PATIENT INFORMATION LEAFLET

LEXILEV

SCHEDULING STATUS: S3

LEXILEV film coated tablets

Levonorgestrel 0,15 mg / Ethinylestradiol 0,03 mg

LEXILEV active tablets contain sugar (lactose monohydrate, 84,32 mg)

LEXILEV placebo tablets contain sugar (lactose anhydrous, 89,50 mg)

Read all of this leaflet carefully before you start taking LEXILEV.

- 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.
- LEXILEV 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 LEXILEV is and what it is used for

2. What you need to know before you take LEXILEV

3. How to take LEXILEV

4. Possible side effects

5. How to store LEXILEV

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1. What LEXILEV is and what it is used for

LEXILEV is a combined oral contraceptive, one of a group of medicines often referred to as the Pill.

It contains two types of hormones: an estrogen, ethinylestradiol, and a progestogen, levonorgestrel.

These hormones stop you from getting pregnant by working in three ways: by preventing an egg being

released from your ovaries; by making the fluid (mucus) in your cervix preventing an egg being released from your ovaries; by making the fluid (mucus) in your cervix thicker, which makes it more difficult for sperm to enter the womb; and by preventing the lining of your womb thickening enough for an egg to grow in it.

LEXILEV is used for the prevention of pregnancy (oral contraception). Sometimes it is also prescribed for the control of cases of dysfunctional bleeding in the womb and in the symptomatic treatment of primary painful menstruation where contraception is also desired.

2. What you need to know before you take LEXILEV

Do not take LEXILEV:

You should not use LEXILEV if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor. Your doctor will discuss with you what other form of birth control would be more appropriate.

- if you are allergic (hypersensitive) to levonorgestrel, ethinylestradiol or any of the other ingredients of this medicine (listed in section 6)
- if you are taking a medicine known as ritonavir
- if you have a recurring condition in which the flow of bile from the liver stops or slows, or if you have liver function problems
- if you have or suspect you have breast cancer, ovarian cancer, cervical cancer, cancer of the womb or any other cancer related to the reproductive system.
- if you, or anyone in your family have ever had breast cancer
- if you have inherited genetic mutations: BRCA1 and BRCA2 genes, as you have a higher risk of developing cancer
- early menstrual periods (before the age of 12 years)
- if you have ever had other non-cancerous breast diseases such as atypical hyperplasia (a precancerous condition that affects cells in the breast) or lobular carcinoma in situ (abnormal cells growing in the lining of the milk glands)

- if you have ever had treatment using radiation therapy to the chest or breast
- if you have ever been exposed to diethylstilbestrol (DES), a synthetic estrogen medicine
- if you have (or ever had) a condition in which a blood clot in a vein causes inflammation and pain, or blood clotting disorders
- if you have severe migraine, or a history of migraine called 'migraine with aura'
- if you have damage or disease in the heart's major blood vessels
- if you experience unexplained vaginal bleeding
- if you have ever had liver tumours
- if you have ever had a severe liver disease, and you have been told by your doctor that your liver function test results are not yet back to normal
- if you have active liver disease
- if you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolism, PE) or other organs.
- if you know you have a disorder affecting your blood clotting, for instance protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden,antiphospholipid antibodies or an inherited disorder that makes your blood more likely to clot.
- if you need an operation or if you are off your feet for a long time
- if you have had a heart attack or a stroke
- if you have, or previously suffered from, angina (severe chest pain that may be the first sign of a heart attack (shortness of breath, nausea, fatigue)) or a transient ischaemic attack (sudden onset of slurred speech, weakness, numbness or paralysis in your face, arm or leg, typically on one side of your body)
- if you suffer from certain forms of migraine which are associated with focal neurological symptoms (such as weakness, speech, vision or hearing problems)
- if you have any of the following diseases that may increase your risk of a clot in the arteries:
  - severe diabetes with blood vessel damage

  - high blood pressure
  - a high level of fat in the blood (cholesterol or triglycerides)
  - a condition known as hyperhomocysteinaemia
- if you are or suspect you might be pregnant (see Pregnancy, breastfeeding and fertility).

Warnings and precautions

It is important that you understand the benefits and risks of taking LEXILEV before you start taking it, or when deciding whether to carry on taking it. Tell your doctor if you have any of the illnesses or risk factors mentioned in this leaflet.

Your doctor will ask about you and your family's medical problems, check your blood pressure and exclude the likelihood of you being pregnant. You may also need other checks, such as a breast examination, but only if these examinations are necessary for you, or if you have any special concerns.

