PATIENT INFORMATION LEAFLET FOR LEVETTE

SCHEDULING STATUS: S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

LEVETTE® 0,15 mg / 0,03 mg Film-Coated Tablet

Levonorgestrel and ethinylestradiol.

Read all of this leaflet carefully before you start taking LEVETTE:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

LEVETTE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

1. WHAT LEVETTE IS AND WHAT IT IS USED FOR:

LEVETTE is used to prevent pregnancy by suppressing ovulation and thickening the cervical mucus.

LEVETTE is also used in the management of dysfunctional or irregular periods and painful periods where birth control is also required.

Each of the 21 yellow tablets contains a small quantity of two different female hormones, called levonorgestrel and ethinylestradiol. The 7 white tablets do not contain active ingredients and are called placebo (inactive)

tablets. Contraceptive pills that contain two hormones are called “combination” pills or combined oral contraceptives (COC).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE LEVETTE:

Do not take LEVETTE:

Do not take LEVETTE if you have any of the conditions listed below. If any of these apply to you, tell your doctor before starting LEVETTE. Your doctor may advise you to use a different type of contraceptive pill or an entirely different (non-hormonal) method of birth control.

- If you have (or have had in the past) venous thrombosis: deep vein thrombosis (formation of blood clots in the blood vessels of the leg); pulmonary embolism (formation of blood clots in the blood vessels of the lungs); or the formation of blood clots in other organs. See also the section “The contraceptive pill and thrombosis”.
- If you have (or have had in the past) arterial thrombosis (formation of blood clots in the arteries such as heart attack or a stroke). See also the section “The contraceptive pill and thrombosis”.
- If you have (or have had in the past) any illness which could lead to a heart attack (for example, angina pectoris which causes serious pain in the chest) or a stroke.
- If you have (or have had in the past) a stroke.
- If you suffer from high blood sugar (diabetes mellitus) with heart or circulatory problems.
- If you suffer from severe high blood pressure.
- If you have severe dyslipoproteinaemia (abnormal distribution of lipoproteins in the blood).
- If you have (or have ever had) a certain form of migraine (with focal neurological symptoms e.g. visual symptoms, speech difficulties, or weakness or numbness in any part of your body).
- If you have (or have had in the past) a liver illness or jaundice and your liver function is still not normal.
- If you have (or have ever had) a liver tumour (benign or malignant).
- If you have (or have ever had), or you suspect you have breast cancer or cancer of the genital organs.
- If you have vaginal bleeding and the cause is unknown.

- If you are pregnant or think you might be pregnant, or if you have had jaundice, itching, blistering skin or hearing problems with a previous pregnancy.
- If you are allergic to levonorgestrel or ethinylestradiol or any other ingredients in LEVETTE.
- If you have an inherited or acquired risk for thrombosis (formation of a blood clot in a blood vessel).
- If you do not have menstrual periods and the cause is not known.
- If you have depression, which is not well controlled with treatment
- If you have had depression with previous use of hormonal contraceptives

If any of these conditions occur for the first time while using LEVETTE, stop taking it at once and consult your doctor. Use a barrier contraceptive measure (e.g. condoms) in the meantime. (See “Take special care with LEVETTE”).

Warnings and precautions:

Take special care with LEVETTE:

Before you can begin taking LEVETTE your doctor will ask you some questions about your personal health and that of your close relatives. The doctor will also measure your blood pressure, and depending upon your personal situation, may also carry out some other tests.

This leaflet describes various situations where you should stop taking LEVETTE or when the effect of LEVETTE could be reduced. In such situations you should not have sexual intercourse or you should use a barrier contraceptive method (e.g. a condom). Do not use the rhythm or temperature method. These methods can be unreliable as LEVETTE alters the monthly changes in body temperature and cervical mucus.

LEVETTE will not protect you against HIV infection (AIDS) or any other sexually transmitted diseases (e.g. chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B and syphilis). Ask your doctor or healthcare provider for advice if you are worried about this.

If any of the following affect you, tell your doctor before starting to use LEVETTE. You should also consult your doctor if the following occur or worsen during your use of LEVETTE:

- If you are on treatment for depression

- If you have had depression with previous use of hormonal contraceptives
- If you have a substance abuse problem
- If you have an underlying psychiatric disorder such as post-traumatic stress disorder or bipolar disorder
- If you have a family history of mental disorders
- If you have a history of physical or sexual abuse

If you have depression or a history of depression this could get worse or reappear. LEVETTE should be discontinued and an alternative method of contraception used. Women with a history of depression should be monitored.

