

## PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

### PILL 72\*

(Levonorgestrel 0.75 mg tablets)

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their condition is the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, tell your health care provider or pharmacist.

#### **What is in this leaflet:**

1. What PILL 72 is and what it is used for
2. What you need to know before you take PILL 72
3. How to take PILL 72
4. Possible side effects
5. How to store PILL 72
6. Contents of the pack and other information

#### **1. WHAT PILL 72 IS AND WHAT IT IS USED FOR**

PILL 72 contains a synthetic hormone-like substance, levonorgestrel.

PILL 72 prevents about 85% of expected pregnancies when the first tablet is taken within 72 hours (3 days) of unprotected sex. PILL 72 will not prevent pregnancy in every instance. The tablets are more effective the sooner after unprotected sex they are taken. You need to take the second tablet 12 hours (but no more than 16 hours) after the first.

PILL 72 are thought to work by:

-stopping your ovaries from releasing an egg;-preventing sperm from fertilising any egg that may have been released already

So PILL 72 stops pregnancy before it is established. It does not work if you are already pregnant.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PILL 72**

Before you take this medicine, your health care provider may check that you are not already pregnant.

You can use PILL 72 at any time during your menstrual cycle, except if your period is late. If your period is late, you should tell your health care provider.

#### **Do not take PILL 72**

- if you are allergic (hypersensitive) to levonorgestrel or to any of the other ingredients of PILL 72. (listed in section 6)

#### **Warnings and precautions**

You may already be pregnant if:

\* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

- your period is more than 5 days late or if you have unusual bleeding when your next period is due
- you have had unprotected sex more than 72 hours ago, and since your last period

You should ask your health care provider for advice about emergency contraception if you

- have a disease of your small bowel (such as Crohn's disease) that interferes with the digestion of your food;
- have severe liver problems;
- have ever had an ectopic pregnancy (where the baby develops outside the womb);
- have ever had salpingitis (inflammation of the Fallopian tubes)
- are taking any of the medicines listed below, as these medicines may prevent PILL 72 from working properly:
  - barbiturates and other medicines used to treat epilepsy (for example, primidone, phenytoin, and carbamazepine);
  - medicines used to treat tuberculosis (for example, rifampicin, rifabutin);
  - a treatment for HIV infection (for example, ritonavir);
  - a medicine used to treat fungal infections (for example, griseofulvin);
  - herbal remedies containing St John's wort (*Hypericum perforatum*);
  - ciclosporin, a medicine used to suppress the immune system

If any of these apply to you, PILL 72 may not be suitable for you, or other types of emergency contraception may be better for you.

#### **If you are worried about sexually transmitted diseases**

This medicine will not protect against sexually transmitted diseases, only condoms can do this. Ask your health care provider or family planning clinic for advice if you are worried about this.

#### **Children**

Levonorgestrel 0.75 mg is not indicated to be used before menarche.

#### **Taking other medicines**

Tell your health care provider if you are taking, have recently taken, or might take, any other medicines including medicines obtained without a prescription. You should tell your health care provider if you are taking any of the medicines listed in the section "Warnings and precautions" above.

#### **Pregnancy and breast-feeding**

##### *Pregnancy*

You should not take this medicine if you are already pregnant. If you have had unprotected sex which was more than 72 hours ago, and since your last period, you may already be pregnant and the treatment won't work. If your last period was more than 5 days late or was unusually light or unusually heavy or you suspect that you might be pregnant (feeling sick, vomiting, breast tenderness etc.), you should check with your healthcare provider that you are not already pregnant.

If you do become pregnant even after taking this medicine, it is important that you see your health care provider. There is no evidence that PILL 72 will harm an unborn baby, but your health care provider may want to check that the pregnancy is not ectopic (where the baby develops somewhere outside the womb). This is especially important if you develop severe abdominal pain or fainting after taking PILL 72, or if you have previously had an ectopic pregnancy, Fallopian tube surgery or pelvic inflammatory disease.