UNDER NO CIRCUMSTANCES SHOULD YOU STOP TAKING LEXILEV WITHOUT HAVING ADOPTED A SATISFACTORY ALTERNATIVE METHOD OF CONTRACEPTION.

CIGARETTE SMOKING

CIGARETTE SMOKING INCREASES THE RISK OF SERIOUS CARDIOVASCULAR SIDE EFFECTS FROM THE USE OF ORAL CONTRACEPTIVES. THE RISK INCREASES WITH AGE AND WITH HEAVY SMOKING (15 OR MORE CIGARETTES PER DAY) AND IS QUITE MARKED IN WOMEN OVER 35 YEARS OF AGE. YOU ARE THEREFORE STRONGLY ADVISED TO STOP SMOKING.

Tell your doctor if any of the following conditions apply to you:

If the condition develops, or gets worse while you are using LEXILEV, you should also tell your doctor.

- if you have a history of diabetes
- if you have epilepsy
- if you have asthma
- if you have the inherited disease called porphyria
- if you have Dubin Johnson's syndrome
- if you have Rotor syndrome
- if you have conditions in which fluid retention occurs
- if you experience is a gradual or sudden, partial or complete loss of vision, double vision, swelling of the eye or any evidence of lesions or damages to the eye
- if you experience severe and persistent abdominal pain and tenderness, you should stop taking LEXILEV
- if you experience migraine, or if it gets worse, persistent or more severe
- if you are pregnant, or suspect that you are pregnant. LEXILEV can harm your unborn child
- if you need an operation, or you are off your feet for a long time
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- if you have systemic lupus erythematosus (SLE - a disease affecting your natural defence system)
- if you have haemolytic uraemic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys)
- if you have sickle cell anaemia (an inherited disease of the red blood cells)
- if you have just given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking LEXILEV
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis)
- if you have varicose veins
- if you or your close family have ever had problems with your heart or circulation, such as high blood pressure

- if you or your close family have ever had problems with blood clotting
- if you are overweight (obese)
- if you have any illness that worsened during pregnancy or previous use of LEXILEV
- LEXILEV 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 LEXILEV
- if you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas)
- if you have hereditary angioedema (allergic swelling or oedema that tends to appear on the face and throat), as LEXILEV 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
- acute or chronic liver function disorders require discontinuation of LEXILEV 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 LEXILEV
- 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 LEXILEV
- 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 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 a history of physical or sexual abuse.

Hormonal contraceptives including LEXILEV, may cause mood changes and depression, which may be severe. Severe depression is associated with a higher risk of suicidal thoughts/behaviour (e.g. 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

Tell your doctor if you notice any of the following:

The following conditions may worsen during pregnancy or previous use of the Pill:

- yellowing of the skin (jaundice)
- persistent itching (pruritus)
- kidney or liver problems
- gall stones
- certain rare medical conditions such as systemic lupus erythematosus
- blister-like rash (herpes gestationis) whilst pregnant
- an inherited form of deafness (otosclerosis)
- a personal or family history of a form of sickle cell disease
- swelling of body parts (hereditary angioedema)
- an inherited disease called porphyria.

Take special care with LEXILEV:

Risk of developing blood clots:

- using a combined oral contraceptive such as LEXILEV increases your risk of developing a blood clot. A blood clot can block vessels and cause serious problems.

These blood clots can be fatal. Blood clots can develop:

- in veins (referred to as a 'venous thrombosis', 'venous thromboembolism' or VTE)
- in the arteries (referred to as an 'arterial thrombosis', 'arterial thromboembolism' or ATE)

- if a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT)
- if a blood clot travels from the leg and lodges in the lung it can cause a pulmonary embolism
- a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke
- the risk of developing a blood clot is highest during the first year of taking LEXILEV for the first time. The risk may also be higher if you restart taking LEXILEV (or a different product) after a break of 4 weeks or more. After the first year, the risk gets smaller but is always higher than if you were not using LEXILEV
- factors that increase your risk of a blood clot:
  - if you are overweight (body mass index or BMI over 30 kg/m^2)
  - if you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of LEXILEV may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop LEXILEV ask your doctor when you can start using it again
  - if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50). In this case you could have a hereditary blood clotting disorder.
  - as you get older (particularly above about 35 years)
  - if you gave birth less than a few weeks ago
  - if you smoke. When using LEXILEV, you are advised to stop smoking. If you are unable to stop smoking and are older than 35 your doctor may advise you to use a different type of contraceptive
  - if you have high blood pressure
  - if a member of your immediate family has had a heart attack or stroke at a young age (less than about 50). In this case you could also have a higher risk of having a heart attack or stroke

- if you get migraines
- if you have diabetes
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides)
- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation).

