008202

PACKAGE INSERT

SCHEDULING STATUS

S 2

PROPRIETARY NAME (AND DOSAGE FORM)

***PLAN B*® (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, uricaria, 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 hursutism, 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), phenytion, carbamazepine, phenylbutazone, rifampicin, ritonavir, ampicillin, griseofulvin and other antibiotics. The requirement for oral antidiabetics 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 CHILRDREN

REGISTRATION NUMBER

36/21.8.2/0212

NAME AND ADDRESS OF APPLICANT

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

DATE OF PUBLICATION

Nov 2016

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?

The inactive ingredients are lactose monohydrate, corn starch, gelatin, talc, silica (colloidal anhydrous) and magnesium stearate.

The product licence is held by:

Elttab Pharmaceuticals CC
6 Helderberg Bld.
76 Andries Pretorious 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 antidiabetics 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:

Nov 2016

VOUBILJET

SKEDULERINGSTATUS

S 2

EIENDOMSNAAM (EN DOSEERVORM)

PLAN B® (tablet)

SAMESTELLING

Elke tablet bevat 750 mikrogram levonorgestrel.

FARMAKOLOGIESE KLASSIFIKASIE

A. 21.8.2 Progesterone met of sonder estrogene

FARMAKOLOGIESE WERKING

Daar word gereken dat nood- hormonale voorbehoeding hoofsaaklik werk deurdat dit bevrugting voorkom deur wysiging van die transport van sperm en/of ova in die buis. Dit mag ook endometriële veranderings veroorsaak, wat inplanting ontmoedig.
Die presiese manier waarop ***PLAN B*** werk, is nie bekend nie.

Farmakokinetika

Levonorgestrel wat per mond toegedien word, word feitlik volledig geabsorbeer. Ná inname van een ***PLAN B*** tablet, was maksimum serumvlakke van die geneesmiddel 14,1 ng/ml teen 1,6 uur.
Daarna verminder serumvlakke van levonorgestrel in twee disposisiefases, met gemiddelde eliminasiehalfleeftye wat wissel van ongeveer 9 uur tot 14,5 uur.
Levonorgestrel word nie in die onveranderde vorm uitgeskei nie, maar as metaboliete. Metaboliete van levonorgestrel word byna eweveel in die urine en in die feses uitgeskei. Die biotransformasie volg die paaie wat bekend is vir steroïedmetabolisme. Geen farmakologies aktiewe metaboliete is bekend nie.
Levonorgestrel is gebind aan serumalbumien en sekshormoonbindende globulien (SHBG). Slegs omtrent 1,5 % van die totale serumvlakke is teenwoordig in die vorm van die vrye steroïed, maar 65 % is spesifiek aan SHBG gebind.
Dit is vasgestel dat die absolute biobeskikbaarheid van levonorgestrel feitlik 100 % is van die dosis wat toegedien is.
Ongeveer 0,1 % van die dosis wat aan die moeder toegedien word, kan deur die melk na die baba wat geborsvoed word, oorgedra word.

INDIKASIES

PLAN B word aangedui vir die voorkoming van swangerskap binne 72 uur ná onbeskermde geslagsomgang, of wanneer gesien word dat meganiese metodes gefaal het.
PLAN B word slegs bedoel vir noodgevalle en is heeltemal ongeskik vir gewone voorbehoeding. Die betroubaarheid daarvan is nie so hoog as dié van die bekende "pil" nie, wat vir ten minste 21 dae van die menstruasiesiklus geneem word.

KONTRA-INDIKASIES

PLAN B moet nie aan swanger en lakterende vroue gegee word nie. Indien menstruele bloeding laat is, indien die vorige menstruasieperiode abnormaal was betreffende tydsberekening of kenmerke, of indien swangerskap om enige ander rede vermoed word, moet swangerskap uitgesluit word (met 'n swangerskaptoets of pelviese ondersoek) voordat behandeling gegee word.
Indien 'n vrou meer as 72 uur vroeër in die dieselfde menstruele siklus onbeskermde omgang gehad het, mag bevrugting reeds plaasgevind het. Behandeling met ***PLAN B*** nadat omgang die tweede keer plaasgevind het, mag dus nie effektief wees om swangerskap te voorkom nie. Dit dra by tot ongewenste hormonale spanning en mag erge siklusversteurings veroorsaak.
Onverklaarde vaginale bloeding, bestaande borskanker, swangerskap of hipersensitiwiteit vir enige van die bestanddele van die bereiding, 'n geskiedenis van of 'n bestaande hoë risiko vir arteriële siekte.

