

PACKAGE LEAFLET: INFORMATION FOR THE USER

Logynon® tablets

levonorgestrel and ethinylestradiol

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

- In this leaflet:**
1. What Logynon is and what it is used for
 2. Before you take Logynon
 3. How to take Logynon
 4. Possible side effects
 5. How to store Logynon
 6. Further information

1. WHAT LOGYNON IS AND WHAT IT IS USED FOR

- Logynon is a contraceptive pill and is used to prevent pregnancy.
- Each tablet contains a small amount of two different female hormones, namely levonorgestrel and ethinylestradiol.
- Contraceptive pills that contain two hormones are called ‘combined’ pills.

2. BEFORE YOU TAKE LOGYNON

General notes

Before you can begin taking Logynon, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure, and depending upon your personal situation, may also carry out some other tests for example a breast exam or cervical screen as appropriate.

In this leaflet, several situations are described where you should stop using Logynon, or where the reliability of Logynon may be decreased. In such situations you should either not have sex or you should take extra non-hormonal contraceptive precautions, e.g., use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because Logynon alters the monthly changes of body temperature and of cervical mucus.

When taken correctly, combined oral contraceptives have a failure rate of approximately 1% per year. The failure rate may increase when pills are missed or taken incorrectly, if you have a stomach upset or when you take certain other medicines or herbal remedies.

Logynon, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

When not to take Logynon

- Do NOT take Logynon:**
- if you have ever had a blood clot in a blood vessel of the leg (thrombosis), of the lung (embolus) or other organs
 - if you have ever had a heart attack or stroke
 - if you have ever had a disease that can be an indicator of a heart attack in the future (for example, angina pectoris, which causes severe pain in the chest) or of a stroke (for example, a passing slight stroke with no residual effects)
 - if you have a disease that may increase the risk of a clot in the arteries (see “When to take special care with Logynon”)
 - if you have diabetes with damaged blood vessels
 - if you have ever had a certain form of migraine (with so-called focal neurological symptoms)
 - if you have ever had severe liver disease and your liver function is still not normal.
 - if you have ever had a tumour in the liver
 - if you have ever had or suspect you have breast cancer or cancer of the genital organs
 - if you have any unexplained bleeding from the vagina
 - if you know or suspect that you are pregnant
 - if you have an allergy (hypersensitivity) to ethinylestradiol, levonorgestrel, or to any of the other ingredients of Logynon. This may cause itching, rash or swelling.

If any of these conditions start while you are using Logynon, stop taking the pills immediately and talk to your doctor.

When to take special care with Logynon

In some situations you need to take special care while using Logynon or any other combined pill, and it may be necessary that you are regularly checked by your doctor. If any of the following conditions applies to you, you must inform your doctor before starting to use Logynon. Also, if any of the following conditions develops or worsens while you are using Logynon you must consult your doctor:

- a close relative has had breast cancer
- you have liver or gallbladder disease
- you have diabetes
- you have depression
- you have Crohn’s disease or inflammatory bowel disease (ulcerative colitis)
- you have a blood disease called HUS (haemolytic uraemic syndrome) that causes kidney damage
- you have epilepsy (see “Logynon and using other medicines”)
- you have a disease of the immune system called SLE (systemic lupus erythematosus), an illness causing generalised skin disorders
- 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)
- 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.
- you have an intolerance to lactose or are on a lactose-free diet
- 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.**
- you have sickle cell disease
- you have a high level of fat in your blood (cholesterol or triglycerides) or someone in your family has had this
- you have high blood pressure. Your doctor may decide to stop Logynon until your blood pressure is lower.
- you have any disturbance of blood clotting (for example, protein C deficiency)

Logynon and venous and arterial blood clots

The use of any combined pill, including Logynon, increases a woman’s risk of developing **a blood clot in a vein (venous thrombosis)** compared with women who do not take any contraceptive pill.

The use of combined pills has also been connected with an increase of the risk of a **blood clot in an artery (arterial thrombosis)**, for example, in the blood vessels of the heart (heart attack) or the brain (stroke). Blood clots may also occur in the liver, gut, kidney or eye but this is very rare.

- The risk of **having a blood clot in a vein or in an artery** increases:
- with increasing age
 - **if you smoke. You are strongly advised to stop smoking when you use Logynon, especially if you are older than 35 years.**
 - if you are overweight
 - if one of your close relatives had a blood clot in the leg, lung (pulmonary embolism), or other organ at a young age
 - if you have major surgery, any surgery to the legs, a serious accident or if you are immobilised for a long time. It is important to tell your doctor in advance that you are using Logynon as the treatment may have to be stopped. Your doctor will tell you when to start Logynon again. This is usually about two weeks after you are back on your feet
 - if you have high levels of blood cholesterol or triglycerides
 - if you have high blood pressure
 - if you suffer from migraine
 - if you have a problem with your heart (valve disorder, a disturbance of the cardiac rhythm)

Stop taking Logynon and contact your doctor immediately if you notice possible signs of a blood clot, such as:

- severe pain, warmth and/ or swelling in one of your legs
- pain or tenderness in the leg which may be felt only when standing or walking
- red or discoloured skin on the leg
- sudden severe pain in the chest which may reach the left arm or may increase with deep breathing
- rapid or irregular heartbeat
- sudden breathlessness or rapid breathing
- sudden cough which may bring up blood, without an obvious cause

- any unusual, severe or long-lasting headache, first occurrence or worsening of migraine
- partial or complete blindness or double vision
- sudden confusion
- difficulty in speaking or understanding or inability to speak
- dizziness, light headedness or fainting
- weakness, strange feeling, or numbness in any part of the body
- difficulty controlling your movements or balance
- difficulty walking
- sudden severe stomach ache
- pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the chest, arm, or below the breastbone;
- discomfort which spreads to the back, jaw, throat, arm, stomach;
- fullness, indigestion or choking feeling;
- sweating, nausea, vomiting, anxiety
- seizure or loss of consciousness.