- the risk of developing a blood clot increases the more conditions you have. If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot may be increased even more
- air travel (> 4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.

Reduced efficacy:

The contraceptive effect can be reduced by forgetting to take the pill (see "If you forget to take LEXILEV"), vomiting, colon diseases with severe diarrhoea (see "If you are sick or have diarrhoea") or by the simultaneous use of other medicines (see "Other medicines and LEXILEV").

Medical examination and consultation:

Prior to starting or resuming treatment with LEXILEV, 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 LEXILEV use.

Breast cancer

LEXILEV contains estrogen (ethinylestradiol) and progestogen (levonorgestrel) which, on prolonged use, may increase the risk of developing breast cancer (see Do not take LEXILEV). The risk increases steadily with duration of use, and women taking LEXILEV have a higher risk than women using estrogen only medicines.

All women on LEXILEV should receive yearly breast examinations by a healthcare provider and perform monthly breast self-examinations. See your doctor if you notice any changes such as dimpling or sinking of the skin, changes in the nipple or any lumps you can see or feel.

Other medicines and LEXILEV

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

Some medicines can have an influence on the blood levels of LEXILEV and can stop it from working properly.

Before you start taking LEXILEV, make sure your doctor knows if you are taking:

- some medicines used to treat HIV and hepatitis C virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors) such as ritonavir, nelfinavir and nevirapine
- some medicines used to treat epilepsy such as barbiturates (including phenobarbitone), primidone, phenytoin, carbamazepine, oxcarbazepine, topiramate and felbamate
- some antibiotics and antifungal medicines (griseofulvin, ampicillin, penicillin V, tetracycline, rifampicin, neomycin, chloramphenicol, sulphonamides, nitrofurantoin, itraconazole, voriconazole, fluconazole, and macrolides (e.g. erythromycin)
- herbal medicine used to treat depression (St John's wort)
- anti-inflammatory medicines such as etoricoxib.

LEXILEV can also affect how well other medicines work – for example:

- ciclosporin (used as immunosuppressant medicine to treat transplant rejection)
- tizanidine (used to relieve the spasms and increased muscle tone caused by multiple sclerosis)
- theophylline (used to treat asthma)

- lamotrigine (used to treat epilepsy).

Do not use LEXILEV if you have hepatitis C and are taking medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir and sofosbuvir/velpatasvir/voxilaprevir, as these medicines may cause increases in liver function blood test results (increase in ALT liver enzyme). Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicines. LEXILEV can be restarted approximately 2 weeks after completion of this treatment.

In addition, LEXILEV can also interfere with the results of some blood tests, so always tell your doctor that you are taking LEXILEV if you have a blood test.

LEXILEV with food, drink and alcohol

LEXILEV should be taken at the same time every day, preferably after the evening meal or at bedtime.

Pregnancy, breastfeeding and fertility

Do not take LEXILEV if you are pregnant or breastfeeding your baby.

If you become pregnant during treatment, you should stop taking LEXILEV.

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 health care provider for advice before taking this medicine.

Driving and using machines

Since adverse reactions such as dizziness have been reported in patients receiving LEXILEV, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that LEXILEV does not adversely affect your ability to do so (see section 4).

LEXILEV contains sugar (lactose)

LEXILEV contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take LEXILEV

Do not share medicines prescribed for you with any other person. Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Take LEXILEV every day for 28 days

LEXILEV comes in strips of 28 pills. There are 21 active yellow tablets, and 7 inactive white tablets.

- take your pill at the same time every day, no longer than 24 hours apart, preferably after the evening meal or at bedtime
- swallow each pill whole, with water if necessary. Do not chew the pill
- if it is the first time you take LEXILEV, take one yellow tablet daily for 21 uninterrupted days, beginning on Day 1 of your menstrual cycle, i.e. the first day of bleeding
- one white inactive tablet is taken daily for the next 7 continuous days
- withdrawal bleeding should usually occur 2 to 4 days after the last yellow tablet is taken
- during this first cycle, an alternative method of contraception, such as a condom, should be used together with LEXILEV until 14 tablets have been taken. If the tablets are begun after Day 5 of your menstrual cycle, or after giving birth, it must be considered that ovulation and conception may have occurred before the tablets were started.