WAARSKUWINGS

Pasiënte wat swanger raak ten spyte van postkoïtale voorbehoeding, moet deeglik geëvalueer word vir moontlike ektopiese swangerskap.
Die uitwerking van ***PLAN B*** op die vrug van die swangerskap in geval van mislukking om bevrugting te voorkom, is nie seker nie.

DOSIS EN GEBRUIKSAANWYSINGS

Vir orale toediening.
2 x 750 mikrogram tablette moet so gou as moontlik geneem word (verkieslik binne 72 uur) ná die eerste onbeskermde geslagsomgang.
Dit is die effektiefste indien die dosis so vroeg as moontlik geneem word. Behandeling moet dus nie uitgestel word nie, aangesien effektiwiteit afneem met tyd.
Indien die pasiënt braak binne twee uur nadat die pille geneem geneem is, moet sy teruggaan na haar dokter of die kliniek, waar 'n bykomende tablet gegee mag word.
Kinders: ***PLAN B*** word nie aanbeveel vir kinders nie.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS

Newe-effekte

Gastro-intestinale versteurings soos naarheid, braking, veranderings in aptyt of gewig, vloeistofterughouding, edeem, aknee, melasma of chloasma, allergiese velreaksies, urtikarie, depressiewe gemoed, borsveranderings insluitend ongemak of minder dikwels ginekomastie.
Bloedingspatrone kan tydelik versteur wees. Sommige vrouens mag bloeding of deurbraakbloedings ervaar nadat ***PLAN B*** geneem is en sommige kan vroeë of vertraagde aanvang van menstruasie ervaar. Indien die volgende menstruasieperiode meer as 7 dae laat is, moet swangerskap uitgesluit word.
Veranderings in libido, haarverlies of hirsutisme, uitputting, lomerigheid of slaaploosheid, koors, hoofpyn, premenstruele sindroom-agtige simptome.
Besoek die dokter 3 weke nadat ***PLAN B*** geneem is.

Anafilakse of anafilaktoïede reaksies mag minder dikwels voorkom. Wysigings in lewerfunksietoetse is minder dikwels tydens verlengde toediening van levonorgestrel aangemeld.
Spesiale sorg moet geneem word met die volgende toestande: erge hipertensie, diabetes mellitus met nefropatie, retinopatie van vaskulêre siekte, iskemiese hartsiekte, beroerte, of 'n geskiedenis van borskanker.
PLAN B moet nie as 'n konvensionele gereelde metode van voorbehoeding gebruik word nie en is slegs geskik as 'n noodmaatreël. Vrouens wat herhaaldelik 'n kursus noodvoorbehoeding benodig, moet aangeraai word om 'n langtermyn metode vir voorbehoeding te oorweeg.
Noodvoorbehoeding beskerm nie teen seksueel oordraagbare infeksies nie.

Voorsorgmaatreëls

- Sluit swangerskap uit indien dit klinies vermoed word.
- Verduidelik die belang van opvolg en die moontlikheid van 'n vroeë of laat aanvang van die volgende menstruasieperiode aan die pasiënt. Adviseer die toepassing van onthouding of versigtige gebruik van 'n versperringsmetode tot die volgende periode begin. 'n Opvolgbesoek moet 3 weke na toediening van terapie gereël word om die effektiwiteit van die metode te evalueer, om toekomstige bestuur te bespreek indien 'n periode nie plaasgevind het nie, en om die pasiënt oor toekomstige voorbehoeding te adviseer.
- Indien swangerskap ná behandeling met PLAN B voorkom, moet die moontlikheid van 'n buisswangerskap oorweeg word.
- Braking, erge diarree of ander oorsake van wanabsorpsie, soos Crohn se siekte, mag die effektiwiteit van PLAN B belemmer. Dit moet oorweeg word om meer tablette te neem.

