

# emcon 1<sup>®</sup> Tablet

1.5mg Levonorgestrel BP

**Read all of this leaflet carefully before you start taking this medicine.**  
If you have further questions, please ask your doctor, or Family Planning Clinic.  
Keep this leaflet. You may need to read it again.

## 1. WHAT IS YOUR MEDICINE:

The name of your medicine is Emcon 1<sup>®</sup> tablet.  
Emcon 1<sup>®</sup> is an emergency contraceptive for women. Emcon 1<sup>®</sup> should be used within 72 hours of unprotected intercourse. It should not be taken as regular birth control pill. This medicine is also known as Post Coital Pill and Morning After Pill. The active substance in this medicine is levonorgestrel.  
Each Emcon 1<sup>®</sup> tablet contains 1.5mg levonorgestrel. Levonorgestrel belongs to a group of medicines called progestogen.  
Each pack of Emcon 1<sup>®</sup> contains 1 round white tablet.

## 2. WHAT IS YOUR MEDICINE FOR AND WHEN SHOULD THIS MEDICINE BE TAKEN:

Emcon 1<sup>®</sup> is an oral emergency contraceptive.

### What is emergency contraception?

Emergency contraception is a rescue method which is aimed to prevent fertilization in case of unprotected intercourse.

### When can emergency contraception be used?

This contraception must be used as soon as possible, preferably within 12 hours and no later than 72 hours (3 days) after the unprotected sexual intercourse, particularly;

- if you have had a sexual intercourse whereas either yourself or your partner did not use a contraceptive method;
- if you have forgotten to take consecutive 3 contraceptive pills; (in this case, read the information leaflet of your contraceptive pill);
- if your partner's condom has broken, slipped or been improperly removed, or if he has forgotten to use it;
- if you fear that your intrauterine device has been expelled;
- if your vaginal diaphragm or your contraceptive cap has moved or if you have removed it too early;
- if you are afraid that the method of coitus interruptus has failed or if you have had sexual intercourse during the period when you are supposed to be fertile while using the rhythm method;
- in the event of rape.

## 3. CAUTION:

### ● When should you not use this medicine:

If you have hypersensitivity to levonorgestrel or any of the excipients of Emcon 1<sup>®</sup>.

### ● Special warnings and precautions for use.

Emergency contraception must be used **exceptionally**, since:

- It does not allow to prevent a pregnancy in every instance;
- The associated hormonal overdosing is not advisable in case of regular intake.
- It cannot replace a regular contraception.

After taking Emcon 1<sup>®</sup>, menstrual period usually occurs at the expected date nevertheless, it can occur earlier or later by a few days. After taking this medicine, it is therefore mandatory to check the absence of pregnancy by performing a pregnancy test in case of abnormal bleeding at the date of expected menses or in case of menstrual delay of more than 5 days.

The use of emergency contraception does not replace the necessary precautions against sexually transmitted diseases and the measures to be taken in case of risk of transmission (see paragraph 7, Advice/Sanitary Education).

Taking this medicine is not recommended if you have had an ectopic pregnancy or if you have had a salpingitis or if you have a severe digestive disease which impairs absorption of medications.

**If vomiting would occur within three hours after taking this medicine, it is recommended to take immediately another Emcon 1<sup>®</sup> tablet.**

### ● Interactions with other medicines and other forms of interaction

Simultaneous administration of certain anticonvulsant agents (phenobarbiton, phenytoin, primidone, carbamazepin), also other medications such as rifampicin, and griseofulvin can reduce or suppress the effectiveness of this emergency contraception.

*IN ORDER TO AVOID POTENTIAL INTERACTIONS BETWEEN SEVERAL MEDICINES, YOU MUST SYSTEMATICALLY NOTIFY YOUR DOCTOR OF ANY OTHER TREATMENT YOU ARE CURRENTLY TAKING.*

### ● Pregnancy and lactation

#### Pregnancy

This medicine is not indicated in case of pre-existing pregnancy and cannot interrupt it. In case of failure of this contraceptive mean with persisting pregnancy, epidemiological studies indicate no adverse effects of progestogen on malformation of a fetus.

#### Lactation

Lactation is possible. However, since levonorgestrel is secreted into breast milk, it is suggested that you breastfeed immediately before taking each Emcon 1<sup>®</sup> tablet and that you skip the nursing following each Emcon 1<sup>®</sup> administration.