Very occasionally thrombosis may cause serious permanent disabilities and may even be fatal. The risk of having a clot is also higher if you have had a baby recently.

- Logynon and cancer**
- Cervical cancer in long-term users has been reported, but the effect of sexual behaviour or other factors such as human papilloma virus (HPV) is not clear.
 - Breast cancer has been observed slightly more often in women using combined pills, but it is not known whether this is caused by the treatment. For example it may be that more tumours are detected in women on combined pills because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the combined hormonal contraceptives. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.
 - Benign liver tumours (non-cancerous) are rare, and malignant liver tumours (cancerous) are even more rarely reported in combined pill users. Contact your doctor if you have unusually severe stomach pain.

Bleeding between periods

During the first few months when you are taking Logynon, you may have unexpected bleeding (bleeding outside the pill-free days). If this bleeding occurs for more than three months, or if it begins after some months, your doctor must find out what is wrong.

What to do if no bleeding occurs during the tablet-free days

If you have taken all the tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant.

If this is not the case or if the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately as pregnancy must be ruled out before the pill is continued. Only start the next strip if you are sure that you are not pregnant.

Logynon and using other medicines

Always tell your doctor which medicines or herbal products you are already using or have recently taken, including medicines obtained without a prescription. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you use Logynon. They can tell you if you need to use additional contraceptive precautions (for example, condoms) and if so, for how long.

- Some medicines can make Logynon less effective in preventing pregnancy, or can cause unexpected bleeding. These include medicines used for the treatment of:
 - epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, or felbamate)
 - tuberculosis (e.g. rifampicin)
 - HIV infections (ritonavir or nevirapine) or other infections (antibiotics such as griseofulvin, penicillin, tetracycline)
 - the herbal remedy St. John’s wort
- Logynon may influence the effect of other medicines, e.g.
 - medicines containing cyclosporine
 - the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures).

Ask your doctor or pharmacist for advice before taking any medicine.

Taking Logynon with food and drink

Logynon may be taken with or without food, if necessary with a small amount of water.

Laboratory tests

If you need a blood test, tell your doctor or the laboratory staff that you are taking the pill, because hormonal contraceptives can affect the results of some tests.

Pregnancy

Do not take Logynon if you are pregnant. If you become pregnant while taking Logynon, stop taking Logynon immediately and contact your doctor. If you want to become pregnant, you can stop taking Logynon at any time (see also “If you want to stop taking Logynon”).
Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

Taking Logynon is not advisable during breast-feeding unless advised to by your doctor. If you want to take the pill while you are breast-feeding you should contact your doctor.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

There is no information suggesting that use of Logynon affects driving or using machines.

Important information about some of the ingredients of Logynon

Logynon contains lactose and sucrose. If you cannot tolerate certain sugars, tell your doctor before you take Logynon.

3. HOW TO TAKE LOGYNON

Take Logynon every day for 21 days.

Logynon comes in strips of 21 pills (6 light brown, 5 white and 10 ochre-coloured tablets).

- Take your pill at the same time every day.
- Start by taking pill number 1 which is marked “Start”. Mark that day of the week under the heading “I took my first pill on” by piercing the small unnumbered foil disc. This will remind you on which day you started taking the course of pills.
- Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 21 pills. The tablets are not all the same so you must take them in the right order, starting with number 1.

Swallow each pill whole, with water if necessary. Do not chew the pill. You may take the tablets with or without food.

Once you have finished all 21 tablets, you will not take any tablets during the next 7 days. Your period (withdrawal bleed) will start during these 7 days, usually 2–3 days after taking the last Logynon tablet.

Start the next blister pack on the 8th day even if your period continues. This way you will always start a new pack on the same day of the week, and the withdrawal bleed will occur roughly at the same time each month.

When can you start with the first strip?

- *If you have not used a contraceptive with hormones in the previous month*
Begin taking Logynon on the first day of the cycle (that is, the first day of your period). If you start Logynon on this day you are immediately protected against pregnancy. You may also begin on day 2-5 of your cycle, but you must use extra protective measures (for example, a condom) for the first 7 days.