Interaksies

Sommige medisynes versnel die metabolisme van orale voorbehoedmiddels indien dit gelyktydig geneem word. Medisynes wat vermoed word dat dit die effektiwiteit van orale voorbehoedmiddels kan verlaag, sluit in barbiturate (insluitend primidoon), fenitoïen, karbamasepien, fenielbutasoon, rifampisien, ritonavir, ampisillien, griseofulvien en ander antibiotika. Die behoefte vir orale antidiabetiese middels en insulien kan verander weens 'n uitwerking op glukoseverdraagsaamheid.

Borsvoeding

Baie klein hoeveelhede van die aktiewe middel word in die melk uitgeskei.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN

Daar is nie ernstige nadelige effekte aangemeld ná akute inname van groot dosisse orale voorbehoedmiddels nie. Oordosering mag naarheid veroorsaak, en onttrekkingsbloeding kan voorkom. Daar is geen spesifieke teenmiddels nie en behandeling moet simptomaties en ondersteunend wees.

IDENTIFIKASIE

Byna wit, plat, tablette met 'n deursnee van ongeveer 6,5 mm, **AANBIEDING**
Een stulpstrook met twee tablette verpak in 'n buitenste gevoude karton.

BEWARINGSINSTRUKSIES

Bêre onder 25˚C. Beskerm teen lig.
Bêre in die oorspronklike verpakking tot nodig vir gebruik.
HOU BUITE BEREIK VAN KINDERS

REGISTRASIENOMMER

36/21.8.2/0212

NAAM EN ADRES VAN DIE APPLIKANT

Elttab Pharmaceuticals BK
6 Helderberg Building, 76 Andries Pretorious Street
Somerset-Wes
Suid-Afrika

DATUM VAN PUBLIKASIE

Nov 2016

PASIËNTINLIGTINGSBLAD

PLAN B

Levonorgestrel tablette

Pasiëntinligtingsblad

Lees asseblief hierdie inligtingsblad noukeurig en indien u twyfel oor hierdie aanwysings, kontak u dokter of apteker.

Bekendstelling van PLAN B

Kliniese farmakologie:

Dit word gereken dat PLAN B (levonorgestrel) ovulasie, bevrugting en inplantasie voorkom. Sodra die proses van inplantasie begin het, is dit nie meer effektief nie.

Hoe werk PLAN B?

Afhangende van op watter stadium tydens u maandelikse siklus u PLAN B gebruik, sal die tablette óf die vrystelling van 'n eiersel stop, bevrugting van 'n eiersel voorkom, óf keer dat 'n bevrugte eiersel aan u uterus heg. Sodra dit gebeur het is PLAN B nie meer effektief nie.
Farmakokinetika:
Die aktiewe bestanddeel van PLAN B is 'n vroulike geslagshormoon: levonorgestrel. Levonorgestrel word vinnig uit die gastroïntestinale weg geabsorbeer. In die meeste vrouens word die maksimum bloedkonsentrasie in minder as 2 uur bereik. Daarna neem levonorgestrel serumvlakke af (gemiddelde eliminasiehalfleeftye wissel van ongeveer 9 uur tot 14,5 uur). Metaboliete van levonorgestrel word byna eweveel in die urine en die stoelgange uitgeskei.

Hoe effektief is PLAN B?

Ná 'n enkele voorval van onbeskermde seksuele omgang, faal die behandeling in ongeveer 2 % van vroue wat dit binne 72 uur ná omgang neem. Behandeling moet nie uitgestel word nie, aangesien die effektiwiteit mag afneem indien behandeling ná die eerste 48 uur begin word.

Hoe dikwels kan u PLAN B gebruik?

Die mislukkingskoers van PLAN B is gegrond op een keer se gebruik. Indien PLAN B by meer as een geleentheid gebruik word, sal die kumulatiewe mislukkingskoers hoër wees. PLAN B word slegs vir die noodsituasies wat hierbo gelys is aanbeveel; dit is nie vir roetinegebruik as voorbehoedmiddel nie.