##### *Breast-feeding*

Very small amounts of the active ingredient of PILL 72 may appear in your breast milk. This is not thought to be harmful to the baby, but if you are worried you can take your tablets immediately after breastfeeding. In this way you are taking the tablets well before the next feed and reducing the amount of active ingredient your baby may take in with the breast milk.

### **Important information about some of the ingredients of PILL 72**

PILL 72 contains lactose. If you know that you cannot tolerate some sugars, contact your health care provider before taking this medicine.

### **3. HOW TO TAKE PILL 72**

- Take one tablet **as soon as possible** (but no later than 72 hours) after you have had unprotected sex. Swallow the tablet whole, with water if necessary. Do not delay taking the first tablet. The tablets work better the sooner you take them after having unprotected sex.
- **It is important** to take the second tablet **12 hours (and no longer than 16 hours) after the first tablet.**

#### **How often can you use PILL 72?**

You should only use PILL 72 in emergencies and not as a regular method of contraception. If PILL 72 is used more than once in a menstrual cycle, it is more likely to upset your menstrual cycle (period).

PILL 72 does not work as well as regular methods of contraception. If you need repeated courses of emergency contraception, you should consider long-term methods of contraception.

#### **If you take more PILL 72 than you should (overdose)**

Although there have been no reports of serious harm from taking too many tablets at once, you may feel sick, vomit, or have vaginal bleeding.

#### **What to do if you are sick (vomit)**

- If you vomit within 2 hours of taking the first tablet, you should take the second tablet in the pack at once.
- If vomiting continues, you may insert either the first or second or both doses in your vagina. You will need a second pack to obtain any extra dose. You should also contact your health care provider, as the tablets may not have worked properly.

#### **If you forget to take a tablet**

- You must take both tablets in the pack (as described above) and leave no longer than 16 hours (preferably 12 hours) between taking the tablets.
- If you are late taking the second tablet (more than a 16 hour gap), take it as soon as you remember and contact your health care provider as soon as possible.

#### **After you have taken PILL 72**

After you have taken PILL 72, if you want to have sex, and are not using the contraceptive pill, you should use condoms or a cap plus spermicide. This is because PILL 72 won't work if you have unprotected sex again, before your next period is due.

After you have taken PILL 72, if your next period is more than 5 days late or is unusually light or unusually heavy, you should contact your health care provider as soon as possible. If you do become pregnant even after taking this medicine, it is important that you see your health care provider.

Your health care provider can also tell you about longer-term methods of contraception which are more effective in preventing you from getting pregnant.

If you continue to use regular hormonal contraception such as the contraceptive pill and you do not have a bleed in your pill-free period, see your health care provider to make sure you are not pregnant.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, PILL 72 can cause side effects, but not everybody gets them.

The most common side effects are nausea, abdominal pain, fatigue, headache, menstrual changes and irregular bleeding until your next period. Dizziness, breast tenderness, vomiting and diarrhoea may also occur.

If you think that this medicine affects you in a way that is not mentioned above, tell your healthcare provider.

## **5. HOW TO STORE PILL 72**

Do not store above 30°C. Store tablets in blister in the provided carton.

Keep this medicine out of the sight and reach of children.

Do not use PILL 72 after the expiry date stated on the label. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What PILL 72 contains**

The active substance is 0.75 mg levonorgestrel in each tablet.

The other ingredients are lactose monohydrate, maize starch, povidone, colloidal anhydrous silica, magnesium stearate.

### **What PILL 72 look like and contents of the pack**

White to off-white, circular, flat, bevelled, uncoated tablets plain on both sides.

#### **Packaging:**

Clear PVC/PE/PVDC-Alu blister card containing 2 tablets. One blister card per carton.

If you are not sure about anything or you have any questions, please ask your pharmacist, your health care provider or visit a family planning clinic.

### **Supplier**

Cipla Ltd.  
Mumbai Central,  
Mumbai 400 008  
India  
Tel: + 91 22 25716015/25716031  
Fax: + 91 22 25785298  
Email: [prc@cipla.com](mailto:prc@cipla.com)  
[vaishalis@cipla.com](mailto:vaishalis@cipla.com)

**This leaflet was last approved in June 2014.**