Hormonal contraceptives including LEVETTE, may cause mood changes and depression, which may be severe. Severe depression is associated with a higher risk of suicidal thoughts/behavior (eg. talking about suicide, withdrawing from social contact, having mood swings, being preoccupied with death or violence, feeling hopeless about a situation, increasing use of alcohol/drugs, doing self-destructive things, personality changes) and suicide. If you experience mood changes and depression contact your doctor for advice.

- If you smoke. Smoking cigarettes increases the risk of serious side-effects on your heart. This risk increases with age and the extent of smoking (15 or more cigarettes per day was associated with a significantly increased risk) and is marked in women over 35 years of age. If you use LEVETTE it is strongly advised that you quit smoking, especially if you are over 35 years of age.
- If you or someone in your immediate family has or has had high blood levels of cholesterol or triglycerides (fatty substances). You may be at an increased risk of pancreatitis (inflammation of the pancreas) when using LEVETTE.
- If you have visual disturbances.
- If you have Crohn's disease or ulcerative colitis (an inflammatory bowel disease).
- If you have HUS (haemolytic uraemic syndrome; a blood illness which damages the kidneys).
- If you have epilepsy (see "Taking other medicines with LEVETTE").
- If you have SLE (Systemic lupus erythematosus; an illness affecting the immune system).

- If you have or have ever had chloasma (patches of tan/brown skin discolouration, especially on the face), especially in women with a history of chloasma gravidarum (occurring during pregnancy). If you experience this, you have to avoid direct sunlight and ultraviolet rays while taking LEVETTE.
- If you have hereditary angioedema (allergic swelling or oedema that tends to appear on the face and throat), as LEVETTE may induce or worsen symptoms of angioedema.
- You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or pharynx and/or difficulty swallowing or hives together with difficulty breathing.
- If you have active pregnancy-related tumours.
- If you have varicose veins (twisted, enlarged veins near the surface of the skin) or if you are undergoing bile duct treatment.

You should not take herbal products containing St. John's Wort while using LEVETTE as St. John's Wort may reduce the efficacy of LEVETTE with the risk of unexpected pregnancy and intermenstrual bleeding. You should use an additional barrier contraceptive method (e.g. condom). (See "Other medicines and LEVETTE").

The contraceptive pill and thrombosis (venous and arterial blood clots):

Venous thrombosis:

The use of LEVETTE increases the risk of developing venous thrombosis (formation of a blood clot in a blood vessel), compared to women who do not take LEVETTE.

The risk of developing venous thrombosis when taking LEVETTE increases:

- With increasing age.
- If you are overweight.
- If any of your close family members have had blood clots in the leg, lungs (pulmonary embolism) or any other organ at an early age.
- If you must have surgery, or are going to be immobilised for a long time or have suffered a serious accident. It is important to tell your doctor in advance that you are using LEVETTE as LEVETTE use may have to be stopped. Your doctor will tell you when to start LEVETTE again. This is usually about two weeks after you are back on your feet.

Arterial thrombosis:

The use of LEVETTE has been linked to an increased risk of developing an arterial thrombosis (formation of a blood clot in an artery), for example, in the blood vessels of the heart (heart attack) or the brain (stroke).

The risk of developing an arterial blood clot when taking LEVETTE increases:

- With increasing age.
- If you smoke. If you use LEVETTE it is strongly advised that you quit smoking, especially if you are over 35 years of age.
- If you have high levels of blood cholesterol or triglycerides.
- If you are overweight.
- If you have high blood pressure.
- If you have migraines.
- If you have heart problems (valve disorders, changes in your heart rhythm).

Stop taking LEVETTE and contact your doctor immediately if you notice possible signs of a blood clot, myocardial infarction or a stroke such as:

- Severe pain and/or swelling in one of your legs.
- Severe pain in your stomach.
- Sudden severe pain in the chest which may reach the left arm.
- Sudden breathlessness.
- Sudden cough without an obvious cause.
- Any unusual, severe or long-lasting headache or worsening of migraine.
- Partial or complete blindness or double vision.
- Difficulty in speaking or inability to speak.
- Dizziness or fainting.
- Weakness, strange feeling or numbness in any part of the body.
- Sudden changes to your hearing, sense of smell, or taste.
- Disturbances of the movements, muscular rigidity or incoordination.

The risk of blood clot formation may be increased in the post natal period (immediately after delivery of a baby).

