AUC_{0-24}), compared to women with normal BMI (< 25 kg/m²). Another study also reported a decrease of levonorgestrel C_{max} by approximately 50 % between obese and normal BMI women, while doubling the dose (3 mg) in obese women appeared to provide plasma concentration levels similar to those observed in normal women who received 1,5 mg of levonorgestrel. The clinical relevance of these data is unclear.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate

Maize starch

Potato starch

Lactose monohydrate

Silica, colloidal anhydrous

Talc

6.2 Incompatibilities

Unknown.

6.3 Shelf life

60 months.

6.4 Special precautions for storage

Store at or below 30 °C.

Keep the blister in the outer carton until required for use.

6.5 Nature and contents of container

Lornestin is packed in clear and transparent PVC blister pack with aluminium foil lidding, containing 1 tablet per blister in a cardboard carton.

6.6 Special precautions for disposal and other handling

No special requirements for disposal. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 HOLDERS OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER(S)

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