Voordat u PLAN B neem

PLAN B bevat levonorgestrel, wat voorkom in 'n aantal mondelikse voorbehoedmiddels. Algemene redes om nie mondelikse voorbehoedmiddels wat levonorgestrel bevat te gebruik nie, word later gelys.

Produkinligting:
Die naam van u medisyne is: PLAN B

Wat bevat u medisyne?

Die onaktiewe bestaanddele is laktosemonihidraat, mieliesteysel, gelatine, talk, silica (anhidriese kolloide) en magnesiumstearaat.

Houer van die registrasiesertifikaat:

Elttab Pharmaceuticals BK
6 Helderberg Building, 76 Andries Pretorious Street
Somerset-Wes
Suid-Afrika
Produk se registrasienommer: 36/21.8.2/0212

Gebruike:

PLAN B is 'n **noodvoorbehoedmiddel** wat gebruik kan word om swangerskap te voorkom indien dit geneem word binne 72 uur (drie dae) ná onbeskermde omgang of 'n kontraseptiewe ongeluk.
Twee PLAN B tablette moet so gou as wat vir u gerieflik is geneem word, maar nie later as 72 uur na onbeskermde seksuele omgang nie. PLAN B kan op enige tydstip tydens die menstruasiesiklus gebruik word.
As 'n **noodvoorbehoedmiddel**, word PLAN B aangedui ná enige onbeskermde geslagsomgang, insluitend:

- wanneer geen voorbehoedmiddel gebruik is nie
- wanneer 'n voorbehoedmiddel misluk het, insluitend:
  - ⇒ kondoom wat skeur, afgly of verkeerd gebruik word
  - ⇒ wanneer die diafragma geskuif, gebreek of vroeg verwyder is
  - ⇒ mislukte coitus interruptus
  - ⇒ verkeerde berekening wanneer metode van periodiese onthouding gebruik is
  - ⇒ IUD uitwerping
  - ⇒ wanneer die gewone mondelikse voorbehoedpil vir vier dae of meer in 'n siklus oorgeslaan is
- in gevalle van seksuele aanranding

Redes om nie PLAN B te neem nie:

- bevestigde swangerskap of indien swangerskap vermoed word
- u menstruele bloeding is laat
- u het reeds onbeskermde omgang meer as 72 uur vroeër in die huidige menstruasiesiklus gehad.

Levonorgestrel is oor die algemeen teenaangedui in die volgende gevalle (ook 'n geskiedenis van): ongediagnoseerde abnormale vaginale bloeding, lewer- en galblaassiektes, goed- of kwaadaardige lewergewasse, tromboëmboliese siektes, ernstige siektes van die slagare, risiko van iskemiese hartsiektes (familiegeskiedenis), borskanker of endometriële karsinoom, versteurings van lipiedmetabolisme, hipersensitiwiteit vir enige van die bestanddele van PLAN B. Geelsug, pruritus, herpes gestationis, verergering van otosklerose gedurende 'n vorige swangerskap.

Wat u moet weet voordat PLAN B geneem word:

Voordat u hierdie medisyne neem, sal u dokter gewoonlik u pelviese organe en borste ondersoek en u bloeddruk meet.

Die volgende toestande moet noukeurig dopgehou word indien u PLAN B neem:

Indien u die volgende het: asma, ernstige kardiovaskulêre siektes, hipertensie, skeelhoofpyn, epilepsie, niersiektes, diabetes mellitus, 'n geskiedenis van ernstige toestande van depressie, tromboflebitis, tromboëmboliese siektes, beroerte.
Die neem van ander medisynes saam met PLAN B:
Sommige middels kan die kontraseptiewe werking van PLAN B verminder of afskaf. Medisynes wat PLAN B kan laat ophou werk, is antibiotika (ampisillien, rifampisien), griseofulvien (behandeling van swaminfeksies), fenielbutasoon (anti-inflammatoriese middel), fenitoïen, fenobarbitaal en sommige ander middels wat gebruik word om epilepsie en ander siektes te behandel. Die hoeveelheid mondelikse antidiabetiese middels en insulien wat nodig is kan verander weens die uitwerking op glukoseverdraagsaamheid. Indien u dus diabeties is, kan u dokter die dosis van hierdie middels wysig.

