



008201

## PACKAGE INSERT

### SCHEDULING STATUS

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### PROPRIETARY NAME (AND DOSAGE FORM)

**PLAN B<sup>®</sup>** (tablet)

### COMPOSITION

Each tablet contains 750 micrograms of levonorgestrel.

### PHARMACOLOGICAL CLASSIFICATION

A. 21.8.2 Progesterones with or without oestrogens

### PHARMACOLOGICAL ACTION

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.

The precise mode of action of **PLAN B** is not known.

### Pharmacokinetics

Orally administered levonorgestrel is almost completely absorbed. Following ingestion of one tablet of **PLAN B** maximum drug serum levels of 14,1 ng/ml were found at 1.6 hours.

Thereafter levonorgestrel serum levels decrease in two disposition phases with mean elimination half-lives which range from about 9 hours to 14,5 hours.

Levonorgestrel is not excreted in unchanged form but as metabolites. Levonorgestrel metabolites are excreted in about equal proportions with urine and faeces. The biotransformation follows the known pathways of steroid metabolism. No pharmacologically active metabolites are known.

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.

The absolute bioavailability of levonorgestrel was determined to be almost 100% of the dose administered. About 0,1% of the maternal dose can be transferred via milk to the nursed infant.

### INDICATIONS

**PLAN B** is indicated for the prevention of pregnancy within 72 hours of unprotected sexual intercourse or the recognisable failure of mechanical methods.**PLAN B** is intended for emergencies only and is completely unsuitable for regular contraception. Its reliability is not as high as that of the familiar "pill", which is taken for at least 21 days of the menstrual cycle.

### CONTRA-INDICATIONS

**PLAN B** should not be given to pregnant and lactating women. If menstrual bleeding is overdue, if the last menstrual period was abnormal in timing or character or if pregnancy is suspected for any other reason, pregnancy should be excluded (by pregnancy testing or pelvic examination) before treatment is given.If a woman has had unprotected intercourse more than 72 hours earlier in the same menstrual cycle conception may have already occurred. Treatment with **PLAN B** following the second act of intercourse may therefore be ineffective in preventing pregnancy. It constitutes undesirable hormonal stress and may result in severe cycle disturbances.

Unexplained vaginal bleeding, current breast cancer, pregnancy or hypersensitivity to any of the ingredients of the preparation, a history of or current high risk of arterial disease.

### WARNINGS

Patients who become pregnant despite post-coital contraception should be carefully evaluated for possible ectopic pregnancy.

The effect of **PLAN B** on the conceptus in the event of failure to prevent conception is not definitely known.

### DOSAGE AND DIRECTIONS FOR USE

For oral administration.

2 x 750 microgram tablets to be taken as soon as possible (preferably within 72 hours) after the first unprotected intercourse.

The highest efficacy is achieved if the first dose is started as early as possible. Therefore treatment should not be delayed as efficacy declines with time.

If the patient vomits within two hours of taking the pills, she should return to her doctor or clinic where an additional pill may be given.

Children: **PLAN B** is not recommended in children.

### SIDE-EFFECTS AND SPECIAL PRECAUTIONS

#### Side-Effects

Gastro intestinal disturbances such as nausea, vomiting, changes in appetite or weight, fluid retention, oedema, acne, melasma or chloasma, allergic skin reactions, urticaria, mental depression, breast changes including discomfort or less frequently gynaecomastia.

Bleeding patterns may be temporarily disturbed. Some women may experience bleeding or spotting after taking **PLAN B** and some may experience early or delayed onset of menses. If the next menstrual period is more than 7 days overdue pregnancy should be excluded.

Changes in libido, hair loss or hirsutism, fatigue, drowsiness or insomnia, fever headache, pre-menstrual syndrome-like symptoms.

Visit your doctor 3 weeks after taking **PLAN B**

Anaphylaxis or anaphylactoid reactions may occur less frequently. Alterations in liver function tests have been reported less frequently, during prolonged levonorgestrel administration

Special care should be exercised in the following conditions: severe hypertension, diabetes mellitus with nephropathy, retinopathy of vascular disease, ischaemic heart disease, stroke, or a past history of breast cancer.

**PLAN B** must not be used 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 a long-term method of contraception.

Emergency contraception does not protect against sexually transmitted infections.