- *Changing from another combined hormonal contraceptive, or vaginal ring or patch*
Start taking Logynon on the day after the last active tablet of your previous pill or, at the latest, on the day following the usual tablet-free break or the last placebo tablet of the previous hormonal contraceptive. In the case of a vaginal ring or patch, start taking Logynon on the day of removal or, at the latest, when the next application would have been due.
 - *Changing from a progestogen-only-method (oral pill, injection, implant or an intrauterine system IUS).*
You may change to Logynon tablets on any day from a progestogen-only pill (from an implant or an IUS 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) for the first 7 days of tablet-taking.
 - *After first trimester miscarriage or abortion*
Follow the advice of your doctor.
 - *After having a baby or second trimester miscarriage or abortion*
Start Logynon between 21 and 28 days after delivery or second trimester miscarriage or abortion. If you start later than day 28, you must use an additional barrier method (for example, a condom) during the first 7 days of Logynon use.
- If, after having a baby, you have had sex before starting Logynon (again), you must first be sure that you are not pregnant or you must wait until your next period before taking Logynon.

- *If you are breast-feeding and want to start Logynon (again) after having a baby*
Read the section on “Breast-feeding”.

Ask your doctor what to do if you are not sure when to start.

Use in children and adolescents

You should not take Logynon before you have started to have a monthly period.

Use in older patients

You should not take Logynon after the menopause.

Use in patients with liver problems

You should not take Logynon if you have severe liver problems.

Use in patients with kidney problems

You should talk to your doctor before taking Logynon if you have kidney problems.

If you take more Logynon than you should

There are no reports of serious harmful results from taking too many Logynon tablets.

If you take several tablets at once then you may have symptoms of nausea or vomiting. Young girls may have bleeding from the vagina.

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

If you forget to take Logynon

- If you are **less than 12 hours** late taking a tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and then take the following tablets at the usual time.
- If you are **more than 12 hours** late taking a tablet, the protection against pregnancy may be reduced. The greater the number of tablets that you have forgotten, the greater is the risk of becoming pregnant.

- Therefore, you should keep to the following rules:
- tablet-taking must never be discontinued for longer than 7 days.
 - the effectiveness of Logynon depends on 7 days of uninterrupted tablet-taking.

If you are more than 12 hours late during days 1-7

(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. In addition, a barrier method such as a condom should be used for the next 7 days. If you have had sex in the 7 days before missing the tablet, the possibility of a pregnancy must be considered. The 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.

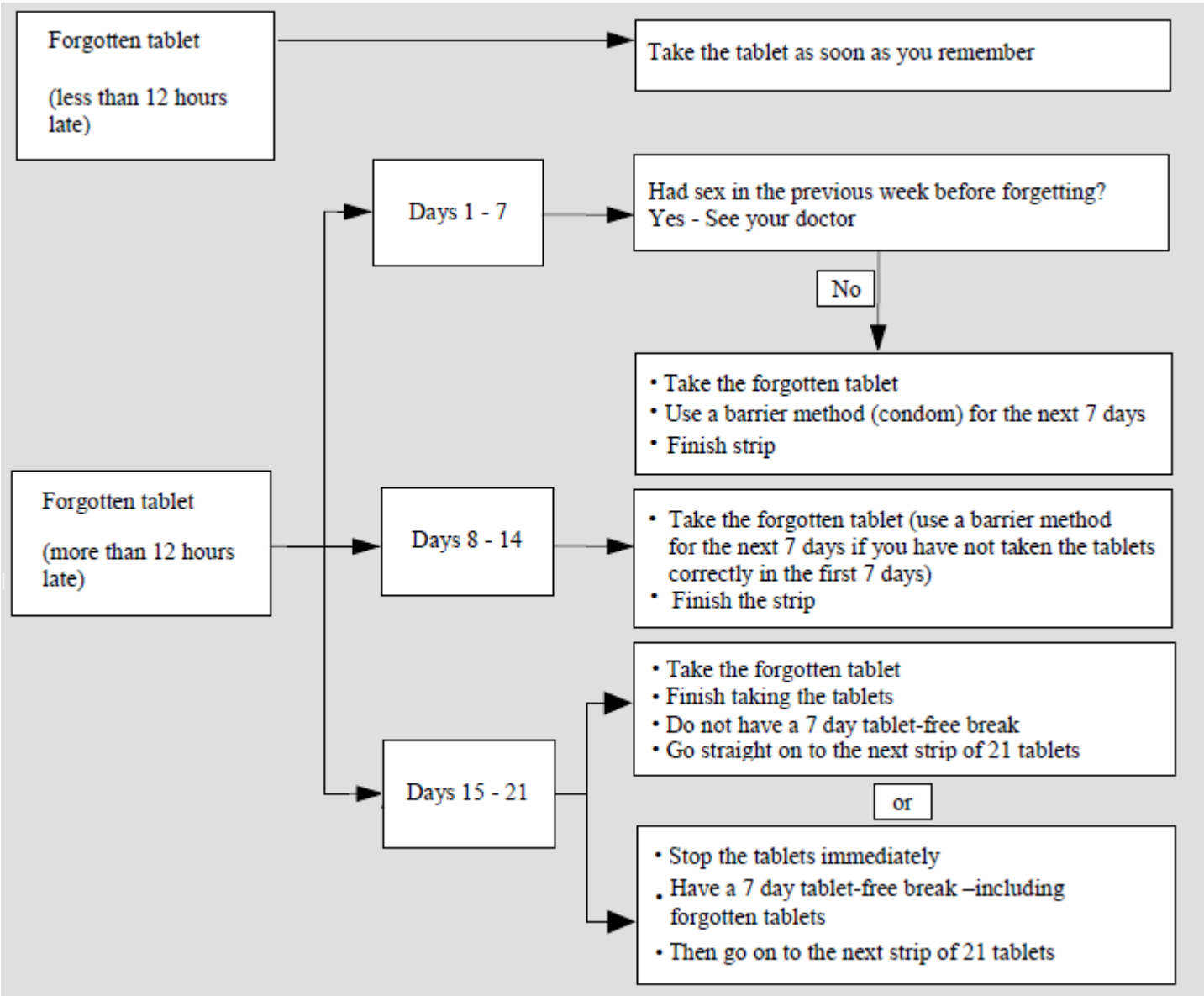
If you are more than 12 hours late during days 15-21

(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.



