

LIZELLE 0.02mg/3mg film-coated tablets

Ethinylestradiol 0.02mg + Drospirenone 3mg

What is in this leaflet

This leaflet answers some common questions about LIZELLE 0.02mg/3mg film-coated tablets.

Read all of leaflet carefully before you start taking this medicine. Keep this leaflet, you may need to read it again. If you have any further question, ask your doctor or pharmacist. This medicine has been prescribed for you, do not pass it on to others. It may harm them. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell; your doctor or pharmacist.

What is in this leaflet:

1. What LIZELLE is used for
2. How LIZELLE works
3. Before you take LIZELLE
4. How to take LIZELLE
5. While you are using LIZELLE
6. Side effects
7. After using LIZELLE
8. Product description

What LIZELLE 0.02mg/3mg film-coated tablets is used for

LIZELLE is a contraceptive and is used to prevent pregnancy.

How LIZELLE 0.02mg/3mg film-coated tablets works

The contraceptive effect of LIZELLE 0.02mg/3mg film-coated tablet is based on the interaction of various factors, the most important of which are seen as the inhibition of ovulation and the changes in the endometrium.

LIZELLE 0.02mg/3mg film-coated tablet is a combined oral contraceptive with ethinylestradiol and the progestogen drospirenone.

Before you take LIZELLE 0.02mg/3mg film-coated tablets

When you must not take it

- if you have (or have had in the past) blood clots (thrombosis) in a blood vessel of the leg, lungs (embolism) or other organs
- if you have (or have had in the past) a heart attack or a stroke
- 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 (for example a temporary or minor stroke without residual effects).
- if you have any illness which could increase the risk of developing artery thrombosis. This refers to the following illnesses:
 - diabetes with damaged blood vessels
 - very high blood pressure
 - very high fat levels in the blood (cholesterol or triglycerides)
- if you have a disturbance of blood clotting (for example, protein C deficiency).
- if you have (or have ever had) a certain form of migraine (with so called focal neurological symptoms)
- if you have (or have had) inflammation of the pancreas (pancreatitis)
- if you have or have had in the past a liver illness and its hepatic functions have not yet normalised.
- if your kidneys do not work well (kidney failure).
- if you have or have had a liver tumour.
- if you have (or have had), or you suspect you have breast

cancer or cancer of the sexual organs.

- if you have vaginal bleeding and the cause is unknown.
- if you are allergic to ethinylestradiol or drospirenone or any other ingredient in LIZELLE. This could cause itching, a rash or inflammation.
- if you have Hepatitis C and are taking the medicinal products containing ombitasvir / paritaprevir / ritonavir and dasabuvir.

Pregnancy and breast-feeding

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

If you want to become pregnant, you can stop taking **LIZELLE** at any time. It is generally not recommended to take **LIZELLE** when you are breastfeeding. If you want to use the contraceptive while you are breastfeeding, you should consult your doctor.

Before you start to take it

In some situations, you will have to take special care when taking LIZELLE or any other combined hormonal contraceptive, and your doctor may need to carry out regular checks. If any of the following affect you, tell your doctor before using LIZELLE. You should also consult your doctor if the following occur or worsen during your use of LIZELLE:

- if any close family member has or has had breast cancer
- if you have any liver or gallbladder illness
- if you have diabetes
- if you have depression
- if you have Crohn's disease or ulcerative colitis (an inflammatory bowel disease)
- if you have HUS (haemolytic uremic syndrome; a blood illness which damages the kidneys)

- if you have sickle cell disease (a hereditary illness affecting red blood cells)
- if you have epilepsy (see "Taking other medicines")
- if you have SLE (Systemic lupus erythematosus; an illness affecting the immune system)
- if you have an illness which appeared for the first time during pregnancy or during previous use of sexual hormones; for example, hearing loss, porphyria (a blood disease), gestational herpes (skin rash with pimples during pregnancy), Sydenham's chorea (an illness affecting the nerves, producing involuntary movements)
- if you have or have had chloasma (patches of tan/brown skin discolouration, also called the "mask of pregnancy", especially on the face). If you experience this, you have to avoid direct sunlight and ultraviolet rays.
- if you have hereditary angioedema, products which contain oestrogen can cause or worsen the symptoms of angioedema. You must go to your doctor immediately if you experience symptoms of angioedema such as swelling of the face, tongue and/or pharynx, and/or have difficulty in swallowing or break out in hives together with having difficulty in breathing.
- Women with elevated lipids in the blood, or a family history thereof, may be at an increased risk of inflammation of pancreas when using COCs.