#### Precautions.

- Exclude pregnancy if suspected clinically.
- Explain the importance of follow-up and the possibility of an early or late onset of the next menstrual period to the patient. Advise the practice of abstinence or careful use of a barrier method until the onset of the next period. Follow-up should be offered 3 weeks after administration of therapy to assess the effectiveness of the method, to discuss future management if a period has not occurred, and to counsel the patient about future contraception.
- If pregnancy occurs after treatment with **PLAN B**, the possibility of an ectopic pregnancy should be considered.
- Vomiting, severe diarrhoea or other causes of malabsorption, such as Crohn's disease, might impair the efficacy of **PLAN B**. Consideration should be given to the taking of more pills.

#### Interactions

Some medicines accelerate the metabolism of oral contraceptives if taken concurrently. Medicines suspected of having the capacity to reduce the efficacy of oral contraceptives include barbiturates (including primidone), phenytoin, carbamazepine, phenylbutazone, rifampicin, ritonavir, ampicillin, griseofulvin and other antibiotics. The requirement for oral anti-diabetics and insulin can change as a result of an effect on glucose tolerance.

#### Lactation

Minute amounts of the active substance are excreted with the milk.

### KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Serious ill 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.

### IDENTIFICATION

Almost white, flat, tablets of about 6,5 mm diameter

### PRESENTATION

One blister sheet of two tablets packaged into an outer folded carton.

### STORAGE INSTRUCTIONS

Store below 25°C. Protect from light.

Store in original container until required for use

KEEP OUT OF REACH OF CHILDREN

### REGISTRATION NUMBER

36/21.8.2/0212

### NAME AND ADDRESS OF APPLICANT

Elttab Pharmaceuticals CC.  
6 Helderberg Bld.76 Andries Pretorius Street  
Somerset West  
South Africa

### DATE OF PUBLICATION

May 2006

## PATIENT INFORMATION LEAFLET

### PLAN B

Levonorgestrel tablets

### Patient Information Leaflet

Please read this leaflet carefully and if you are in doubt about these instructions contact your doctor or pharmacist.

### Introduction of PLAN B

#### Clinical pharmacology:

**PLAN B** (levonorgestrel) is believed to act to prevent ovulation, fertilization and implantation. It is not effective once the process of implantation has begun.

#### How does PLAN B work?

Depending on when you use **PLAN B** during your monthly cycle, the pills will either stop the release of an egg, prevent fertilization of an egg, or stop a fertilized egg from becoming attached to your uterus. Once this has happened **PLAN B** is no longer effective.

#### Pharmacokinetics:

The active substance of **PLAN B** is a female sexual hormone: levonorgestrel. The absorption of levonorgestrel from the gastrointestinal tract is rapid. The maximum blood concentration is achieved in less than 2 hours in most women. Thereafter, levonorgestrel serum levels decrease (mean elimination half-lives range from about 9 hours to 14,5 hours). Levonorgestrel metabolites are excreted at about equal proportions with urine and faeces.

#### How effective is PLAN B?

After a single act of unprotected intercourse the treatment fails in about 2 % of women who use it within 72 hours after intercourse. Treatment should not be delayed as efficiency may decline if treatment is initiated after the first 48 hours.

#### How often can you use PLAN B?

The failure rate of **PLAN B** is based on one-time use. If **PLAN B** is used on more than one occasion the cumulative failure rate will be higher. **PLAN B** is recommended only for the emergency situations listed above; it is not for routine use as a contraceptive.

#### Before you take PLAN B

**PLAN B** contains levonorgestrel that is contained in a number of oral contraceptives. Reasons for not using levonorgestrel containing oral contraceptives generally are listed later.

#### Product information:

The name of your medicine is: **PLAN B**

#### What does your medicine contain?

Each **PLAN B** tablet contains 0,75 mg of levonorgestrel, a totally synthetic progestogen. The inactive ingredients are silica (colloidal anhydrous), potato starch, gelatin, magnesium stearate, talc, maize starch, lactose monohydrate.

#### The product licence is held by:

Elttab Pharmaceuticals CC  
6 Helderberg Bld.76 Andries Pretorius Street  
Somerset West  
South Africa

Product registration number: 36/21.8.2/0212

#### Uses:

**PLAN B** is an emergency contraceptive which can be used to prevent pregnancy if taken within 72 hours (three days) following unprotected intercourse or a contraceptive accident.Two **PLAN B** tablets should be taken as soon as convenient but not later than 72 hours after unprotected intercourse. **PLAN B** can be used at any time during the menstrual cycle.As an emergency contraceptive, **PLAN B** is indicated following any unprotected act of sexual intercourse, including:

- when no contraceptive has been used
- when a contraceptive method may have failed, including:
  - ⇒ condom rupture, slippage or misuse
  - ⇒ diaphragm or cap dislodgement, breakage or early removal
  - ⇒ failed coitus interruptus
  - ⇒ miscalculation of periodic abstinence method
  - ⇒ IUD expulsion
  - ⇒ Missed regular oral contraceptive pills for four or more days in cycle
- in cases of sexual assault

#### Reasons for not taking PLAN B:

- confirmed or suspected pregnancy
- your menstrual bleeding is overdue
- you have already had unprotected intercourse more than 72 hours previously in the present menstrual cycle.

