

INFORMATION FOR THE USER

Logynon® Tablets

(oestradiol / levonorgestrel)

When using the name Logynon Tablets as Logynon throughout this leaflet.

Read this leaflet carefully before you start taking this medicine.

You may need to read it again.

If you have further questions, ask your doctor or pharmacist.

Logynon has been prescribed for you. Do not pass it on to other people. It may harm them, even if their symptoms seem to be similar to yours.

If any of the side effects gets serious, or if you notice anything not listed in this leaflet, please tell your doctor or pharmacist.

What you need to know about combined hormonal contraceptives (CHCs):

There are many different methods of using CHCs correctly.

Using CHCs increases the risk of having a blood clot in the veins, especially in the first year or so of use. The risk of a blood clot is higher if you are taking a combined hormonal contraceptive for 4 or more weeks.

If you think you may have a blood clot, see your doctor if you think you may have a blood clot (see section 2 "Blood clots").

What Logynon is and what it is used for

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Logynon is a combined hormonal contraceptive pill and is used to prevent pregnancy.

Logynon contains a small amount of two different hormones, namely oestradiol and levonorgestrel.

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What you need to know before you take Logynon

When taking Logynon you should read the information leaflet. It is particularly important to read it if you have symptoms of a blood clot – see section 2 "Blood clots".

When taking Logynon, your doctor will ask you about your personal health history and that of your partner. Your doctor will also measure your blood pressure. Your doctor, taking into account your personal situation, may recommend other tests for example a breast exam or a pelvic exam if appropriate.

Logynon is a combined hormonal contraceptive pill and is used to prevent pregnancy. It is important to know that Logynon is not 100% effective. There are many different methods of using CHCs correctly. Using CHCs increases the risk of having a blood clot in the veins, especially in the first year or so of use. The risk of a blood clot is higher if you are taking a combined hormonal contraceptive for 4 or more weeks.

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- if you need an operation, or you are off your feet for a long time (see in section 2 "Blood clots")
- 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 Logynon
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis)
- if you have varicose veins
- if you have epilepsy (see "Logynon and using other medicines")
- if you have a disease that first appeared during pregnancy or with earlier use of sex hormones (for example, hearing loss, a blood disease called porphyria, skin rash with blisters during pregnancy (gestational herpes), or a nerve disease causing sudden movements of the body (Sydenham's chorea)
- if you have ever had golden brown pigment patches (chloasma), so called "pregnancy patches", especially on the face. If this is the case, avoid direct exposure to sunlight or ultraviolet light
- if you have hereditary angioedema (rapid swelling of the skin, mucosal tissues, internal organs or brain); products containing oestrogens may cause or worsen the symptoms. **If you experience symptoms of angioedema such as swollen face, tongue, throat/neck area, difficulty swallowing or hives together with difficulty in breathing, you should see your doctor immediately.**

BLOOD CLOTS

Using a combined hormonal contraceptive such as Logynon increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block blood vessels and cause serious problems.

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).

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, they may be fatal.

It is important to remember that the overall risk of a harmful blood clot due to Logynon is small.

HOW TO RECOGNISE A BLOOD CLOT

Seek urgent medical attention if you notice any of the following signs or symptoms.

Are you experiencing any of these signs?	What are you possibly suffering from?
- 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.	Deep vein thrombosis
- 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').	Pulmonary embolism
Symptoms most commonly occur in the legs.	Retinal vein thrombosis

- The risk of having a blood clot will increase if you have a personal medical history (see "Factors that increase your risk of a blood clot" below).

	Risk of blood clot
Women who are not using a combined hormonal pill and are not pregnant	About 1 in 10,000 women per year
Women using a combined hormonal contraceptive pill containing levonorgestrel	About 1 in 5,000 women per year
Women using Logynon	About 1 in 5,000 women per year

Factors that increase your risk of a blood clot

The risk of a blood clot with Logynon is small. However, certain conditions will increase the risk. Your risk of a blood clot is higher if you have any of the following conditions:

- if you are very overweight (body mass index >30kg/m²);
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (the age of about 50). In this case you may also have a hereditary blood clotting disorder;
- if you need to have an operation, or if you are off your feet for a long time because of an injury or illness. If you have your leg in a cast. The use of a cast should be stopped several weeks before you are mobile. If you need to have an operation, ask your doctor when you can start taking Logynon again.
- as you get older (particularly above 60 years of age);
- if you gave birth less than a few weeks ago.

