

LOETTE® 21 TABLET

Levonorgestrel/Ethinylestradiol (100 mcg/20 mcg)

What is in this leaflet

1. What LOETTE 21 is used for
2. How LOETTE 21 works
3. Before you use LOETTE 21
4. How to use LOETTE 21
5. While you are using it
6. Side Effects
7. Storage and Disposal of LOETTE 21
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What LOETTE 21 is used for

LOETTE 21 is a combined oral contraceptive pill for the prevention of pregnancy. It is also used to treat moderate acne in women when this condition is not improved with acne treatments (such as medicines applied to the skin and oral antibiotics), and in women above 14 years of age who are willing to be on a contraceptive.

How LOETTE 21 works

LOETTE 21 contains two different female hormones (a progestin and an estrogen), similar to the hormones that your body normally produces.

LOETTE 21 prevents pregnancy by suppressing sex hormones called gonadotropins and it prevents the production of egg.

Before you use LOETTE 21

- When you must not use it

Do not take LOETTE 21:

- if you have, previously had tendency to have blood clots;
- if you have, diseases of the blood vessels of brain or heart;
- if you have a heart rhythm disorder or a heart valve disorder;
- if you suffer from severe types of headache or migraine;
- if you have diabetes along with a disease of the blood vessels;
- if you have uncontrolled high blood pressure;
- if you have breast cancer or cancer of the womb, or a type of cancer that is sensitive to female sex hormones (oestrogen), or you are suspected of having any of these cancers;

- if you have or have had a tumour of the liver, or if you have recently had any liver disease. In these cases your doctor will ask you to stop taking LOETTE 21 until your liver is working properly again;
- if you have vaginal bleeding of unknown cause;
- if you have or have had a history of inflammation of the pancreas associated with high blood levels of triglycerides (fatty substances);
- if you are pregnant or suspected to be pregnant;
- if you are allergic to any of the ingredients of LOETTE 21;
- if you have problems with digestion of lipids or fats;
- if you have a blood disease called sickle cell anaemia;
- if you have Hepatitis C and are taking the medicinal products containing ombitasvir / paritaprevir / ritonavir and dasabuvir.

Pregnancy and lactation

Do not take LOETTE 21 if you are pregnant. If you think you may have become pregnant while using LOETTE 21 stop taking the tablet and tell your doctor immediately.

It is not recommended to take LOETTE 21 while you are breastfeeding as the hormones can affect your milk. If you wish to breastfeed, your doctor will be able to advise you on suitable alternative methods of contraception.

- Before you start to use it

Tell your doctor if:

- you smoke: Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels from oral contraceptive use.
- you are overweight;
- you are on prolonged immobilisation (e.g. when you have your leg or legs in plaster or splints, major surgery, any surgery to the legs, major trauma.) In these situations it is better to stop taking LOETTE 21 (if the surgery is planned you should stop at

- least four weeks beforehand) and not to start again until two weeks after you are fully on your feet again;
- you recently gave birth, or had a second-trimester abortion;
- you have an increased fat content in your blood (cholesterol or triglycerides);
- you have or had high blood pressure or have diseases due to high pressure;
- have undiagnosed abnormal vaginal bleeding;
- you have any family history of breast cancer;
- you never have a baby or have first full-term pregnancy at late age;
- you have or had gallbladder disease or have problems with decrease in bile flow (cholestasis) during pregnancy or while using any other combined oral contraceptives;
- you have hereditary angioedema. You should see your doctor immediately if you experience symptoms of angioedema, such as swollen face, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing;
- you have diabetes or a tendency to have diabetes;
- you have swollen enlarged veins;
- you have history of inflammation of a vein;
- you have a loss of hearing;
- you have disease of the brain and spinal cord (multiple sclerosis);
- you have a group of disorders called porphyria that can cause nerve or skin problems;
- you have tetany, involuntary muscle cramps
- you have movement disorder called chorea;
- you have kidney problems;
- you have sugar intolerance
- you have an immune system disorder called systemic lupus erythematosus;
- you have a history of depression;
- you have had during a pregnancy temporary brown patches on your skin (chloasma). The pill can make this recur so you should avoid strong sunlight or sunbeds while taking LOETTE 21;
- if you use contact lenses.

