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PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS: S3

LOGYNON® ED Tablets
Ethinylestradiol and Levonorgestrel
Contains sugar (lactose)

Read all of this leaflet carefully before you start taking LOGYNON ED.
- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor or pharmacist.**
- **LOGYNON ED 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 LOGYNON ED is and what it is used for

LOGYNON ED tablets are contraceptive pills used to prevent pregnancy.

Each of 21 active tablets contains a small amount of the female hormones ethinylestradiol and levonorgestrel.

Contraceptive pills that contain two hormones are called ‘combined pills’ or ‘combined oral contraceptives’.

2 What you need to know before you take LOGYNON ED

LOGYNON ED does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

Do not take LOGYNON ED:

Do not use LOGYNON ED if you have any of the condition listed below. If any of these apply to, tell your doctor before starting to use LOGYNON ED. Your doctor may advise you to use a different type of pill or an entirely different (including noon-hormonal) method of birth control.
- If you are allergic to levonorgestrel, ethinylestradiol or any of the other ingredients of LOGYNON ED. This may cause, for example, itching, rash or swelling.

- If you have, or have ever had a disorder affecting the blood circulation: in particular, those conditions relating to thrombosis (the formation of a blood clot) in the blood vessels of the legs (deep vein thrombosis), the lungs (pulmonary embolism), the heart (heart attack), or other parts of the body.
- If you have or have had a stroke (caused by a blood clot or a rupture of a blood vessel in the brain).
- If you have or have ever had a condition that may be a first sign of a heart attack (such as angina pectoris or chest pain) or stroke (such as transient ischaemic attack or small reversible stroke).
- If you have a history of migraine accompanied by e.g. visual symptoms, speech disability, or weakness or numbness in any part of your body.
- If you have diabetes mellitus with blood vessel damage.
- If you have jaundice (yellowing of the skin) or severe liver disease.
- If you are taking any antiviral medicines which contains ombitasvir, paritaprevir, or dasabuvir, and combination of these. These antiviral medicines are used to treat chronic (long-term) hepatitis C (an infectious disease that affects the liver, caused by the hepatitis C virus).
- If you have or have had a cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs).
- If you have or have had a benign or malignant liver tumour.
- If you have any unexplained vaginal bleeding.
- If you are pregnant or think you might be pregnant.

If any of these conditions appear for the first time while using LOGYNON ED, stop taking it at once and consult your doctor. In the meantime, use non-hormonal contraceptive measures, e.g. condom.

Additional information on special populations

Use in children
LOGYNON ED is not intended for use in females whose periods have not yet started

Use in older women
LOGYNON ED is not intended for use after menopause

Women with renal impairment
Talk to your doctor. Available data do not suggest a need to change the use of LOGYNON ED.

Women with liver impairment
Do not take LOGYNON ED if you suffer from liver disease. See “Do not take LOGYNON ED”.

Warnings and precautions

If LOGYNON ED is used in the presence of any of the conditions listed below you may need to be kept under close observation. Your doctor can explain this to you. Therefore, if any of these apply to you, tell your doctor before starting to use LOGYNON ED.

- you smoke;
- you have diabetes;
- you are overweight;
- you have high blood pressure;
- you have a heart valve disorder or a certain heart rhythm disorder;

- you have an inflammation of your veins (superficial phlebitis);
- you have varicose veins;
- anyone in your immediate family has had a thrombosis, a heart attack or a stroke;
- you suffer from migraine;
- you suffer from epilepsy; (see "Other medicines and LOGYNON ED).
- you or someone in your immediate family has or has had high blood levels of cholesterol or triglycerides (fatty substances);
- anyone in your immediate family has had breast cancer;
- you have liver or gallbladder disease;
- you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- you have systemic lupus erythematosus (SLE; a disease affecting the skin all over the body);
- you have haemolytic uraemic syndrome (HUS; a disorder of blood coagulation causing failure of the kidneys);
- you have sickle cell disease;
- you have a condition that occurred for the first time or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, a metabolic disease called porphyria, a skin disease called herpes gestationis, a neurological disease called Sydenham's chorea);
- you have or have had chloasma (yellowish-brown/brown pigmentation patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet radiation;
- you have hereditary angioedema; exogenous oestrogens may induce or exacerbate 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;
- the period of up to about six weeks after childbirth (puerperium).