The risk of developing a blood clot increases if you have any of the following conditions you have.

Air travel (>4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the conditions listed.

It is important to tell your doctor if any of the above conditions apply to you, even if you are unsure. Your doctor will advise that Logynon needs to be stopped.

If any of the above conditions change while you are taking Logynon, for example a close family member has had a blood clot or thrombosis for no known reason; or you have a new blood clot, tell your doctor.

BLOOD CLOTS IN AN ARTERY

What can happen if a blood clot forms in an artery?

Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

Factors that increase your risk of a blood clot in an artery

It is important to note that the risk of a blood clot in an artery from using Logynon is very small but can be increased by:

- with increasing age (beyond about 60 years of age);
- if you smoke.** When using a combined hormonal contraceptive like Logynon you are increasing your risk of smoking. If you are unable to stop smoking, tell your doctor. After 35 your doctor may advise you to use a different type of contraceptive;
- if you are overweight;
- 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 50). In this case you could also have a high cholesterol level; heart attack or stroke;
- if you, or someone in your immediate family, has a high level of fat in the blood (cholesterol);
- if you get migraines, especially migraines with aura;
- if you have a problem with your heart rhythm called atrial fibrillation;
- if you have diabetes.

If you have more than one of these conditions, your risk of a blood clot may be increased even more.

If any of the above conditions change while you are taking Logynon, for example you start smoking, or a family member experiences a thrombosis for no known reason, or you gain a lot of weight, tell your doctor.

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you have hepatitis C and are taking the
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may cause increases in liver function
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type of contraceptive prior to start of
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"Do not use Logynon".

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and drink

with or without food, if necessary with
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ct the results of some tests.

you are pregnant. If you become
Logynon, stop taking Logynon
ct your doctor. If you want to become
taking Logynon at any time (see also
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e, with water if necessary. Do not chew
the tablets with or without food.

d all 21 tablets, you will not take any
7 days. Your period (withdrawal bleed)
7 days, usually 2–3 days after taking

ack on the 8th day even if your period
u will always start a new pack on the
and the withdrawal bleed will occur
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with the first strip?

sed a contraceptive with hormones in
th Begin taking Logynon on the first
that is, the first day of your period). If
on this day you are immediately
pregnancy. You may also begin on day
but you must use extra protective
ample, a condom) for the first 7 days.
other combined hormonal

more tablets have been missed and the closer they are to the
regular tablet-free break, the higher the risk of pregnancy.
See your doctor if this has happened to you.

If you are more than 12 hours late during days 8-14 (see also the diagram):

Take the last missed tablet as soon as you remember, even if
this means taking two tablets at the same time. Then continue
to take the next tablets at the usual time. Provided you have
taken the tablets correctly in the 7 days preceding the first
missed tablet, there is no need to use extra contraceptive
precautions. If you have not taken the tablets correctly or
have missed more than one tablet, you should use extra
contraceptive precautions for the next 7 days.

If you are more than 12 hours late during days 15-21 (see also the diagram):

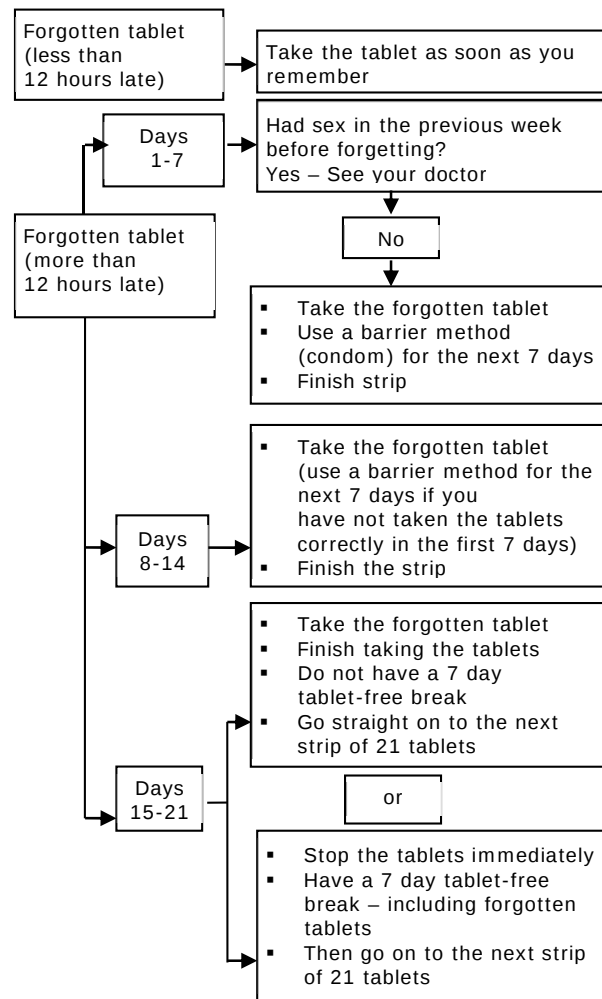
The risk of pregnancy increases the nearer you are to the
tablet-free break of 7 days. However, pregnancy can still be
prevented by adjusting the dosage.