Surgery, long periods of immobilization or serious accidents during treatment with LIZELLE

It is important that you tell your doctor in advance that you are taking LIZELLE as your risk of venous thrombosis is increased in these circumstances and the treatment may have to be stopped. Your doctor will tell you when to start to take LIZELLE again. This is usually about two weeks after you are back on your feet.

Taking other medicines

Always tell the doctor who has prescribed you LIZELLE about the medication or herbal preparations you are taking. Also tell any other doctor or dentist that has prescribed other medication (or your pharmacist) that you are taking LIZELLE. They may tell you that you need to use additional contraceptives (condoms for example) and, if they do, they will tell you how long for.

Some medicine can cause LIZELLE to lose its contraceptive effect, or can cause unexpected bleeding.

- This applies to medicines used to treat epilepsy (primidone, phenytoin, hydantoins, topiramides, felbamate, barbiturates, carbamazepine, oxcarbazepine) and tuberculosis (for example; rifampicin), HIV (ritonavir, nevirapine), high blood pressure in the blood vessels in the lungs (bosentan), other infectious diseases (griseofulvin, ampicillin, tetracyclines) and the medicinal herb St John's wort.
- If you want to use herbal preparations which contain St John's wort while you are taking LIZELLE, you should consult your doctor beforehand.
- LIZELLE can affect other medicines, for example, those which contain ciclosporin or the anticonvulsant drug lamotrigine (this can increase the frequency of convulsions).

Do not use LIZELLE 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.

Consult your doctor or pharmacist before taking any

medicine. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Take a LIZELLE tablet every day, with some water if needed. You can take the tablets with or without food, but you should take them approximately at the same time every day.

**How to take LIZELLE
0.02mg/3mg film-coated tablets**

How much to take

Take an LIZELLE tablet every day, with some water if needed. You can take the tablets with or without food, but you should take them approximately at the same time every day.

One pack (blister) contains 21 tablets. The day of the week to take the tablet is printed at the side of each tablet. If, for example, you start on Wednesday, you should take a tablet with "WED" at the side. Follow the arrow on the pack until you have used the 21 tablets. You should then not take any tablet for 7 days. During these 7 days when you do not take any tablets (called drug-free interval), you should menstruate. Menstruation, which can also be called withdrawal bleeding, usually starts on the 2nd or 3rd day of the drug-free interval.

On the eighth day from taking the last LIZELLE tablet (that is after 7 day drug-free interval), start the following pack, even if you have not stopped menstruating. This means that you should start the following package on the same day which you started the previous week and menstruation should occur during the same dates of every month.

If you are breastfeeding and you want to start taking LIZELLE (again) after having a baby, read the section "Pregnancy and breastfeeding".

If you use LIZELLE as described, you are also protected against

pregnancy during the 7 days you do not take any tablet.***When to take it***

- *If you have not taken any hormonal contraceptive in the previous month.*

Start taking LIZELLE on the first day of your cycle (that is the first day of your menstruation). If you start taking LIZELLE on the first day of your menstruation, you will be immediately protected against pregnancy. You can also start from the second to the fifth day of your cycle, but you should use additional contraceptives (a condom for example) for the first 7 days.

- *Changing from another combined hormonal contraceptive, combined contraceptive vaginal ring or patch.* You can start taking LIZELLE the next day after the drug-free interval of your previous contraceptive (or after taking the last inactive tablet). When changing from a combined contraceptive vaginal ring or patch, follow your doctor's recommendations.