Other diseases in which the blood vessels may be involved include diabetes and sickle cell disease (inherited change in haemoglobin).

Your doctor may check for biochemical substances in your body which may indicate if you have an inherited or acquired risk for thrombosis (formation of a blood clot in a blood vessel).

The contraceptive pill and cancer:

Breast cancer has been observed slightly more often in women using combined pills such as LEVETTE.

Some studies indicate that the long-term use of hormonal agents for contraception such as LEVETTE represents a risk factor for the development of cervical cancer.

Benign and malignant liver tumors have been reported in COC users. This may cause internal bleeding resulting in intense pain in the abdomen. If this occurs, you should contact your doctor immediately.

A slight increase in the relative risk of cervical cancer and cervical intraepithelial neoplasia (serious diseases affecting the neck of the uterus) has been observed.

Other diseases:

- Women who have been treated for hyperlipidaemia (increased blood fat, such as triglycerides and/or cholesterol) should be monitored if they decide to take LEVETTE.
- A small increase in blood pressure has been reported in women who take COCs such as LEVETTE. If you suffer from a constant high blood pressure during LEVETTE use, you must see your doctor.
- In women with endometrial hyperplasia (thickening of the lining of the uterus). Your doctor should carefully assess the risk-benefit ratio before prescribing LEVETTE and should carefully monitor you during the treatment period, performing periodical smear tests.
- Acute or chronic liver function disorders require discontinuation of LEVETTE use until liver function values return to normal. The recurrence of cholestatic jaundice (yellow colour in mucous membranes, eyes and/or skin related to blocked or reduced flow of bile) that first appeared during pregnancy or during previous hormone use requires discontinuation of the LEVETTE.
- LEVETTE may have an effect on peripheral insulin resistance and glucose tolerance. If you have diabetes, your doctor will monitor your blood sugar levels while taking LEVETTE.
- If you start experiencing headache or worsening of the headache that occurs repeatedly, contact your doctor immediately.

Medical examination and consultation:

Prior to starting or resuming treatment with LEVETTE, your doctor must take a complete medical history and physical examination to rule out contraindications and take into account precautions and these should be repeated at least once a year during LEVETTE use.

Reduced efficacy:

The contraceptive effect can be reduced by forgetting to take the pill (see “If you forget to take LEVETTE”), vomiting, colon diseases with severe diarrhoea (see “Advice in case of gastrointestinal disorders”) or by the simultaneous use of other medicines (see “Taking other medicines with LEVETTE”).

Cycle control irregularities:

When using LEVETTE, spotting or vaginal bleeding may occur between periods, especially during the first few months of use. If these bleeding irregularities persist or occur after previously regular cycles, your doctor must investigate the cause.

In some women withdrawal bleeding (period) may not occur during the week off (placebo tablet interval). If you have taken all the tablets according to the instructions given in the “How to take LEVETTE” section, it is unlikely that you are pregnant. However, if you have not taken the tablets according to these instructions prior to the first missed withdrawal bleed or if two withdrawals bleeds are missed, pregnancy must be ruled out before LEVETTE use is continued.

Laboratory tests:

If you need a blood test, tell the doctor or laboratory staff that you are taking LEVETTE, as LEVETTE can affect the results of some tests.

Other medicines and LEVETTE:

Always tell your healthcare provider if you are taking any other medicine (this includes all complementary or traditional medicines).

Please consult your doctor, pharmacist, or other healthcare professional for advice.
They may advise you to use additional contraceptive precautions (e.g. condoms) and, if so, for how long.
Certain medicines can make LEVETTE less effective in preventing pregnancy or can cause unexpected bleeding. It is especially important that you tell your doctor if you are using any of the following medicines:

- Antacids (including lansoprazole and magnesium containing antacids).
- Medicines that increase intestinal motility (e.g. metoclopramide).
- Laxatives.
- Medicines for the treatment of epilepsy (such as phenytoin, barbiturates (phenobarbital), primidone, carbamazepine, oxcarbazepine, topiramate).
- Medicines for the treatment of tuberculosis (such as rifampicin, rifabutin).
- Antibiotics (such as penicillin and derivatives, tetracycline, griseofulvin, erythromycin).
- Certain medicines for the treatment of HIV infections (ritonavir, nevirapine).
- Herbal products containing St. John's Wort (Hypericum Perforatum) can lower the concentration of oestrogens in the blood. This decrease may continue for approximately two weeks after use. St. John's Wort should therefore not be used at the same time as LEVETTE.
- Modafinil (agent for treating narcolepsy, a disorder of the nervous system).
- Certain medicines for the treatment of high blood pressure (bosentan).