Psychiatric disorders:
Some women using hormonal contraceptives including {product name} have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

If any of the above conditions appear for the first time, recur or worsen while using LOGYNON ED, you should contact your doctor.

Other medicines and LOGYNON ED

If you are taking other medicines on a regular basis, including complementary and traditional medicines, concomitant use of LOGYNON ED may cause undesirable effects. Please inform your doctor or pharmacist of any other medication you may be taking.

Some medicines:
- can have an influence on the blood levels of LOGYON ED
- can make it less effective in preventing pregnancy
- can cause unexpected bleeding.

These include:
- medicines used for the treatment of:

  - epilepsy (e.g. phenytoin, barbiturates, primidone, carbamazepine, oxcarbazepine, topiramate, felbamate, ciclosporin or anti-epileptic lamotrigine.
  - tuberculosis (e.g. rifampicin)
  - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors,
  - fungal infections (griseofulvin, azole antifungals, e.g. itraconazole, voriconazole, fluconazole)
  - bacterial infections (macrolide antibiotics, e.g. clarithromycin, erythromycin)
  - certain heart diseases, high blood pressure (calcium channel blockers, e.g. verapamil, diltiazem)
  - arthritis, arthrosis (etoricoxib)
- the herbal remedy St John's wort
- grapefruit juice

LOGYNON ED may influence the effect of other medicines, e.g.
- lamotrigine
- ciclosporin
- melatonin
- midazolam
- theophylline
- tizanidine

Laboratory tests

If you need a blood test or other laboratory tests tell your doctor or the laboratory staff that you are taking LOGYNON ED because oral contraceptive can affect the results of some tests.

Pregnancy and breastfeeding

Do not take LOGYNON ED if you are pregnant, or if you think you may be pregnant. If you suspect that you are pregnant while you are already using LOGYNON ED, you should stop taking it immediately and contact your healthcare provider as soon as possible.

Pregnancy must be excluded before you start taking LOGYNON ED.

LOGYNON ED is not recommended for use during breastfeeding.

Driving and using machine

No studies on the effects of the ability to drive and use machines have been performed.

LOGYNON ED contains lactose

Each coated tablet of LOGYNON ED contains 31 mg lactose per tablet. If you are intolerant to some type of sugar contact your doctor before taking LOGYNON ED.

3 How to take LOGYNON ED

Always take LOGYNON ED exactly as your healthcare professional has instructed you. You should check with your doctor or pharmacist if you are unsure.

The LOGYNON ED pack contains 28 tablets. Take your tablets at about the same time each day, with some liquid if necessary. The first tablet should be taken from the red section of the calendar pack by selecting the appropriate tablet for that day of the week (e.g. "MO" for Monday). Follow the direction of the arrows until all 28 tablets have been taken. Do not leave a gap between packs, i.e. start taking your next pack on the day after you have finished the current one, even if your period continues. Usually a period will start on day 2 to 3 after starting the inactive tablets and may not have finished before the next pack is started.

How to start LOGYNON ED

If you have not used a contraceptive with hormones during the previous month
Start taking LOGYNON ED on the first day of the cycle (that is, the first day of your period) from the coloured section of the pack and select the right tablet for that day of the week (e.g. "MO" for Monday). If you start the pack with an inactive tablet (large white coated non-hormonal tablets) on day 1 of your cycle, make sure you use an additional contraceptive method (barrier method) for the first 14 days of tablet-taking. You may start on days 2 to 5 of your cycle, but in that case make sure you use an additional contraceptive method (barrier method) for the first 14 days of tablet-taking.