What to do in the case of vomiting or severe diarrhoea

Vomiting or diarrhoea may make Logynon less effective in preventing pregnancy.

If you vomit within 3-4 hours of taking a tablet or have severe diarrhoea, there is a risk that the active substances in the pill will not be fully taken up by your body. The situation is almost the same as forgetting a tablet. After vomiting or diarrhoea, take another tablet as soon as possible. If possible, take it within 12 hours of when you normally take your pill. If this is not possible or 12 hours have passed, follow the advice given under “If you forget to take Logynon”.

If you do not want to change your normal tablet-taking routine, you can take the extra tablet from another pack.

If the vomiting or diarrhoea continues, talk to your doctor. You will need to use extra contraceptive measures.

Delaying your period: what you need to know

Although it is not recommended, you can delay your period by continuing with the last ten tablets of another pack of Logynon immediately after finishing this pack. The extension can be carried on for a maximum of ten days, until the end of your second pack. You may experience spotting (droplets or flecks of blood) or breakthrough bleeding while using this second pack. When the second pack is finished, you must have a 7-day tablet-free break.

It is advisable to consult your doctor before deciding to delay your menstrual period.

Changing the first day of your menstrual period: what you need to know

If you want to change the starting day or have your period on another day of the week, you can shorten your next tablet-free break by as many days as you like. The shorter the break, the higher the risk that there will be no withdrawal bleed and that you will experience breakthrough bleeding and spotting during the second pack. Never lengthen your tablet-free break.

If you are not sure what to do, talk to your doctor.

If you want to stop taking Logynon

You can stop taking Logynon whenever you want. 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 and wait for a menstrual period before trying to become pregnant. You will be able to calculate the expected delivery date more easily.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Logynon can cause side effects although not everybody gets them. The following is a list of the side effects that have been linked with the use of Logynon:

- Common side effects** (between 1 and 10 in every 100 users may be affected):
- mood swings, depression
 - headache
 - nausea, abdominal pain
 - breast pain or tenderness
 - weight increase

- Uncommon side effects** (between 1 and 10 in every 1,000 users may be affected):
- decreased interest in sex
 - skin rash
 - migraine
 - vomiting, diarrhoea
 - itching or raised bumps on the skin
 - swollen breasts
 - fluid retention

- Rare side effects** (between 1 and 10 in every 10,000 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

The following serious adverse events have been reported slightly more often in women using contraceptive pills (see Section 2: When to take special care with Logynon?)

- venous or arterial blood clots
- stroke
- high cholesterol
- changes in glucose tolerance
- golden brown pigment patches (chloasma), so called “pregnancy patches”
- raised blood pressure
- liver tumours or breast cancer
- disturbances of liver function

The following conditions may occur or get worse with combined oral contraceptives:

Crohn’s disease, ulcerative colitis, cervical cancer, migraine, porphyria (metabolism disorder which causes abdominal pains and mental disorders), systemic lupus erythematosus (where the body attacks and injures its own organs and tissues), herpes in late pregnancy, Sydenham's chorea (rapid involuntary jerking or twitching movements), haemolytic uraemic syndrome (a condition which occurs after diarrhoea caused by *E.coli*), liver problems shown by jaundice, gall bladder disorders or gallstone formation, loss of hearing.

In women with hereditary exogenous angioedema, the oestrogens in contraceptive pills may induce or exacerbate symptoms of angioedema.

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

5. HOW TO STORE LOGYNON

Do not store above 30°C.

Keep Logynon out of the sight and reach of children.

Do not take Logynon after the date on the packaging after “EXP.”.

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.

6. FURTHER INFORMATION

What Logynon contains

The **active substances** are ethinylestradiol and levonorgestrel.

- Each light-brown tablet contains 50 micrograms of levonorgestrel and 30 micrograms of ethinylestradiol
- Each white tablet contains 75 micrograms of levonorgestrel and 40 micrograms of ethinylestradiol
- Each ochre tablet contains 125 micrograms of levonorgestrel and 30 micrograms of ethinylestradiol.

The **other ingredients** are:

lactose, maize starch, povidone, talc, sucrose, magnesium stearate (E572), polyethylene glycol 6000, calcium carbonate (E170), glycerin (E422), titanium dioxide (E171), ferric oxide pigment yellow (E172), ferric oxide pigment red (E172), montan glycol wax.

What Logynon looks like and contents of the pack

Each calendar blister strip of 21 tablets contains 6 light-brown coated tablets, 5 white coated tablets and 10 ochre coated tablets. Logynon is available in packs of 21 tablets.

Procured from within the EU by the Parallel Product Authorisation Holder: Clear Pharma Limited, 157-173 Roden Street, Belfast BT12 5QA, UK.

