

## Information for the user

# Boots Emergency Contraceptive 1.5 mg Tablet (Levonorgestrel)

### Patient Information Booklet

#### **Read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription for emergency contraception. However, you still need to take it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice

#### **What this medicine is for**

This medicine contains Levonorgestrel, which is a progestogen-based emergency hormonal contraceptive.

It can be used to help prevent a pregnancy when taken within 72 hours (3 days) of having had unprotected sex or if your usual method of contraception has failed (e.g. a split condom).

It is more effective the sooner you take it after unprotected sex or failure of your usual contraception.

This medicine is intended for occasional use only.

It should not be used on a regular basis, or as a substitute for long-term contraception.

This medicine will not stop a pregnancy if you are already pregnant.

#### **Before you take this medicine**

This medicine can be taken by women aged 16 years and over. However, some women should not take this medicine or should seek the advice of their pharmacist or doctor first.

#### **X Do not take:**

- **If you are allergic** to any of the ingredients in this medicine (see "What is in this medicine")
- **If you have an intolerance to some sugars**, unless your doctor tells you to (this medicine contains lactose)
- **If you are pregnant**

You may already be pregnant if:

- you have had unprotected sex or a failure of contraception more than 72 hours ago and since your last period
- your last period was later, heavier or lighter than normal
- your current period is late

#### **! Talk to your doctor:**

- If you have severe liver problems
- If you have severe digestive problems (e.g. Crohn's disease)
- If you have ever had an ectopic pregnancy (where a baby develops outside the womb), fallopian tube surgery or pelvic inflammatory disease

#### **! Talk to your pharmacist or doctor:**

- If you are under 16 years of age (your local family planning clinic may also be able to help)
- If you are breastfeeding

#### **If you take other medicines**

Before you take this tablet, make sure that you tell your doctor or pharmacist about ANY other medicines you might be using at the same time, particularly the following:

- Barbiturates, primidone, phenytoin or carbamazepine (normally used to treat epilepsy)
- Rifampicin or rifabutin (normally used for tuberculosis)
- Ritonavir (for HIV infection)
- Griseofulvin (for fungal infections)
- Ciclosporin (given after transplant surgery, or for psoriasis or rheumatism)
- Herbal remedies containing St John's Wort (*Hypericum perforatum*)

If you are unsure about interactions with any other medicines, talk to your doctor or pharmacist. This includes medicines prescribed by your doctor or medicines you have bought for yourself including herbal and homeopathic remedies.

## Other important information

This medicine can sometimes disturb your normal monthly cycle (period). Your next period may start a few days earlier or later than expected. If your next period is more than 5 days late, or is unusually light or heavy, or there is any other reason to suspect you might be pregnant, you should talk to your doctor as soon as possible and have a pregnancy test.

If you have any questions about this medicine, or need any further help and advice, talk to your pharmacist, doctor, nurse or family planning clinic.

**Driving and using machines:** This medicine may make you feel dizzy or tired. Do not drive or use machines until you are sure you are not affected.

**Effectiveness of this medicine:** If taken correctly this medicine can prevent about 84% of expected pregnancies when taken as directed within 72 hours (3 days) of having had unprotected sex or if usual methods of contraception have failed. However, this medicine will not prevent a pregnancy every time.

It is more effective to take the tablet as soon as possible (preferably within 12 hours) after unprotected sex or when contraception has failed. Do not wait until the 72 hours are almost up. If you need advice, your pharmacist, doctor, nurse or family planning clinic will be able to help.

**How the medicine works:** It is unclear exactly how these tablets help prevent pregnancy, but it is thought to work by:

- Stopping you from releasing an egg (ovulating)
- Preventing sperm from meeting an egg that has been or is about to be released (fertilisation)
- Stopping a fertilised egg from attaching itself to your womb

The tablet will not work if you are already pregnant, or have had unprotected sex or a failure of contraception more than 72 hours ago and since your last period. You **MUST NOT** take the tablet but should speak to your doctor as soon as possible.

**Protection against sexually transmitted diseases:** This medicine will not protect you against sexually transmitted diseases, only condoms can help do this. If you are worried about any sexually transmitted disease, talk to your pharmacist, doctor, nurse or family planning clinic for advice.

**How often to take this medicine:** This medicine should **only** be used for emergencies and not as a regular method of contraception, because it is not as reliable as regular methods of contraception and offers no protection against sexually transmitted diseases. It is also not recommended to take this medicine more than once in a monthly cycle as they can disturb your period.

To discuss long-term methods of contraception, which may be more effective, talk to your doctor, nurse or family planning clinic.

Your pharmacist may also be able to help answer any questions you have about long-term methods of contraception.