Changing from another combined oral contraceptive, vaginal ring, or transdermal (contraceptive) patch
You can start taking LOGYNON ED the day after you take the last active tablet from your current Pill pack. In case you have used a vaginal ring or transdermal patch, you should start using LOGYNON ED preferably on the day of removal of the last ring or patch of a cycle pack. If you follow these instructions, it is not necessary to use an additional contraceptive method.

Changing from a progestogen-only method (minipill, injection, implant) or from a progestogen-releasing intrauterine system)
The woman may switch on any day from the minipill (from an implant or the intrauterine system on the day of its removal, from an injectable when the next injection would be due), but in all of these cases you must use extra protective measures (for example, a condom) during the first 14 days of use.

After a miscarriage
You may start taking LOGYNON ED immediately, following the instructions for "*If you have not used a contraceptive with hormones in the previous month"*. Remember to use extra protective measures (for example, a condom) during the first cycle for the first 14 days of tablet-taking.

After having a baby
If you have just had a baby, your doctor may tell you to wait until after your first normal period before you start taking LOGYNON ED. Sometimes it is possible to start sooner. Your doctor will advise you, but remember to use extra protective measures (for example, a condom) during the first cycle for the first 14 days of tablet-taking.
If, after having a baby, you have had sex before starting LOGYNON ED, be sure that you are not pregnant or wait until your next menstrual period.

If you want to start LOGYNON ED after having a baby and are breast-feeding, discuss this first with you doctor.

If you take more LOGYNON ED than you should

There are no reports of serious harmful effects of taking too many LOGYNON ED tablets.

If you take several active tablets at once, you may feel sick or vomit or may bleed from the vagina. Even girls who have not yet started to menstruate but have accidentally taken this medicine may experience such bleeding.

If you have taken too many LOGYNON ED tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

If you forget to take LOGYNON ED

Depending on the day of the cycle on which one tablet has been missed, you may need to take additional contraceptive precautions, for example a barrier method such as a condom. **In case of doubt, contact your doctor.**

- If you forgot to take any of the 7 large white inactive tablets, you should continue with your next tablet at the normal time and discard the forgotten large white inactive tablet(s) to avoid any confusion. If you forgot the last tablet of your current pack it is important that you still take the first tablet from the next pack at the correct time.

The following advice refers to the brown, white or ochre tablets (those containing hormones):

- If you are **less than 12 hours** late when taking a brown, white or ochre tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and then continue taking the tablets again at the usual time.
- If you are **more than 12 hours** late in taking any brown, white or ochre tablets your protection against pregnancy may be reduced. The more brown, white or ochre tablets you have forgotten, the greater the risk that the protection from pregnancy is reduced. There is a particularly high risk of becoming pregnant if you miss brown tablets at the beginning, right after the large white inactive tablets, or ochre tablets at the end (the last of the 10 ochre tablets).
- If a brown, white or ochre tablet has been missed for more than 12 hours, use extra contraceptive precautions (barrier method) for the next 7 days.
- **More than one tablet forgotten in a pack**
  Contact your doctor.

Do not take more than 2 active tablets (brown, white or ochre) on a given day, to make up for missed pills.

If you have forgotten brown, white or ochre tablets in a pack, and you do not have the expected bleeding that should start while taking tablets from the coloured section of your pack, you may be pregnant. Contact your doctor before you start the next pack.

What to do if you vomit or have severe diarrhoea

If you vomit or have severe diarrhoea after taking any of the brown, white or ochre tablets, the active ingredients in that tablet may not have been completely absorbed. If you vomit within 3 to 4 hours after taking your tablet, this is like missing a tablet. Therefore, follow the advice under ‘If you forget to take LOGYNON ED’. If you have severe diarrhoea, please contact your doctor. Vomiting or diarrhoea while

taking the 7 large white inactive tablets at the end of your blister does not have an influence on the contraceptive reliability.

If you stop taking LOGYNON ED

You can stop taking LOGYNON ED at any time. If you do not want to become pregnant, ask your doctor for advice about other reliable methods of birth control. If you want to become pregnant, stop taking LOGYNON ED and wait for a menstrual period before starting to try to become pregnant. You will be able to calculate the expected delivery date more easily.