Then start your next strip

The next and all the following courses will begin on the day after the last package was

completed, even if withdrawal bleeding has not occurred or is still in progress. Each course of LEXILEV is therefore begun on the same day of the week and follows the same schedule (21 days of yellow tablets, 7 days of white inactive tablets) as the first course.

Changing to LEXILEV from another contraceptive Pill

If you are changing from another oral contraceptive product to LEXILEV, start LEXILEV on the day you would usually start a new package of the other product. During the first LEXILEV cycle, an alternative method of contraception, such as a condom, should be used until 14 uninterrupted tablets have been taken. If temporary spotting or breakthrough bleeding occurs, continue the treatment since such bleeding is usually without significance. If the bleeding is persistent or prolonged, contact your doctor.

- **If you are currently taking a 21-day Pill or a 28-day Pill:**
  - start LEXILEV the next day after the end of the previous strip.
- **Or, if you are taking a progestogen-only Pill (POP or 'mini Pill'):**
  - start LEXILEV on the first day of bleeding, even if you have already taken the progestogen-only Pill for that day. The remaining progestogen-only tablets should be discarded.

Starting LEXILEV after a miscarriage or abortion

If you have had a miscarriage or an abortion during the first three months of pregnancy, your doctor may tell you to start taking LEXILEV straight away. Discuss this with your healthcare provider.

If you have had a miscarriage or an abortion after the third month of pregnancy, ask your doctor for advice. You may need to use extra contraception, such as condoms, for a short time.

Contraception after having a baby

If you have just had a baby, your doctor may advise you that LEXILEV should be started 21 days after delivery provided that you are fully mobile. You do not have to wait for a period.

You will need to use another method of contraception, such as a condom, until you start LEXILEV and for the first 7 days of pill taking.

If you are sick or have diarrhoea

If you are sick (vomit) or have very bad diarrhoea within 4 hours of taking LEXILEV, your body may not get its usual dose of hormones from that tablet. Take another tablet and continue with the pack.

Talk to your doctor if your stomach upset carries on or gets worse. Your doctor may recommend another form of contraception.

Missed a period - could you be pregnant?

Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you have taken your pills correctly. Start your next strip at the normal time. If you think that you might have put yourself at risk of pregnancy (for example, by missing pills or taking other medicines), or if you miss a second bleed, you should do a pregnancy test.

You can buy these from the pharmacy. If you are pregnant, stop taking LEXILEV and see your doctor.

When you want to get pregnant

If you are planning a baby, it's best to use another method of contraception after stopping LEXILEV until you have had a proper period. Your doctor relies on the date of your last natural period to tell you when your baby is due.

If you have missed a LEXILEV tablet, see **If you forget to take LEXILEV**.

If you have the impression that the effect of LEXILEV is too strong or too weak, tell your doctor or pharmacist.

If you take more LEXILEV than you should

It is unlikely that taking more than one pill will do you any harm, but you may feel sick, vomit or have some 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 LEXILEV

Always take LEXILEV as prescribed.

Take a missed yellow tablet as soon as you remember. If two consecutive yellow tablets are missed, they should both be taken as soon as you remember. In either case, the next tablet should be taken at its usual time. Each time you miss one or two consecutive yellow tablets, a mechanical method of contraception, such as a condom, should be supplemented until 14 consecutive daily tablets have been taken or until the package is finished if less than 14 yellow tablets remain.

If you miss one or more white placebo tablets, you are still protected against pregnancy, provided you begin the yellow tablets on the proper day. If three consecutive yellow tablets are missed, LEXILEV should be discontinued and the remainder of the package discarded. A new package should be started on the eighth day after the last tablet was taken.

A mechanical method of contraception, such as a condom, should be used until 14 consecutive daily tablets have been taken.

If withdrawal bleeding does not occur and LEXILEV has been taken according to directions, it is unlikely that you could be pregnant. Begin a second course of LEXILEV on the usual day. If bleeding does not occur at the end of this second cycle, you should not take LEXILEV until you are certain that you are not pregnant, by consulting your doctor and having a pregnancy test done.

If you have missed one or more yellow tablets or started taking them on a day later than recommended,

the probability of pregnancy should be considered at the time of the first missed period before LEXILEV is restarted.

If you stop taking LEXILEV

Your doctor will tell you how long your treatment with LEXILEV will last.