LOETTE® 21 TABLET

Levonorgestrel/Ethinylestradiol (100 mcg/20 mcg)

LOETTE 21 is not for use in children or in post-menopausal women.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Do not use LOETTE 21 if you have Hepatitis C and are taking the medicinal products containing ombitasvir / paritaprevir / ritonavir and dasabuvir. Your doctor will prescribe another type of contraceptive before starting the treatment with these medicinal products

Tell your doctor if you are taking:

- anti-viral hepatitis C virus medicinal products such as ombitasvir, paritaprevir, ritonavir and dasabuvir;
- medicines used for treatment of HIV infections (such as, indinavir);
- medicines used for treatment of epilepsy and other conditions (phenytoin, primidone, topiramate, barbiturates and lamotrigine);
- medicines used for treatment of tuberculosis (such as rifabutin, rifampicin);
- antibiotics (such as ampicillin, troleandomycin, other penicillin or tetracycline);
- antifungal medicines (such as griseofulvin, fluconazole);
- theophylline (used for asthma and other breathing difficulties);
- medicines used to treat certain types of depression (such as St. John's Wort);
- medicines used for pain relief and reducing fever (such as paracetamol and phenylbutazone);
- flunarizine (used to prevent migraine headaches);
- cyclosporine (used to prevent organ rejection);
- medicines used to reduce inflammation (corticosteroids, such as dexamethasone);
- atorvastatin (used to treat high cholesterol);
- modafinil (used to treat excessive sleepiness);

- ascorbic acid (Vitamin C).

If you are on treatment with liver enzyme inducers or certain broad spectrum antibiotics or rifampicin, you need additional contraceptive precautions.

If you are scheduled for any laboratory tests, tell your doctor you are taking LOETTE 21. Some blood tests may be affected by taking LOETTE 21.

How to use LOETTE 21

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully.

The recommended dose for prevention of pregnancy and the treatment of acne is the same.

Tablets must be taken in the order directed on the package every day at the same time. One tablet is to be taken daily for 21 consecutive days followed by a 7-day tablet-free interval. Each subsequent pack is started on the day after the tablet-free interval. A withdrawal bleeding usually starts on Days 2-3, after the last tablet, and may not have finished before the next pack is started.

If this is the first time you are starting the pill or you have not used a hormonal contraceptive for the past month:

- Take the first tablet on the first day of your period.
- Starting later than the first day of bleeding (from days 2-7 of the cycle) will mean you will have to use additional barrier contraception (e.g. condom) for the first 7 days.

If you are changing from another contraceptive pill:

Finish the pack you are on (if your present pill pack also contains hormone-free tablets, do not take them). Then start the LOETTE 21 pack the next day without any pill-free break.

If you were using a progestin-only

method (progestin-only pill, an injectable method or an implant):

- When changing from a progestin-only pill you can start LOETTE 21 at any time during your menstrual cycle, the day after stopping the progestin-only pill.
- When changing from an implant, start LOETTE 21 on the same day that the implant is removed.
- When changing from an injectable contraceptive start LOETTE 21 on the day your next injection is scheduled.

In all cases you must use a barrier contraceptive method (e.g. a condom) during the first 7 days of taking LOETTE 21.

If you are starting LOETTE 21 after a termination that occurred during the first trimester (three months) of pregnancy:

You can start taking LOETTE 21 immediately but should follow the advice of your doctor before doing so. No additional barrier contraception is needed.

If you are starting LOETTE 21 after giving birth or after a termination of pregnancy that occurred during the second trimester:

LOETTE 21 should not be started less than 28 days after giving birth or after termination of a second trimester pregnancy because you are at an increased risk of blood clots. You are advised to use a barrier contraceptive method during the first 7 days of taking the pill. If you have had sex before starting LOETTE 21 be sure you are not pregnant or wait until your next period.

How to delay a period:

You can delay your period by starting another pack of LOETTE 21 without any tablet-free week. You may have some spotting or bleeding while taking the second pack, this is nothing to worry about. You should have a normal bleed after finishing the second course of tablets.

If you have vomiting or diarrhoea:

LOETTE® 21 TABLET

Levonorgestrel/Ethinylestradiol (100 mcg/20 mcg)

Vomiting or severe diarrhoea within 4 hours of taking the pill is similar to if you forget to take a tablet. After vomiting or diarrhoea, you must take another tablet from a reserve pack as soon as possible.