If you use the following advice, there is no need to use extra
contraceptive precautions, provided that all the tablets have
been taken correctly in the 7 days before the first missed
tablet. If this is not the case, you should follow the first of
these two options and use extra contraceptive precautions for
the next 7 days as well.

1. Take the forgotten tablet as soon as you remember, even
if that means taking two tablets at the same time. Then
take the rest of the tablets at the usual time. Instead of
having a 7 day tablet-free break, continue immediately
with the next pack of 21 tablets. There will probably be
no withdrawal bleed until the end of the second pack, but
you may experience spotting or breakthrough bleeding on
tablet-taking days.
2. You can stop taking the tablets from the current pack and
have a tablet-free break of 7 days, including the days you
missed tablets, and then continue with the next pack.

If you miss several tablets and have no withdrawal bleed
during the first normal tablet-free break, the possibility of a
pregnancy must be considered.

Missed Pill Chart



What to do in the case of vomiting or severe

Rare side effects (between 1 and 10 users may be affected):

- contact lens intolerance
- allergic reactions
- increased interest in sex
- breast or vaginal discharge
- red skin lesions or nodules
- skin redness or blotchiness
- weight decrease
- harmful blood clots in a vein or artery
 - in a leg or foot (i.e. DVT)
 - in a lung (i.e. PE)
 - heart attack
 - stroke
 - mini-stroke or temporary stroke known as a transient ischaemic attack
 - blood clots in the liver, stomach or eye.

The chance of having a blood clot may be higher if you have any other conditions that increase this risk. For more information on the conditions that increase the risk of blood clots and the symptoms of a blood clot).

Description of selected adverse reactions

Adverse reactions with very low frequency. Onset of symptoms which are considered serious. Group of combined oral contraceptives and also sections "Do not take Logynon", "Take Logynon"):

Tumours

- breast cancer has been seen slightly more often in women using combined pills, but it is not clear if this is caused by the treatment. For this reason, that more tumours are detected in women using pills because they are examined by ultrasound more often. As breast cancer is rare in women of age the excess number is small. The overall risk of breast cancer is not increased.
- liver tumours (benign and malignant)

Other conditions

- in women with increased blood fats (lipids) the risk of infarction (heart attack) or stroke is increased. This is not caused by the treatment. For this reason, women with increased blood fats (lipids) should be treated with other measures (e.g. diet, exercise, medication) when using contraceptives
- high blood pressure
- occurrence or worsening of conditions such as: combined oral contraceptives is not recommended in women with: gallstone formation; a blood disease (e.g. sickle cell disease, systemic lupus erythematosus (a disease of the natural defence system); hemolytic anaemia (a blood clotting disease); a nerve disease (e.g. Sydenham's chorea; a type of skin disease (e.g. during pregnancy (herpes gestationis) (otosclerosis-related)
- in women with hereditary angioedema (swelling) include sudden swelling of e.g. the face, lips, tongue, etc.) products containing oestrogen may worsen symptoms of angioedema
- disturbed liver function
- if you are a diabetic, your blood glucose may be affected. There is generally no need for special diabetic treatment while using Logynon
- Crohn's disease or ulcerative colitis (inflammation of the inflammatory bowel disease)
- chloasma (a discolouration of the skin, especially on the face/neck known as 'pregnancy mask')

Interactions

Unexpected bleeding and/or contraceptive failure may result from interactions of other drugs with oral contraceptives. The herbal remedy St. John's wort, or drugs for tuberculosis, HIV infections and other infections. "Taking other medicines".

The following conditions may occur with combined oral contraceptives

Crohn's disease, ulcerative colitis, cervical intraepithelial neoplasia (precancerous changes), porphyria (metabolism disorder which causes skin and mental disorders), systemic lupus erythematosus (a disease of the body attacks and injures its own organs), herpes in late pregnancy, Sydenham's chorea

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