Manufacturer:

- Bayer Pharma AG, Berlin, Germany
- Bayer Weimar GmbH & Co KG, Weimar, Germany

Repackager

Cast Healthcare Ltd, Unit B6 The Business Centre, 5-7 Tobermore Road, Draperstown, BT45 7AG, UK.

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Logynon® tablets

levonorgestrel and ethinylestradiol

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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- Each tablet contains a small amount of two different female hormones, namely levonorgestrel and ethinylestradiol.
- Contraceptive pills that contain two hormones are called ‘combined’ pills.

2. BEFORE YOU TAKE LOGYNON

General notes

Before you can begin taking Logynon, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure, and depending upon your personal situation, may also carry out some other tests for example a breast exam or cervical screen as appropriate.

In this leaflet, several situations are described where you should stop using Logynon, or where the reliability of Logynon may be decreased. In such situations you should either not have sex or you should take extra non-hormonal contraceptive precautions, e.g., use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because Logynon alters the monthly changes of body temperature and of cervical mucus.

When taken correctly, combined oral contraceptives have a failure rate of approximately 1% per year. The failure rate may increase when pills are missed or taken incorrectly, if you have a stomach upset or when you take certain other medicines or herbal remedies.

Logynon, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

When not to take Logynon

- Do NOT take Logynon:**
- if you have ever had a blood clot in a blood vessel of the leg (thrombosis), of the lung (embolus) or other organs
 - if you have ever had a heart attack or stroke
 - if you have ever had a disease that can be an indicator of a heart attack in the future (for example, angina pectoris, which causes severe pain in the chest) or of a stroke (for example, a passing slight stroke with no residual effects)
 - if you have a disease that may increase the risk of a clot in the arteries (see “When to take special care with Logynon”)
 - if you have diabetes with damaged blood vessels
 - if you have ever had a certain form of migraine (with so-called focal neurological symptoms)
 - if you have ever had severe liver disease and your liver function is still not normal.
 - if you have ever had a tumour in the liver
 - if you have ever had or suspect you have breast cancer or cancer of the genital organs
 - if you have any unexplained bleeding from the vagina
 - if you know or suspect that you are pregnant
 - if you have an allergy (hypersensitivity) to ethinylestradiol, levonorgestrel, or to any of the other ingredients of Logynon. This may cause itching, rash or swelling.

If any of these conditions start while you are using Logynon, stop taking the pills immediately and talk to your doctor.

When to take special care with Logynon

In some situations you need to take special care while using Logynon or any other combined pill, and it may be necessary that you are regularly checked by your doctor. If any of the following conditions applies to you, you must inform your doctor before starting to use Logynon. Also, if any of the following conditions develops or worsens while you are using Logynon you must consult your doctor:

- a close relative has had breast cancer
- you have liver or gallbladder disease
- you have diabetes
- you have depression
- you have Crohn’s disease or inflammatory bowel disease (ulcerative colitis)
- you have a blood disease called HUS (haemolytic uraemic syndrome) that causes kidney damage
- you have epilepsy (see “Logynon and using other medicines”)
- you have a disease of the immune system called SLE (systemic lupus erythematosus), an illness causing generalised skin disorders
- 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)
- 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.
- you have an intolerance to lactose or are on a lactose-free diet
- 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.**
- you have sickle cell disease
- you have a high level of fat in your blood (cholesterol or triglycerides) or someone in your family has had this
- you have high blood pressure. Your doctor may decide to stop Logynon until your blood pressure is lower.
- you have any disturbance of blood clotting (for example, protein C deficiency)

Logynon and venous and arterial blood clots

The use of any combined pill, including Logynon, increases a woman’s risk of developing **a blood clot in a vein (venous thrombosis)** compared with women who do not take any contraceptive pill.

The use of combined pills has also been connected with an increase of the risk of a **blood clot in an artery (arterial thrombosis)**, for example, in the blood vessels of the heart (heart attack) or the brain (stroke). Blood clots may also occur in the liver, gut, kidney or eye but this is very rare.

- The risk of **having a blood clot in a vein or in an artery** increases:
- with increasing age
 - **if you smoke. You are strongly advised to stop smoking when you use Logynon, especially if you are older than 35 years.**
 - if you are overweight
 - if one of your close relatives had a blood clot in the leg, lung (pulmonary embolism), or other organ at a young age
 - if you have major surgery, any surgery to the legs, a serious accident or if you are immobilised for a long time. It is important to tell your doctor in advance that you are using Logynon as the treatment may have to be stopped. Your doctor will tell you when to start Logynon again. This is usually about two weeks after you are back on your feet
 - if you have high levels of blood cholesterol or triglycerides
 - if you have high blood pressure
 - if you suffer from migraine
 - if you have a problem with your heart (valve disorder, a disturbance of the cardiac rhythm)

Stop taking Logynon and contact your doctor immediately if you notice possible signs of a blood clot, such as:

- severe pain, warmth and/ or swelling in one of your legs
- pain or tenderness in the leg which may be felt only when standing or walking
- red or discoloured skin on the leg
- sudden severe pain in the chest which may reach the left arm or may increase with deep breathing
- rapid or irregular heartbeat
- sudden breathlessness or rapid breathing
- sudden cough which may bring up blood, without an obvious cause

- any unusual, severe or long-lasting headache, first occurrence or worsening of migraine
- partial or complete blindness or double vision
- sudden confusion
- difficulty in speaking or understanding or inability to speak
- dizziness, light headedness or fainting
- weakness, strange feeling, or numbness in any part of the body
- difficulty controlling your movements or balance
- difficulty walking
- sudden severe stomach ache
- pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the chest, arm, or below the breastbone;
- discomfort which spreads to the back, jaw, throat, arm, stomach;
- fullness, indigestion or choking feeling;
- sweating, nausea, vomiting, anxiety
- seizure or loss of consciousness.