- *Changing from a method based exclusively on progestogens (progestogen only tablet, injection, progestogen-releasing intrauterine device or implant).*

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), but it is recommended, in all cases, that you use additional protection (a condom for example) for the first 7 days of taking the tablets.

- *After an abortion.*

Follow your doctor's recommendations.

- *After having a child.*

You can start taking LIZELLE between 21 and 28 days after having your child. If you start later, you

should use a barrier contraceptive (a condom for example) for the first 7 days you take LIZELLE.

If, after having a child, you have already had sexual relations before starting LIZELLE (again), you must be sure that you are not pregnant or wait for your next period.

Seek your doctor's advice if you are not sure when to start.***How long to take it***

One tablet is to be taken daily for 21 consecutive days. Each subsequent pack is started after 7-day tablet-free interval, during which time withdrawal bleed occurs. This usually starts on day 2-3 after the last tablet and may not have finished before the next pack is started.

If you forget to take it

If you are **less than 12 hours** late in taking a tablet, the protection from pregnancy is not reduced. Take the tablet as soon as you realise and the following tablets at the usual time.

If you are **more than 12 hours** late in taking a tablet, protection from pregnancy may be reduced. The more tablets you have forgotten to take, the greater the risk of reducing the contraceptive effect.

The risk of reduced protection against pregnancy is highest if you forget to take the tablet at the beginning 1st row and end of week 3 -3rd row in the pack.

Consequently, you should adopt the following measures (also see the diagram in the last page):

- **Forgetting to take more than one tablet in a pack**

Consult your doctor.

• Forgetting to take one tablet in week 1

Take the tablet you have forgotten as soon as you realise, even if this means that you have to take two tablets at the same time. Continue taking the following tablets at the usual time and take **additional precautions**, for example a condom, for the next 7 days.

If you have had sexual relations in the week before you forgot to take the tablet, there is a risk you may be pregnant. In this case, consult your doctor.

• Forgetting to take one tablet in week 2

Take the tablet you have forgotten as soon as you realise, even if this means that you have to take two tablets at the same time. Continue taking the following tablets at the usual time. The contraceptive effect will not be reduced and you do not need to take additional precautions.

• Forgetting to take one tablet in week 3

You can choose one of two possibilities:

- o Take the tablet you have forgotten as soon as you realise, even if this means that you have to take two tablets at the same time. Continue taking the following tablets at the usual time. Instead having a drug-free week, start taking the next pack. You will probably have your period (withdrawal bleeding) at the end of the second pack, but you could also have some specks or bleeding when taking the second pack.

- o You can also stop taking the active tablets pink in colour. You should start a drug-free interval of 7 days (taking note of the day you forgot to take the tablet). If you want to start a new pack on your fixed start date, the drug-free interval should be less than 7 days.

If you follow one of these two recommendations, you will be protected against pregnancy.

- **If you have forgotten to take a tablet and you do not have a period during**

the drug-free interval, this could mean that you are pregnant. In this case, you should consult your doctor before continuing with the second pack.

Delaying your period

Even though it is not recommended, you can delay your period by going straight to a new strip of LIZELLE instead of the tablet-free period and finishing it. You may experience light or menstruation-like bleeding while using this second strip. After the usual tablet-free period of 7 days, *start* the next strip.

You might ask your doctor for advice before deciding to delay your menstrual period.

.If you take too much (overdose)

There is no proof that overdosing on Ethinylestradiol/ drospirenone causes serious damage.

However, sickness and vomiting can occur from taking lots of tablets at once. Adolescent females could suffer vaginal bleeding.

If you have taken too many LIZELLE tablets, or you discover that a child has taken them, consult your doctor or pharmacist

While you are using LIZELLE 0.02mg/3mg film-coated tablets

Things you must do

If you do not have two consecutive periods, you could be pregnant.

Contact your doctor immediately. Do not start taking the next strip until you are sure that you are not pregnant.