If you are treated with one of the medicines named above, a barrier method (e.g. condom) should be used in addition to LEVETTE. For some of the medicines named above, these additional contraceptive measures must be used not only while taking the additional medicines, but also, depending on the medicine, after you stop taking the medicine. The effect of some of these medicines may last up to 28 days after discontinuing treatment. Ask your doctor or pharmacist, if necessary.

LEVETTE may reduce the effect of oral anticoagulants (blood thinning medicines), analgesics (paracetamol and salicylates), fibrates (medicines used to lower triglyceride and/or cholesterol levels), lamotrigine (antiepileptic), oral antidiabetic medicines and insulin, and increase the effect of other medicines such as beta-blockers (metoprolol), theophylline (to treat asthma), corticosteroids (such as prednisolone), ciclosporin

(increasing the risk of liver toxicity), flunarizine (increasing the risk of milk secretion), thyroxine (thyroid hormone).

LEVETTE may potentiate the effect of lidocaine (lignocaine) (pain relieving medicines used during surgery), selegiline (medicine used for depression), melatonin (hormone that helps to regulate sleep) and benzodiazepines (medicines used to treat anxiety).

You should never take other medicines on your own initiative without your doctor's approval given that some combinations should be avoided. You should consult the prescribing information of all medicines you are taking to identify possible interactions.

Pregnancy and Breast-feeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Pregnancy:

If you are pregnant you must not take LEVETTE. If you become pregnant while taking LEVETTE you must stop immediately and contact your doctor.

Breastfeeding:

It is not recommended to take LEVETTE when you are breast-feeding. If you want to use LEVETTE while you are breast-feeding, you should consult your doctor.

If you want to use LEVETTE after having a baby or an abortion in the 2nd trimester: see “How to take LEVETTE”.

Driving and using machinery:

LEVETTE may cause headache and vertigo (an illusion or sense of whirling or spinning movements). You should not drive or use machines until you know how LEVETTE affects you.

LEVETTE contains lactose:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking LEVETTE.

If you have any further questions on using LEVETTE, ask your doctor or pharmacist.

3. HOW TO TAKE LEVETTE

Always take LEVETTE exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

Do not share medicines prescribed for you with any other person.

Remember to take your medicine because missing tablets could reduce the effectiveness of LEVETTE.

Each blister strip contains 21 active yellow tablets and 7 white placebo (inactive) tablets. The two differently coloured tablets of LEVETTE are arranged in order. Each blister strip contains 28 tablets in total.

Take one tablet of LEVETTE every day, if necessary with a small amount of water. You should take the tablets every day around the same time.

Follow the direction of the arrows on the blister strip until you have taken all 28 tablets. Do not confuse the tablets: take a yellow tablet once per day for the first 21 days, and then one white tablet once per day for the last 7 days. Then you should start a new strip (21 yellow tablets and 7 white tablets). Consequently there is no tablet-free interval between strips.

During the 7 days when you are taking the white placebo tablets (the placebo days), bleeding should begin (withdrawal bleeding). This usually starts on the 2nd to 4th day after the last yellow (active) tablet of LEVETTE. Once you have taken the last white tablet, you should start with the next pack (strip), whether your bleeding has stopped or not.

If you use LEVETTE in this manner, you are protected against pregnancy also during the 7 days when you are taking a placebo tablet.

Starting the first pack of LEVETTE:

If you have not taken any “contraceptive pill” in the previous month:
Start taking LEVETTE on the first day of your menstrual cycle. You can also start from the 2nd– 5th day of your cycle, but you must use an additional barrier contraceptive method (e.g. condom) for the first 7 days.

Changing from another combined oral contraceptive:
You can start taking LEVETTE on the day following the usual tablet-free interval of your previous COC or on the day after finishing the placebo (inactive) tablets of your previous COC or you can start on the day after taking the last active tablet (the last tablet containing the active substances) of your previous COC.
Changing from a progestogen-only-method (minipill, injection, implant) or intrauterine device (IUD):
You can change from the progestogen-only tablet whenever you like. If you had an implant or an intrauterine device, use the new tablet the day you remove it. If you used injections, use the new tablet on the day when you would have injected again. It is recommended, in all cases, that you use additional protection (e.g. condom) for the first 7 days of taking the tablets.

After a miscarriage or an abortion in the first trimester:
You can start taking LEVETTE immediately. When doing so, you do not need to take additional contraceptive measures. Follow your doctor’s advice.