Waarskuwings:

Indien u onbeskermde seks het nádat PLAN B gebruik is, sal dit u nie beskerm nie. Gebruik 'n gewone kontraseptiewe metode om swangerskap in die toekoms te voorkom. Noodvoorbehoedmiddels word nie vir roetinegebruik aanbeveel nie weens die groter moontlikheid van mislukking in vergelyking met gewone voorbehoedmiddels en die verhoogde insidensie van newe-effekte.
Braking of diarree wat inmeng met die absorpsie van die middel, kan die werking daarvan verminder.
Aangesien dit lyk of PLAN B slegs endometriële inplantasie beïnvloed, kan buis (ektopiese) swangerskap voorkom. Dit is dus moontlik dat daar 'n groter kans as gewoonlik vir 'n buisswangerskap sal wees in pasiënte wat swanger raak ten spyte van die gebruik van PLAN B.
Daar is geen bewyse dat PLAN B wat slegs in 'n noodsituasie geneem word die hoeveelheid borsmelk verminder nie. Klein hoeveelhede van die aktiewe middel word egter in die melk uitgeskei.
Gebaseer op die beskikbare inligting is daar geen rede om te glo dat die swangerskap abnormaal sal wees of die baba op enige manier skade aangedoen sal word indien hierdie medisyne binne 72 uur ná onbeskermde seks geneem word en waar daar nie 'n voorafbestaande swangerskap is nie.
U moet u dokter drie weke na toediening van die terapie konsulteer, om die effektiwiteit daarvan te evalueer en om toekomstige bestuur van u kontrasepsie te bespreek.

Hoe om u medisyne te neem:

Twee PLAN B tablette moet so gou as moontlik mondeliks geneem word, maar nie meer as 72 uur na onbeskermde geslagsomgang nie.

Wat om te doen indien u mislikheid ervaar?

In die geval van diarree en braking kan die kontraseptiewe effek weens verlaagde absorpsie verminder wees.
In geval van braking binne 2 uur nadat die tablette geneem is, moet u die dokter of kliniek onmiddellik kontak vir 'n ander tablet.

Wat om te verwag nadat u die medisyne geneem het:

- Naarheid: Kom voor in ongeveer 25 % van vrouens wat PLAN B neem
- Braking: Kom voor in ongeveer 5 % van vrouens wat PLAN B neem
- Ongereelde bloeding van die uterus: Sommige vrouens mag deurbraakbloedings ervaar nadat PLAN B geneem is. Die meerderheid vrouens sal hulle volgende menstruasieperiode op die verwagte tyd of vroeër hê; indien daar 'n vertraging van meer as een week in die aanvang van menses is, moet seker gemaak word dat u nie swanger is nie.
- Ander: Borsteerheid; hoofpyn; duiseligheid en uitputting. Hierdie newe-effekte duur gewoonlik nie meer as 24 uur nie.

Oordosering:

Ernstige nadelige effekte is nie aangemeld ná akute inname van groot dosisse mondelikse vorbehoedmiddels nie. Oordosis kan naarheid veroorsaak, en onttrekkingsbloeding kan in vroulike pasiënte voorkom. Kontak u dokter of apteker indien u enigsins bekommerd is.

Berging:

Bêre onder 25˚C. Beskerm teen lig.
Bêre in die oorspronklike verpakking tot nodig vir gebruik.
HOU ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

Hoe dit verskaf word:

PLAN B tablette (0,75 mg levonorgestrel) is beskikbaar in pakke van twee tablette elk.
Byna wit, plat, tablette met 'n deursnee van ongeveer 6,5 mm,

Datum van laaste hersiening:

Nov 2016

本頁為文件說明頁, 請勿印刷

VERSION NUMBER	SLT0082H-02-ZA-PlanB-PI-2017.01.10
REVISION DATE YYYY.MM.DD	2017.01.10
DIMENSIONS (MM) WIDTH * HEIGHT	140*540