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

If you vomit 3-4 hours after taking an active pink/peach tablet or you have severe diarrhoea, there is a risk that the active ingredients in the pill have not been totally absorbed by the body. This is similar to what

happens when you forget to take a tablet. After vomiting or having diarrhoea, you must take another pink/peach tablet from a reserve strip as soon as possible. If possible, take it within 12 hours of the usual time that you take the tablet. If this is not possible, or more than 12 hours have passed, follow the advice in the section "If you forget to take it".

Stop using LIZELLE and immediately go to your doctor if you have possible signs of thrombosis, such as:

- extreme pain and/or inflammation of one of your legs.
- intense and sudden chest pain, which may reach your left arm
- sudden difficulty in breathing
- sudden cough without clear cause
- unusual headache, intense or prolonged, or worsening of a migraine
- partial or complete vision loss, or double vision
- difficulty or inability to speak
- vertigo or fainting
- weakness, abnormal sensations, or numbness of any part of the body.

Things you must not do

If you are pregnant you must not take LIZELLE.

Do not have this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Things to be careful of

In some situations, you will have to take special care when taking LIZELLE or any other combined hormonal contraceptive, and your doctor may need to carry out regular checks. If any of the following affect you, tell your doctor before using LIZELLE. You should also consult your doctor

if the following occur or worsen during your use of LIZELLE:

- if any close family member has or has had breast cancer
- if you have any liver or gallbladder illness
- if you have diabetes
- if you have depression
- if you have Crohn's disease or ulcerative colitis (an inflammatory bowel disease)
- if you have HUS (haemolytic uremic syndrome; a blood illness which damages the kidneys)
- if you have sickle cell disease (a hereditary illness affecting red blood cells)
- if you have epilepsy (see "Taking other medicines")
- if you have SLE (Systemic lupus erythematosus; an illness affecting the immune system)
- if you have an illness which appeared for the first time during pregnancy or during previous use of sexual hormones; for example, hearing loss, porphyria (a blood disease), gestational herpes (skin rash with pimples during pregnancy), Sydenham's chorea (an illness affecting the nerves, producing involuntary movements)
- if you have or have had chloasma (patches of tan/brown skin discolouration, also called the "mask of pregnancy", especially on the face). If you experience this, you have to avoid direct sunlight and ultraviolet rays.
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Surgery, long periods of immobilization or serious accidents during treatment with LIZELLE

It is important that you tell your doctor in advance that you are taking

LIZELLE as your risk of venous thrombosis is increased in these circumstances and the treatment may have to be stopped. Your doctor will tell you when to start to take LIZELLE again. This is usually about two weeks after you are back on your feet.

Side effects

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

- Common (affecting more than 1 in 100, but less than 1 in 10 women) side effects: mood swing, headache, nausea, sore breasts, enlargement of breasts, painful or irregular menstruations.

Kindly inform your doctor or pharmacist if you experience any undesired side effects.

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

After using LIZELLE
0.02mg/3mg film-coated tablets

Storage

Keep out of the reach and sight of children. This medicinal product does not require any special storage conditions. Do not use LIZELLE after the expiry date which is stated on the blister pack and carton after the phrase "Do not use after:" or "EXP:"

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 protect the environment.

Product description

What it looks like?

Active tablets are pink/peach, round film-coated tablets.

LIZELLE is available in boxes of 1, 2, 3, 6 and 13 packs (blisters), each one containing 21 tablets.

Not all pack sizes may be marketed

Ingredients

The active ingredients are ethinylestradiol 0.02 mg and drospirenone 3 mg.

The other ingredients are:

- Tablet core: lactose monohydrate, pregelatinized starch (maize), povidone, croscarmellose sodium, polysorbate 80, magnesium stearate.
- Coating: Polyvinyl alcohol partial hydrolized, titanium dioxide (E171), macrogol 3350, talc, yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172).

MAL No: MAL12085077AZ

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DATE OF REVISION
13/10/2025

SERIAL NO

NPRA(R2/1)190128/33

ATTACHMENT 1 :