After having a baby or an abortion in the second trimester:
LEVETTE should be started 21 to 28 days after having a baby or an abortion in the second trimester. If you start later than day 28, you must use a barrier contraceptive (a condom for example) for the first 7 days you take LEVETTE. If you have already had sexual intercourse before starting LEVETTE you must be sure that you are not pregnant or wait for your next period.
If you are breast-feeding and you want to start taking LEVETTE (again) after having a baby:
See "Pregnancy and breast-feeding".
Let your doctor advise you in case you are not sure when to start.

If you take more LEVETTE than you should:

If you take more LEVETTE than you should, consult your doctor or pharmacist immediately.

Symptoms that may occur in this case are: Nausea, vomiting and, in adolescents, slight vaginal bleeding. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take LEVETTE:

The white tablets in the 4th row of the strip are the placebo tablets. If you forget one of these tablets, this has no effect on the reliability of LEVETTE. Throw away the forgotten placebo tablet.

If you miss a yellow (active) tablet from the 1st, 2nd or 3rd row, do as follows:

If you are less than 12 hours late taking a tablet, the protection from pregnancy is not reduced. Take the tablet as soon as you remember and then take the following tablets again at the usual time (even if this means taking two tablets on the same day). In this case you do not need to use any additional method of contraception.

If you are more than 12 hours late taking a tablet, the protection from pregnancy may be reduced. The guidelines to be followed if tablets are missed are governed by two basic rules:

1. Never stop taking the tablets for more than 7 days.
2. Tablets must be taken without a break for 7 days to attain adequate suppression of the hypothalamic-pituitary-ovarian axis.

Based on this, the following procedure should be followed when you forget to take a tablet.

- In week 1:

Take the forgotten tablet as soon as possible, even if that means that you have to take two tablets at the same time. Then continue to take the tablets as usual. In the next 7 days, however, a barrier method (e.g. condom) must be used for contraception. If you have had sexual intercourse in the week before you forgot to take a tablet, there is a risk of pregnancy. The probability of pregnancy becomes greater the closer you are to the usual time for the placebo tablet interval.

- In week 2:

Take the forgotten tablet as soon as possible, even if that means you have to take two tablets at the same time. Then continue to take the tablets as usual. If you took LEVETTE regularly in the 7 days before the forgotten tablet, the contraceptive effect of LEVETTE is ensured and you do not have to use any additional contraceptive measures. If more than 1 tablet was forgotten, the use of an additional barrier method for contraception (e.g., condom) for 7 days is recommended.

- In week 3:

Because of the upcoming 7-day placebo tablets interval, contraceptive protection is no longer fully ensured. By adjusting the tablet taking schedule, however, the contraceptive effect can be maintained. By adhering to one of the two procedures explained below, additional contraceptive measures are not necessary, but only if you have taken the tablets correctly in the 7 days before the forgotten tablet. If this was not the case, you should proceed as described in point 1. In addition, a barrier method should also be used for contraception (e.g.,condom) in the next 7 days.

1. Take the forgotten tablet as soon as possible, even if that means that you have to take two tablets at the same time. The remaining active tablets are then taken at the usual time. As soon as the active tablets of the current pack are finished throw away the placebo tablets and start taking the active tablets from the next blister pack immediately. Most likely, there will be no withdrawal bleeding until you have used up this second blister pack, but spotting and breakthrough bleeding may occur while taking the second pack.

Or

2. You can also stop taking tablets from the current blister pack immediately and, after the placebo tablets interval of no more than 7 days (the day on which the tablet was forgotten must be included in this count), start taking tablets from the next blister pack right away.

If you forget to take tablets and have no withdrawal bleeding (period) during the first placebo tablet interval, you should consider the possibility that you may be pregnant. However, ask your doctor if in doubt.

If you have any further questions on using LEVETTE, ask your doctor or pharmacist.

Advice in case of gastrointestinal disorders:

In case of severe gastrointestinal disorders, absorption may not be complete and you should take additional contraceptive measures.

If you vomit within 3-4 hours of taking the tablet, you should follow the advice concerning missed tablets, see "If you forget to take LEVETTE" section. If you do not want to change your normal tablet-taking schedule, you should take the necessary number of extra tablets from another pack.

How to delay withdrawal bleeding (period):

To delay a period, you should continue with the next pack of LEVETTE without taking the usual placebo tablets. This duration can be carried on for as long as you wish up until the end of the second pack. During this period, you may have some bleeding or spotting. After this period, take the usual 7 placebo tablets and continue to take LEVETTE regularly.

