



## Read this entire leaflet carefully before you start taking the medicine.

### 1. WHAT NORIX® IS:

- NORIX® is an oral emergency contraceptive pill for women which prevents pregnancy if taken within 72 hours of unprotected intercourse. It should not be taken as regular birth control pill
- In each tablet of NORIX® there is 0.75 mg of levonorgestrel as active substance
- Each pack of NORIX® contains 2 round, white tablets
- Levonorgestrel belongs to a group of medicines called progestin

#### • What is emergency contraception?

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

### 2. WHEN CAN NORIX® BE TAKEN:

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 where neither you nor your partner used a contraceptive method
- if you have forgotten to take contraceptive pills for 3 consecutive days (in this case, read the information leaflet of your contraceptive pill)
- if your partner's condom has broken, slipped or been improperly used
- if you fear that your intrauterine device (IUD) 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 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 NORIX®:

- If you have hypersensitivity to levonorgestrel or any of the ingredients of NORIX®

#### • Special warnings and precautions for use of NORIX®:

- It does not allow prevention of 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 NORIX®, 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 menstruation 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.

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

- If vomiting occurs within three hours after taking this medicine, it is recommended to take another NORIX® tablet immediately.

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

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

#### • Pregnancy and lactation

##### Pregnancy

This medicine is not recommended in case of pre-existing pregnancy and cannot interrupt it. In case of failure of this contraceptive and the following pregnancy, epidemiological studies indicate no adverse effects of progestin on malformation of a fetus.

### Lactation

Lactation is possible even after taking of this medicine. However, since levonorgestrel is secreted into breast milk, it is suggested that you breastfeed immediately before taking each NORIX® tablet and that you skip the nursing following each NORIX® administration.

### 4. HOW SHOULD THIS MEDICINE BE USED:

The first NORIX® tablet must be taken within 72 hours of the intercourse and the second tablet should be taken after 12 hours of the intake of first tablet. NORIX® must be taken within 48 hours of unprotected intercourse and in no way after 72 hours because the effectiveness of the medicine starts reducing after 48 hours of intercourse. NORIX® can be taken at any time of menstrual cycle.

After using an emergency contraception, it is recommended to use a regular contraceptive method (condom, spermicide, and cervical cap) until the next menstrual period resumes.

The use of NORIX® is not recommended during the continuation of regular hormonal contraception. If you have used 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 NORIX® a pregnancy test should be performed to rule out pregnancy.

The efficacy of this medicine is not guaranteed if it has not been taken within prescribed time

### 5. SIDE EFFECTS:

Like all medicines, there could be some undesirable effects of this pill on some people.

#### Undesirable effects which have been observed are:

- Nausea and vomiting
- Dizziness, fatigue, headache
- Abdominal pain
- A feeling of breast tenderness
- Vaginal 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 use after the expiry date printed on the outer packaging
- Special precaution for storage

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

Return the pack of NORIX® to your pharmacist if you observe any sort of problem in the tablets or in the pack.

### 7. CONTRACEPTIVE METHODS ARE AIMED TO PREVENT:

- The ovulation: this is the case for the contraceptive pill
  - The fertilization (merge of the sperm with the ovum): this is the case for condoms
  - 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 starts.

If you have taken NORIX® and 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 for you.

If you need further information about NORIX®, ask your doctor or visit a family planning center.



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