- When to use it

LOETTE 21 must be taken as directed and at the same time every day, preferably after evening meal or bedtime to achieve maximum benefit or effective contraception.

- How long to use it

Continue taking LOETTE 21 for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

If you forget to take a tablet there is a risk you could become pregnant:

- **If you forget one LOETTE 21 tablet but it is less than 12 hours late**, take the missed tablet immediately. Take the next tablet at your usual time.
- **If you have missed one LOETTE 21 tablet and it is more than 12 hours late or two or more tablets are missed**, take the last missed tablet as soon as you remember even if this means taking two tablets in one day. Continue to take tablets at your usual time but you must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm but not the rhythm or temperature methods) for the next 7 days.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause nausea, vomiting, breast tenderness, dizziness, abdominal pain, drowsiness/fatigue and withdrawal bleeding in some cases.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking LOETTE 21.

Tell your doctor immediately if you become pregnant while taking this medication.

Stop taking the tablet and tell your doctor immediately if you notice any of the following:

- crushing chest pain or heaviness in the chest;
- disturbances of vision, speech or hearing;
- worsen breast nodules;
- unusual pain in or swelling of the legs;
- stabbing pain on breathing, or coughing for no apparent reason
- severe pain or tenderness in the stomach area;
- yellowing of the skin or eyeballs, often with fever, fatigue, loss of appetite and dark coloured urine;
- migraine headaches for the first time or more frequent if you already suffer from them;
- itching;
- you are an epileptic and your fits become more frequent;
- severe depression.

Bleeding between periods:

During the first few months that you are taking LOETTE 21, you may have unexpected bleeding, especially during the first 3 months of use. If this bleeding lasts longer than a few months, or if it begins after some months, your doctor must investigate the cause.

If you miss a period and you have not taken your tablets correctly (missing one or more tablets or starting a new pack later than you should have) or you

miss two menstrual periods, contact your doctor immediately. You must use a non-hormonal method of contraception, (such as condoms or a diaphragm) during this time. Your doctor should make sure you are not pregnant before you start taking LOETTE 21 again.

You must have a thorough medical check-up, including, a Pap smear, breast check, blood pressure check and urine test.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give LOETTE 21 to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, LOETTE 21 can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Very frequent and frequent side effects:

- inflammation of vagina resulting in discharge, itching and pain, vaginal thrush (candidiasis);
- painful periods, missed periods, changes in bleeding patterns, including breakthrough bleeding/spotting, changes in mucus from the vagina, changes in the cervix (lower part of the womb), breast pain, tenderness, enlargement, possible milk secretion;

LOETTE® 21 TABLET

Levonorgestrel/Ethinylestradiol (100 mcg/20 mcg)

- mood changes, including depression, changes in sex drive;
- headache, including migraines, nervousness, dizziness;
- nausea, vomiting, stomach pain;
- acne;
- swelling, fluid retention;
- weight change (increase or decrease).

Being a combined oral contraceptive LOETTE 21 has been associated with increased risk of following.

- blood clots in arteries or veins leading to blockage, heart attack or stroke
- cervical cancer and abnormal cells in cervix;
- breast cancer;
- liver tumours.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of LOETTE 21

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Round, pink biconvex tablet with 'W' debossed on one side and '912' debossed on the other.

LOETTE 21 is supplied in blisters of 21 tablets.

- Ingredients

- Active ingredients

Levonorgestrel and ethinylestradiol

- Inactive ingredients
Microcrystalline Cellulose
Lactose Monohydrate
Magnesium Stearate
Polacrillin Potassium
Opadry Pale Pink YS-1-14587A
Polyethylene Glycol 1450
Purified Water
Wax E Pharma

- MAL number

MAL19992694AZ

Manufacturer

Pfizer Ireland Pharmaceuticals Unlimited Company
Little Connell, Newbridge,
W12 HX57,
Ireland
Under the authority of
Pfizer Inc., New York, N.Y., USA.

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.
Level 10 & 11
Wisma Averis, Tower 2
Avenue 5, Bangsar South
No. 8, Jalan Kerinchi
59200 Kuala Lumpur, Malaysia

Date of Revision

27/03/2025

Serial Number

NPRA (R1/2) 26032025/059

PLD-LOETTE 21- 0325