To change the starting day of your periods to another day of the week, you are advised to shorten the placebo tablets by as many days as you like. The shorter the interval, the higher the risk that you will not have withdrawal bleeding (period) and will experience breakthrough bleeding or spotting during the next pack (just as when delaying a period).

4. POSSIBLE SIDE EFFECTS:

LEVETTE can have side effects.

Not all side effects reported for LEVETTE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LEVETTE, please consult your doctor, pharmacist or other healthcare provider for advice.

The following side effects may occur when taking LEVETTE:

If any of the following happen, stop taking LEVETTE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Hives or rash, itching.
- Collapse or fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to LEVETTE. You may need urgent medical attention or hospitalisation.

Stop taking LEVETTE and tell your doctor immediately if any of the following happens (see "Take special care with LEVETTE – The contraceptive pill and thrombosis"):

- Yellowing of the skin and whites of the eyes, also called jaundice.
- Severe pain and/or swelling in one of your legs, stomach and chest which may reach the left arm.
- Sudden breathlessness, cough without an obvious cause.
- Any unusual, severe or long-lasting headache or worsening of migraine.
- Partial or complete blindness or double vision.
- Difficulty speaking or inability to speak.
- Dizziness or fainting.
- Weakness, strange feeling or numbness in any part of the body.
- Sudden changes to your hearing, sense of smell or taste.
- Disturbances of movements, muscular rigidity or incoordination.

These are all very serious side effects. They are all signs of a blood clot, heart attack or a stroke. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Vaginal inflammation (including fungal infection), manifested as itching, pain and/or discharge.
- Changes in appetite (increase or decrease), glucose intolerance, nausea, vomiting, stomach pain, diarrhea, colic, bloating, weight changes (increase or loss), fluid retention.
- Inflammation of the pancreas, manifested as severe stomach pain, nausea, fatigue, irritability, headache, or fast heartbeat.
- Mood swings including depression, suicidal thoughts/behavior and suicide, change in sex drive, headache, nervousness, illusion or sense of whirling or spinning movements.
- Intolerance to contact lens, complete or partial loss of vision.
- Acne, skin patches and skin discolouration, hair loss, excessive hair growth in certain parts of the body.

- Bleeding, spotting, breast pain / tenderness, breast enlargement, breast discharge, changes in menstrual flow, painful periods, changes in cervix and vaginal discharge, lack of periods.
- Haemolytic uraemic syndrome, manifested as bloody diarrhea, stomach pain, pale skin, irritability, fatigue, fever, unexplained bruises or bleeding, decreased urination.
- Worsening of varicose veins (swollen and twisted veins under the skin), porphyria (metabolic disorder), worsening of abnormal involuntary movements in certain parts of the body.

The following side effects may be noticed when doing blood tests:

- Changes in lipid levels, reduction in folate levels, increased blood pressure, cancer tumors of the liver, gallstones.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Cipla Medpro (Pty) Ltd. by email: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of LEVETTE.

5. HOW TO STORE LEVETTE:

Store at or below 30 °C. Keep blisters in the carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use LEVETTE after the expiry date which is stated on the blister strip and carton. Medicines should not be disposed in drains or sewerage systems (e.g. toilets). Return all unused medicines to your pharmacist. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What LEVETTE contains:

21 yellow (active) film-coated tablets:

The active substances are levonorgestrel and ethinylestradiol.

Each tablet contains 0,15 mg levonorgestrel and 0,03 mg ethinylestradiol.-

The other ingredients are: Lactose monohydrate, povidone K-30, crospovidone, magnesium stearate,

polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, iron oxide yellow.

7 white (inactive) film-coated tablets:

The inactive tablets do not contain active substances.

The other ingredients are: Lactose anhydrous, povidone K-30, magnesium stearate, polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc.

What LEVETTE looks like and contents of the pack:

Active tablets: 21 Round, biconvex, yellow film-coated tablets.

Inactive tablets: 7 Round, plain, white film-coated tablets

LEVETTE film-coated tablets are supplied in a clear to a slightly opaque PVC-PVDC-Aluminium blister strip enclosed in a carton.

Each carton contains one blister of 28 (21+7) tablets.

Holder of Certificate of Registration:

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

This leaflet was last revised in:

21 January 2025

Registration number:

47/18.8/0525

Access to the corresponding Professional Information:

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER:

The QR Code to be generated and included after approval.