Levonorgestrel is generally contraindicated in the following cases (even in the history): undiagnosed abnormal vaginal bleeding, hepatic and gallbladder diseases, benign or malignant liver tumors, thromboembolic diseases, severe arterial diseases, risk of ischemic heart diseases (family history), mammary or endometrial carcinoma, disorders of lipid metabolism, hypersensitivity to any of the ingredients of **PLAN B**. Jaundice, pruritus, herpes gestationis, worsening of otosclerosis during previous pregnancy.

#### What you should know before taking PLAN B:

Before you take this medicine your pelvic organs, breasts and blood pressure will normally be checked by your doctor.

#### The following conditions need watching carefully if you take PLAN B:

If you have: asthma, severe cardiovascular diseases, hypertension, migraine, epilepsy, renal diseases, diabetes mellitus, a history of severe depressive states, thrombophlebitis, thromboembolic diseases, stroke.

#### Taking other medicines with PLAN B:

Some drugs may reduce or abolish the contraceptive effect of **PLAN B**. Medicines which may stop **PLAN B** from working are antibiotics (ampicillin, rifampicin), griseofulvin (treatment of fungal infections), phenylbutazone (anti-inflammatory drug), phenytoin, phenobarbital and some other drugs used to treat epilepsy and other diseases. The requirement for oral anti-diabetics and insulin can change as a result of the effect on glucose tolerance. So, if you are diabetic you doctor may alter the dose of these drugs.

#### Warnings:

If you have unprotected sex after using **PLAN B**, it will not protect you. Use a regular contraceptive method to prevent pregnancy in the future. Emergency contraceptives are not recommended for routine use because of the increased possibility of failure compared to regular contraceptives and the increased incidence of side effects.

Vomiting or diarrhoea that interfere with the absorption of the drug may reduce its effect.

Since **PLAN B** appears to affect only endometrial implantation, tubal (ectopic) pregnancy may occur. It is thus possible that there will be a greater chance of ectopic pregnancy in patients who become pregnant despite the use of **PLAN B** than usual.There is no evidence that **PLAN B** taken only in emergency situation diminishes the yield of breast milk. However, minute amounts of the active substance are excreted with the milk.

Based on available information, there is no reason to believe that the pregnancy would be abnormal or the baby hurt in any way if this medicine is taken within 72 hours of unprotected sex and in the absence of a pre-existing pregnancy.

Three weeks after administration of therapy you should consult your doctor to assess the effectiveness and to discuss future management of your contraception.

#### How to take your medicine:

Two **PLAN B** tablets should be taken orally as soon as convenient but not later than 72 hours after unprotected intercourse.

#### What to do if you are sick?

In case of diarrhoea and vomiting – due to reduced absorption – contraceptive effect may be reduced.

In case of vomiting within 2 hours of taking the tablets you should contact your doctor or clinic immediately for another tablet.

#### What to expect after you have taken your medicine:

- Nausea: Occurs in about 25 % of women taking **PLAN B**
- Vomiting: Occurs in about 5 % of women taking **PLAN B**
- Irregular uterine bleeding: Some women may experience spotting after taking **PLAN B**. The majority of women will have their next menstrual period at the expected time or early; if there is a delay in the onset of menses of more than one week the possibility of pregnancy should be excluded.
- Other: Breast tenderness; headache; dizziness and fatigue. These side effects generally do not last more than 24 hours.

#### Overdose:

Serious ill effects have not been reported following acute ingestion of large doses of oral contraceptives. Overdose may cause nausea, and withdrawal bleeding may occur in females. Contact your doctor or pharmacist if you are worried at all.

#### Storage:

Store below 25°C. Protect from light.

Store in original container until required for use.

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

#### How supplied:

**PLAN B** tablets (0,75 mg of levonorgestrel) are available in packages of two tablets each.

Almost white, flat, tablets of about 6,5 mm diameter

#### Date of last revision:

May 2006



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