Very occasionally thrombosis may cause serious permanent disabilities and may even be fatal. The risk of having a clot is also higher if you have had a baby recently.

- Logynon and cancer**
- Cervical cancer in long-term users has been reported, but the effect of sexual behaviour or other factors such as human papilloma virus (HPV) is not clear.
 - Breast cancer has been observed slightly more often in women using combined pills, but it is not known whether this is caused by the treatment. For example it may be that more tumours are detected in women on combined pills because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the combined hormonal contraceptives. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.
 - Benign liver tumours (non-cancerous) are rare, and malignant liver tumours (cancerous) are even more rarely reported in combined pill users. Contact your doctor if you have unusually severe stomach pain.

Bleeding between periods

During the first few months when you are taking Logynon, you may have unexpected bleeding (bleeding outside the pill-free days). If this bleeding occurs for more than three months, or if it begins after some months, your doctor must find out what is wrong.

What to do if no bleeding occurs during the tablet-free days

If you have taken all the tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant.

If this is not the case or if the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately as pregnancy must be ruled out before the pill is continued. Only start the next strip if you are sure that you are not pregnant.

Logynon and using other medicines

Always tell your doctor which medicines or herbal products you are already using or have recently taken, including medicines obtained without a prescription. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you use Logynon. They can tell you if you need to use additional contraceptive precautions (for example, condoms) and if so, for how long.

- Some medicines can make Logynon less effective in preventing pregnancy, or can cause unexpected bleeding. These include medicines used for the treatment of:
 - epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, or felbamate)
 - tuberculosis (e.g. rifampicin)
 - HIV infections (ritonavir or nevirapine) or other infections (antibiotics such as griseofulvin, penicillin, tetracycline)
 - the herbal remedy St. John’s wort
- Logynon may influence the effect of other medicines, e.g.
 - medicines containing cyclosporine
 - the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures).

Ask your doctor or pharmacist for advice before taking any medicine.

Taking Logynon with food and drink

Logynon may be taken with or without food, if necessary with a small amount of water.

Laboratory tests

If you need a blood test, tell your doctor or the laboratory staff that you are taking the pill, because hormonal contraceptives can affect the results of some tests.

Pregnancy

Do not take Logynon if you are pregnant. If you become pregnant while taking Logynon, stop taking Logynon immediately and contact your doctor. If you want to become pregnant, you can stop taking Logynon at any time (see also “If you want to stop taking Logynon”).
Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

Taking Logynon is not advisable during breast-feeding unless advised to by your doctor. If you want to take the pill while you are breast-feeding you should contact your doctor.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

There is no information suggesting that use of Logynon affects driving or using machines.

Important information about some of the ingredients of Logynon

Logynon contains lactose and sucrose. If you cannot tolerate certain sugars, tell your doctor before you take Logynon.

3. HOW TO TAKE LOGYNON

Take Logynon every day for 21 days.

Logynon comes in strips of 21 pills (6 light brown, 5 white and 10 ochre-coloured tablets).

- Take your pill at the same time every day.
- Start by taking pill number 1 which is marked “Start”. Mark that day of the week under the heading “I took my first pill on” by piercing the small unnumbered foil disc. This will remind you on which day you started taking the course of pills.
- Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 21 pills. The tablets are not all the same so you must take them in the right order, starting with number 1.

Swallow each pill whole, with water if necessary. Do not chew the pill. You may take the tablets with or without food.

Once you have finished all 21 tablets, you will not take any tablets during the next 7 days. Your period (withdrawal bleed) will start during these 7 days, usually 2–3 days after taking the last Logynon tablet.

Start the next blister pack on the 8th day even if your period continues. This way you will always start a new pack on the same day of the week, and the withdrawal bleed will occur roughly at the same time each month.

When can you start with the first strip?

- *If you have not used a contraceptive with hormones in the previous month*
Begin taking Logynon on the first day of the cycle (that is, the first day of your period). If you start Logynon on this day you are immediately protected against pregnancy. You may also begin on day 2-5 of your cycle, but you must use extra protective measures (for example, a condom) for the first 7 days.

- *Changing from another combined hormonal contraceptive, or vaginal ring or patch*
Start taking Logynon on the day after the last active tablet of your previous pill or, at the latest, on the day following the usual tablet-free break or the last placebo tablet of the previous hormonal contraceptive. In the case of a vaginal ring or patch, start taking Logynon on the day of removal or, at the latest, when the next application would have been due.
 - *Changing from a progestogen-only-method (oral pill, injection, implant or an intrauterine system IUS).*
You may change to Logynon tablets on any day from a progestogen-only pill (from an implant or an IUS 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) for the first 7 days of tablet-taking.
 - *After first trimester miscarriage or abortion*
Follow the advice of your doctor.
 - *After having a baby or second trimester miscarriage or abortion*
Start Logynon between 21 and 28 days after delivery or second trimester miscarriage or abortion. If you start later than day 28, you must use an additional barrier method (for example, a condom) during the first 7 days of Logynon use.
- If, after having a baby, you have had sex before starting Logynon (again), you must first be sure that you are not pregnant or you must wait until your next period before taking Logynon.