4 Possible side effects

LOGYNON ED can have side effects.

Not all side effects reported for LOGYNON ED are included in this leaflet. Should your general health worsen while taking LOGYNON ED, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor if you notice any side effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by the Pill.

Stop taking the pill and contact a doctor immediately if you notice signs of:

Deep venous thrombosis, such as: swelling of one leg or along a vein in the leg, pain or tenderness in the leg *which may be felt only when standing or walking*, increased *warmth in the affected leg, red or discoloured skin on the leg.*

Pulmonary embolism, such as: sudden onset of unexplained shortness of breath or rapid breathing, sudden coughing *which may bring up blood*, sharp chest pain *which may increase with deep breathing, sense of anxiety*, severe light-headedness or dizziness, *rapid or irregular heartbeat.* Some of these symptoms (e.g. "shortness of breath", "coughing") are non-specific and be misinterpreted as more common or less severe events (e.g. respiratory tract infection).

Arterial thromboembolism (arterial blood vessels blocked by blood clots and such blood clots which have broken away)

- **Stroke** such as: sudden numbness or weakness of the face, arm or leg, especially on one side of the body; sudden *confusion*, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking, dizziness, loss of balance or coordination; sudden, severe or prolonged headache with no known cause; loss of consciousness or fainting with or without seizure.
- **Blood clots blocking other arterial blood vessels,** such as: *sudden pain, swelling and slight blue discolouration of an extremity*, "acute" abdomen.
- **Heart attack** such as pain, *discomfort, pressure, heaviness, sensation of squeezing or fullness* in the chest, arm, or below the breastbone; discomfort radiating to the back, *jaw, throat, arm, stomach, fullness, indigestion or choking feeling; sweating, nausea, vomiting* or dizziness; extreme weakness, *anxiety*, or shortness of breath; *rapid or irregular heartbeats.*

The following side effects were reported in Pill users:

Frequent side effects

- nausea and abdominal pain
- weight gain
- headache
- depressed or altered mood
- breast pain including breast tenderness

Less frequent side effects

- vomiting and diarrhoea
- fluid retention
- migraine
- reduced or increased interest in sex
- breast enlargement, vaginal discharge and breast discharge
- rash, urticaria (hives), erythema nodosum or multiforme (skin disorders)
- contact lens intolerance
- allergic reactions (hypersensitivity)
- weight loss
- venous and arterial thromboembolic disorders

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

Reporting side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"** , found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 . By reporting side effects, you can help provide more information on the safety of LOGYNON ED.

5 How to store LOGYNON ED

In original packs at room temperature (at or below 25 °C).
Protect from light.
KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.
Return unused or expired medicines to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets)

6 Contents of the pack and other information

What LOGYNON ED contains

21 coated tablets containing ethinylestradiol and levonorgestrel in the following order:

- 6 brown tablets each containing 0,03 mg ethinylestradiol and 0,05 mg levonorgestrel
- 5 white tablets each containing 0,04 mg ethinylestradiol and 0,075 mg levonorgestrel
- 10 ochre tablets each containing 0,03 mg ethinylestradiol and 0,125 mg levonorgestrel

Thereafter follow 7 large, white inactive coated tablets at the end of the blister (last row).

The other ingredients are: calcium carbonate, ferric oxide pigment red, ferric oxide pigment yellow, glycerol 85 %, lactose monohydrate, magnesium stearate, maize starch, montanglycol wax, macrogol 6 000, povidone 25 000, povidone 700 000, sucrose, talc and titanium dioxide.

What LOGYNON ED looks like and contents of the pack

LOGYNON ED is presented as a blister pack containing 21 coated tablets containing hormones and 7 inactive coated tablets.
LOGYNON ED tablets are contained in blister packs consisting of transparent films of polyvinyl chloride and metallic foils made of aluminium.
Cartons with one or three blister calendar packs containing 28 tablets.

Holder of Certificate of Registration

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