**Safe sex for the rest of the monthly cycle:** Taking this medicine does not provide you with ongoing contraception for the rest of your monthly cycle. Once you have taken the tablet, you should use condoms or other barrier methods of contraception until your next period starts.

If you have unprotected sex or a method of contraception fails again in the same monthly cycle, you should speak to a pharmacist, doctor, nurse or family planning clinic for a further supply of emergency contraception.

**Effect on the monthly cycle:** Once you have taken this medicine, your next period will normally be around the expected date. However, this medicine can sometimes make your period start earlier or later than normal by a few days.

If your next period is more than 5 days late or is unusually light or heavy, you should contact your doctor as soon as possible to make sure you are not pregnant.

If you have continued to use your regular method of hormonal contraception (such as the contraceptive pill) and not had a bleed in your pill-free break, you should contact your doctor as soon as possible to make sure you are not pregnant.

**What to do if pregnancy occurs:** A pregnancy will not normally be affected by this medicine, however there is a risk that a pregnancy may continue outside of the womb (ectopic pregnancy). It is important that you talk to your doctor if you become pregnant despite taking this medicine, as they will need to check it is not ectopic.

This is especially important if you have previously had an ectopic pregnancy, fallopian tube surgery or pelvic inflammatory disease.

## ✓ How to take this medicine

Check the foil is not broken before use. If it is, do not take the tablet.

Age	How many	How often
Women aged 16 years and over	One tablet	<b>As soon as possible</b> , preferably within 12 hours and no later than 72 hours after unprotected sex or failure of contraception

Swallow the tablet whole with water.

Do not take more than the amount recommended in the table.

**If you are sick within 3 hours of taking the tablet**, you will need to take another tablet.

Talk to your pharmacist, doctor, nurse or family planning clinic immediately for advice and to obtain another tablet.

Once you have taken this medicine, it is recommended that you use barrier methods of contraception (such as condoms) until your next period starts.

If you are already using a regular method of hormonal contraception (such as the contraceptive pill), continue using these as normal at your regular times, as well as using barrier methods of contraception until your next period.

Once you have taken this medicine, talk to a pharmacist or doctor if your next period is more than 5 days late or you suspect you may be pregnant.

! If you get any lower stomach pain or discomfort, talk to a doctor straight away.

**If you take too many tablets:** Although there have been no reports of serious effects of taking too many tablets at once, you may feel sick or notice vaginal bleeding. Talk to your pharmacist or doctor for advice.

## Possible side effects

Most people will not have problems, but some may get some.

! **If you get any of these serious side effects, stop taking the tablets. See a doctor at once:**

- Difficulty in breathing, swelling of the face, neck, tongue or throat (severe allergic reactions)

**These other effects are less serious. If they bother you talk to a pharmacist:**

Very common (more than 1 in 10 women)

- Feeling sick, lower stomach pain
- Headache, tiredness
- Unexpected bleeding not related to your period

Common (more than 1 in 100 women, but less than 1 in 10)

- Being sick – if you are sick within 3 hours of taking the tablet, you will need to take another tablet. Talk to your pharmacist, doctor, nurse or family planning clinic immediately for advice and to obtain another tablet
- Diarrhoea, dizziness
- Breast tenderness
- Irregular bleeding or spotting
- Temporary disturbance of your normal monthly cycle

Very rare (less than 1 in 10,000 women)

- Allergic reaction (e.g. skin rash, raised, red, itchy skin)

**If any side effect becomes severe, or you notice any side effect not listed here, please tell your pharmacist or doctor.**

## **How to store this medicine**

Store in the original package, in order to protect from light.

Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

Use by the date on the end flap of the carton or on the foil. After this date return any unused product to your nearest pharmacy for safe disposal.

## **What is in this medicine**

The tablet contains Levonorgestrel 1.5 mg, which is the active ingredient.

As well as the active ingredient, the tablet also contains lactose monohydrate, maize starch, talc (E533b), magnesium stearate (E572), colloidal silica anhydrous, potato starch.

This pack contains one round, white tablet marked G00 on one side.

## **Who makes this medicine**

Manufactured for and distributed by The Boots Company PLC Nottingham NG2 3AA by Bayer Schering Pharma AG Berlin Germany or Schering GmbH & Co Produktions KG Weimar Germany or Gedeon Richter Plc Gyömrői út 19-21 H-1103 Budapest Hungary. Marketing Authorisation held by Medimpex UK Limited London W9 2EP

Leaflet prepared October 2011

If you would like any further information about this product, please contact The Boots Company PLC Nottingham NG2 3AA.

## **Other formats**

To request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only)

Please be ready to give the following information:

Product name: Boots Emergency Contraceptive 1.5 mg Tablet

Reference number: 05276/0020

This is a service provided by the Royal National Institute of Blind People.

BTC 90049 vs E