- *If you are breast-feeding and want to start Logynon (again) after having a baby*
Read the section on “Breast-feeding”.

Ask your doctor what to do if you are not sure when to start.

Use in children and adolescents

You should not take Logynon before you have started to have a monthly period.

Use in older patients

You should not take Logynon after the menopause.

Use in patients with liver problems

You should not take Logynon if you have severe liver problems.

Use in patients with kidney problems

You should talk to your doctor before taking Logynon if you have kidney problems.

If you take more Logynon than you should

There are no reports of serious harmful results from taking too many Logynon tablets.

If you take several tablets at once then you may have symptoms of nausea or vomiting. Young girls may have bleeding from the vagina.

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

If you forget to take Logynon

- If you are **less than 12 hours** late taking a tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and then take the following tablets at the usual time.
- If you are **more than 12 hours** late taking a tablet, the protection against pregnancy may be reduced. The greater the number of tablets that you have forgotten, the greater is the risk of becoming pregnant.

- Therefore, you should keep to the following rules:
- tablet-taking must never be discontinued for longer than 7 days.
 - the effectiveness of Logynon depends on 7 days of uninterrupted tablet-taking.

If you are more than 12 hours late during days 1-7

(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. In addition, a barrier method such as a condom should be used for the next 7 days. If you have had sex in the 7 days before missing the tablet, the possibility of a pregnancy must be considered. The 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.

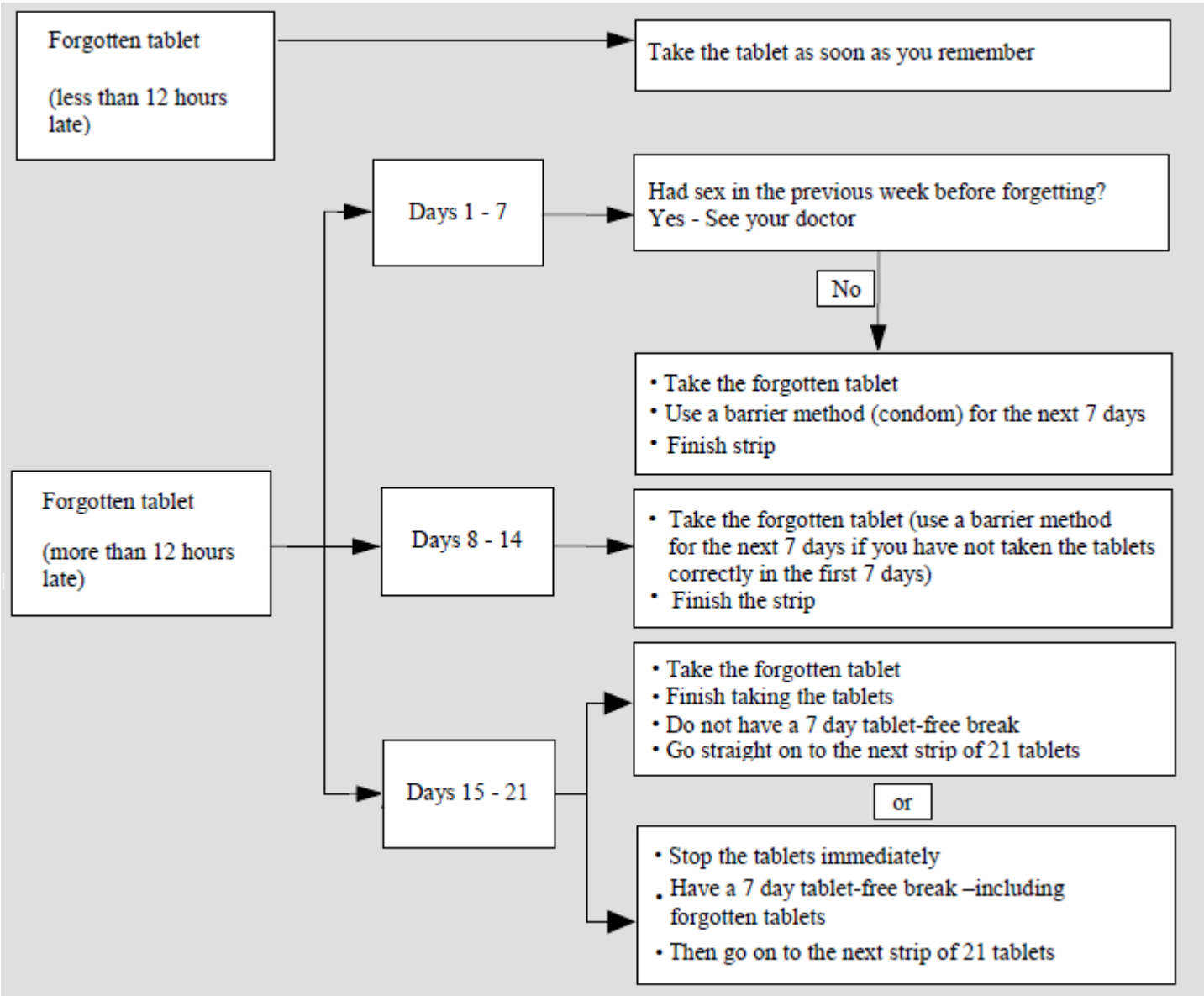
If you are more than 12 hours late during days 15-21

(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.