## 4. HOW SHOULD THIS MEDICINE BE USED:

### ● Posology

The treatment necessitates the intake of **one tablet**.

The Emcon 1<sup>®</sup> tablet must be taken **as soon as possible, preferably within 12 hours, after the unprotected intercourse** and no longer than within 72 hours (3 days) after the intercourse. Emcon 1<sup>®</sup> can be taken at any moment during the menstrual cycle.

After using an emergency contraception, it is recommended to use a local contraceptive mean (condom, spermicide, and cervical cap) until the next menstrual period resume. The use of Emcon 1<sup>®</sup> does not contraindicate the continuation of regular hormonal contraception.

If you have used this medicine while you were using an oral contraception (contraceptive pill), you should carry on taking the usual tablets until the end of the treatment. In case no menstrual period occurs in the next pill-free period following the use of Emcon 1<sup>®</sup> a pregnancy test should be performed to rule out a pregnancy.

### ● Method and route of administration

#### Oral use

The tablet should be taken with a glass of water.

### ● How often and when should the medicine be taken:

See Posology.

### ● Duration of treatment

See Posology.

### ● What should you do if you take an overdose

No acute toxicity has been demonstrated with this medicine in case of intake of several doses.

### ● What should you do if you miss dose

The efficacy of this medicine is not guaranteed if dose has been omitted.

## 5. UNDESIRABLE EFFECTS:

Undesirable effects which have been observed are:

- Nausea and vomiting,
- Dizziness, fatigue, headache,
- Abdominal pain,
- A feeling of breast tenderness.
- Bleeding can occur after taking this medicine.

**INFORM YOUR DOCTOR OF ANY UNWANTED EFFECT WHICH IS NOT MENTIONED IN THIS LEAFLET.**

## 6. STORAGE CONDITIONS:

### ● Do not exceed the expiry date printed on the outer packaging

### ● Special precautions for storage

- Keep the tablet in the outer carton.
- Keep the medicine away from children.
- Store in cool dry conditions (below 30° c)

## 7. ADVICE / SANITARY EDUCATION:

### ● Some information about the menstrual cycle and contraception.

The **menstrual cycle** is the time elapsed between two menstrual periods. Normally, the cycle lasts for 28 days but its length can vary noticeably from one woman to another.

Menstrual periods occur when a woman is not pregnant. At the middle of the cycle, an ovum is expelled by one of the 2 ovaries (this moment is called "ovulation"). Usually ovulation takes place at the middle of the cycle, but it can occur at any moment during the cycle.

If sperms are near the ovum, fertilization (i.e. the merge between the ovum and a sperm cell in order to create an embryo) can take place. After a few days, the fertilized ovum implants in the womb and the pregnancy starts.

Contraceptive methods are aimed to prevent:

- either the ovulation: this is the case for the contraceptive pill,
- either the fertilization (merge of the sperm with the ovum): this is the case for condoms,
- or the implantation of a fertilized ovum: this is the case for intrauterine devices.

Emergency contraception aims to block ovulation or prevent implantation if the sexual intercourse has taken place in the hours or days preceding ovulation, i.e. at a time when the likelihood of fertilization is the highest. It could also prevent implantation. It becomes inefficient as soon as implantation has started.

Without a contraceptive method, a woman cannot exclude the possibility of becoming pregnant after a sexual intercourse.

If you have taken this medicine and that you do not use a regular contraception, it is highly recommended to visit your doctor in order to obtain advice on a method of contraception suitable to you.

### ● Advice in case of risk of transmission of sexually transmitted disease.

If you fear a pregnancy, this can mean that you have not used a condom (or that you have used it improperly) during the sexual intercourse. You may therefore have contracted a sexually transmitted disease or the AIDS virus, if you are not aware of your partner's health status, or if you have several partners. You should ask advice to your doctor as soon as possible for early detection and, if necessary, early treatment.

During your next sexual intercourses, it is recommended to take the appropriate measures in order to prevent an unwanted pregnancy and/or a sexually transmitted disease and to avoid AIDS contamination.

If you need further information about **Emcon 1<sup>®</sup>**, ask your doctor, or a family planning center.

®Trade Mark

Manufactured by



**Renata Limited**

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