4. Possible side effects

LEXILEV can have side effects.

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

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

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- liver tumours (with symptoms including severe abdominal pain and tenderness and in some cases internal bleeding), breast cancer and cervical cancer
- deep vein thrombosis (DVT) which include swelling of one leg or along a vein in the leg or foot

especially when accompanied by: pain or tenderness in the leg which may be felt only when standing or walking, increased warmth in the affected leg, change in colour of the skin on the leg e.g. turning pale, red or blue

- pulmonary embolism includes sudden unexplained breathlessness or rapid breathing, sudden cough without an obvious cause, which may bring up blood, sharp chest pain which may increase with deep breathing, severe light headedness or dizziness, rapid or irregular heartbeat, severe pain in your stomach. If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a 'common cold')
- stroke with symptoms including sudden weakness or numbness of the face, arm or leg, especially on one side of the body, sudden confusion, trouble speaking or understanding, loss of consciousness or fainting with or without seizure
- blood clots blocking other blood vessels causing swelling and slight blue discolouration of an extremity, severe pain in your abdomen
- heart attack (chest pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the chest, arm or below the breastbone, extreme weakness, anxiety, or shortness of breath, rapid or irregular heartbeats
- inflammation of the pancreas (pancreatitis)
- liver function disturbances
- systemic lupus erythematosus (SLE), an inflammatory disease caused when the immune system attacks its own tissues. SLE can affect the joints, skin, kidneys, blood cells, brain, heart and lungs.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- vaginal infection (vaginitis, vaginal candidiasis)

- depressed mood, altered mood, nervousness, decreased or increased libido
- headache, migraine
- nausea (feeling sick), abdominal pain, vomiting (being sick)
- acne
- breast pain, breast tenderness, spotting, break-through bleeding, enlarged breast, breast secretions
- fluid retention/swelling
- increase or decrease in weight.

Less frequent side effects:

- a high level of a certain type of fat (triglycerides) in the blood, changes in appetite
- exacerbation of chorea (movement disorder), dizziness
- changes in corneal curvature (steepening), intolerance to contact lenses, cataracts
- increase in blood pressure
- diarrhoea, Crohn's disease, chronic, inflammatory bowel disease that causes inflammation in the digestive tract, abdominal cramps, bloating, gastrointestinal irritation
- gallbladder disease, a condition in which the flow of bile from the liver stops or slows, exacerbation of existing disease
- rash, skin inflammation located in a part of the fatty layer of skin causing reddish, painful, tender lumps, erythema multiforme, brown patches on the face (chloasma or melasma) which may be persistent, skin pigmentation
- vaginal discharge, reduced menstrual flow, missed withdrawal bleeding, post pill amenorrhoea, change in cervical erosion or cervical secretion, premenstrual-like syndrome
- changes in blood fat levels.

Side effects with unknown frequency:

- porphyria
- unwanted male-pattern hair growth on a woman's face, chest and back, loss of scalp hair, haemorrhagic eruption
- chronic bladder health issue, low red blood cells, acute kidney failure, and low platelets
- suicidal thoughts/behaviour and suicide.

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 online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8 or http://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problemreporting-form/.

By reporting side effects, you can help provide more information on the safety of LEXILEV. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store LEXILEV

Store all medicines out of reach of children.

Store at or below 25 ºC. Keep blister in the outer carton.

Do not take after the expiry date stated on the package.

Return all unused medicine to your pharmacist.

Do not dispose of unused capsules in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LEXILEV contains

The active substances are 0,15 mg levonorgestrel and 0,03 mg ethinylestradiol.

The other ingredients of LEXILEV active tablets are crospovidone, lactose monohydrate, magnesium stearate and povidone K30.

LEXILEV active tablet coating contains iron oxide yellow, macrogol, polyvinyl alcohol, talc and titanium dioxide.

LEXILEV placebo tablets contain sugar (lactose anhydrous), magnesium stearate and povidone K30.

LEXILEV placebo tablet coating consists of Opadry® II White (containing macrogol, polyvinyl alcohol, talc, titanium dioxide).

What LEXILEV looks like and contents of the pack

LEXILEV 21 active tablets: Round, yellow, plain, biconvex film coated tablets.

LEXILEV 7 placebo tablets: Round, white, plain film coated tablets.

PVC-PVDC/aluminium push-through foil blister strip.

Blister strip is packed into an outer carton.

Pack size: 21 active and 7 placebo film coated tablets.

Holder of certificate of registration

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