What to do in the case of vomiting or severe diarrhoea

Vomiting or diarrhoea may make Logynon less effective in preventing pregnancy.

If you vomit within 3-4 hours of taking a tablet or have severe diarrhoea, there is a risk that the active substances in the pill will not be fully taken up by your body. The situation is almost the same as forgetting a tablet. After vomiting or diarrhoea, take another tablet as soon as possible. If possible, take it within 12 hours of when you normally take your pill. If this is not possible or 12 hours have passed, follow the advice given under “If you forget to take Logynon”.

If you do not want to change your normal tablet-taking routine, you can take the extra tablet from another pack.

If the vomiting or diarrhoea continues, talk to your doctor. You will need to use extra contraceptive measures.

Delaying your period: what you need to know

Although it is not recommended, you can delay your period by continuing with the last ten tablets of another pack of Logynon immediately after finishing this pack. The extension can be carried on for a maximum of ten days, until the end of your second pack. You may experience spotting (droplets or flecks of blood) or breakthrough bleeding while using this second pack. When the second pack is finished, you must have a 7-day tablet-free break.

It is advisable to consult your doctor before deciding to delay your menstrual period.

Changing the first day of your menstrual period: what you need to know

If you want to change the starting day or have your period on another day of the week, you can shorten your next tablet-free break by as many days as you like. The shorter the break, the higher the risk that there will be no withdrawal bleed and that you will experience breakthrough bleeding and spotting during the second pack. Never lengthen your tablet-free break.

If you are not sure what to do, talk to your doctor.

If you want to stop taking Logynon

You can stop taking Logynon whenever you want. 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 and wait for a menstrual period before trying to become pregnant. You will be able to calculate the expected delivery date more easily.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Logynon can cause side effects although not everybody gets them. The following is a list of the side effects that have been linked with the use of Logynon:

- Common side effects** (between 1 and 10 in every 100 users may be affected):
- mood swings, depression
 - headache
 - nausea, abdominal pain
 - breast pain or tenderness
 - weight increase

- Uncommon side effects** (between 1 and 10 in every 1,000 users may be affected):
- decreased interest in sex
 - skin rash
 - migraine
 - vomiting, diarrhoea
 - itching or raised bumps on the skin
 - swollen breasts
 - fluid retention

- Rare side effects** (between 1 and 10 in every 10,000 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

The following serious adverse events have been reported slightly more often in women using contraceptive pills (see Section 2: When to take special care with Logynon?)

- venous or arterial blood clots
- stroke
- high cholesterol
- changes in glucose tolerance
- golden brown pigment patches (chloasma), so called “pregnancy patches”
- raised blood pressure
- liver tumours or breast cancer
- disturbances of liver function

The following conditions may occur or get worse with combined oral contraceptives:

Crohn’s disease, ulcerative colitis, cervical cancer, migraine, porphyria (metabolism disorder which causes abdominal pains and mental disorders), systemic lupus erythematosus (where the body attacks and injures its own organs and tissues), herpes in late pregnancy, Sydenham's chorea (rapid involuntary jerking or twitching movements), haemolytic uraemic syndrome (a condition which occurs after diarrhoea caused by *E.coli*), liver problems shown by jaundice, gall bladder disorders or gallstone formation, loss of hearing.

In women with hereditary exogenous angioedema, the oestrogens in contraceptive pills may induce or exacerbate symptoms of angioedema.

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

5. HOW TO STORE LOGYNON

Do not store above 30°C.

Keep Logynon out of the sight and reach of children.

Do not take Logynon after the date on the packaging after “EXP.”.

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.

6. FURTHER INFORMATION

What Logynon contains

The **active substances** are ethinylestradiol and levonorgestrel.

- Each light-brown tablet contains 50 micrograms of levonorgestrel and 30 micrograms of ethinylestradiol
- Each white tablet contains 75 micrograms of levonorgestrel and 40 micrograms of ethinylestradiol
- Each ochre tablet contains 125 micrograms of levonorgestrel and 30 micrograms of ethinylestradiol.

The **other ingredients** are:

lactose, maize starch, povidone, talc, sucrose, magnesium stearate (E572), polyethylene glycol 6000, calcium carbonate (E170), glycerin (E422), titanium dioxide (E171), ferric oxide pigment yellow (E172), ferric oxide pigment red (E172), montan glycol wax.

What Logynon looks like and contents of the pack

Each calendar blister strip of 21 tablets contains 6 light-brown coated tablets, 5 white coated tablets and 10 ochre coated tablets. Logynon is available in packs of 21 tablets.

Procured from within the EU by the Parallel Product Authorisation Holder: Clear Pharma Limited, 157-173 Roden Street, Belfast BT12 5QA, UK.

Manufacturer:

- Bayer Pharma AG, Berlin, Germany
- Bayer Weimar GmbH & Co KG, Weimar, Germany

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