Package leaflet: Information for the user

Levonorgestrel/Ethinylestradiol 150 micrograms/30 micrograms coated tablets
levonorgestrel/ethinylestradiol

Important things to know about combined hormonal contraceptives (CHCs):
- They are one of the most reliable reversible methods of contraception if used correctly.
- They slightly increase the risk of having a blood clot in the veins and arteries, especially in the first year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks.
- Please be alert and see your doctor if you think you may have symptoms of a blood clot (see section 2 "Blood clots").

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Levonorgestrel/Ethinylestradiol is and what it is used for
2. What you need to know before you take Levonorgestrel/Ethinylestradiol
3. How to take Levonorgestrel/Ethinylestradiol
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1. What Levonorgestrel/Ethinylestradiol is and what it is used for

Levonorgestrel/Ethinylestradiol 150 micrograms/30 micrograms coated tablets (called 'Levonorgestrel/Ethinylestradiol' throughout this leaflet) is a combined oral contraceptive pill ('the Pill'). **You take it to stop you getting pregnant.**

This contraceptive contains two types of female sex hormones, oestrogen and progestogen. These hormones stop you getting pregnant by working in three ways: by preventing an egg being released from your ovaries; by making the fluid (mucus) in your cervix thicker, which makes it more difficult for sperm to enter the womb; and by preventing the lining of your womb thickening enough for an egg to grow in it.

2. What you need to know before you take Levonorgestrel/Ethinylestradiol

General notes
Before you start using Levonorgestrel/Ethinylestradiol, you should read the information about blood clots in section 2. It is particularly important to read the description of blood clot symptoms (see section 2, '*Blood clots*').

This package leaflet describes various situations in which you should stop using Levonorgestrel/Ethinylestradiol, or in which the reliability of the pill may be reduced. In such situations, you must either abstain from sexual intercourse or take additional non-hormonal contraceptive measures, e.g., condom or other barrier method. Do not use the rhythm or temperature method. These methods may not be reliable because Levonorgestrel/Ethinylestradiol alters the normal fluctuations in body temperature and lining of the cervix that occur during the menstrual cycle.

As with all contraceptive pills, Levonorgestrel/Ethinylestradiol does not protect against HIV infection (AIDS), or against other sexually transmitted diseases.

Do not take Levonorgestrel/Ethinylestradiol
You should not use Levonorgestrel/Ethinylestradiol if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor. Your doctor will discuss with you what other form of birth control would be more appropriate.

- if you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6);
- if you have (or have ever had) a clot in a blood vessel in the leg (deep vein thrombosis [DVT]), lung (pulmonary embolism [PE]) or other organs;
- if you know you have a blood clotting disorder – for example, protein C deficiency, protein S deficiency, antithrombin III deficiency, factor V Leiden or the presence of antiphospholipid antibodies;
- if you need to have an operation or if you are off your feet for a long time (see section 'Blood clots');
- if you have ever had a heart attack or stroke (or cerebrovascular accident, CVA);
- if you have (or have ever had) angina pectoris (a condition causing severe pain in the chest which may be a warning sign of a heart attack) or transient ischaemic attack (TIA - temporary stroke symptoms);
- if you have any of the following conditions which may increase the risk of a clot in the arteries:
  - severe diabetes with damage to blood vessels
  - very high blood pressure
  - very high levels of fats in the blood (cholesterol or triglycerides)
  - a condition called hyperhomocysteinaemia;
- if you have (or have ever had) a type of migraine called 'migraine with aura';
- if you have jaundice (yellow discolouration of the skin) or severe liver disease;
- if you have or have had cancer influenced by sex hormones (e.g., breast cancer or vaginal cancer);
- if you have or have had a tumour (benign or malignant) of the liver;
- if you experience vaginal bleeding for which the cause is unknown;
- if you are pregnant or think you might be.

Do not use Levonorgestrel/Ethinylestradiol if you suffer from hepatitis C and are taking medicines containing the combination ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see also section '*Other medicines and Levonorgestrel/Ethinylestradiol*').

Should any of these situations occur for the first time while using the pill, stop taking it immediately and consult your doctor. Use non-hormonal contraceptive measures in the meantime. See also '*General notes*'.

Warnings and precautions

When should you contact your doctor?
Seek urgent medical attention
- if you notice possible signs of a blood clot, which could mean that you have a blood clot in your leg (deep vein thrombosis), a blood clot in your lung (pulmonary embolism), or that you are having a heart attack or stroke (see section '*Blood clots*' below).

For a description of the symptoms of these serious side effects, see '*How to recognise a blood clot*'.

If the combined pill is used in any of the following situations, you may need to be kept under close medical supervision. Your doctor can explain this to you.

Talk to your doctor if any of the following situations apply to you.
If the condition develops, or gets worse while you are using Levonorgestrel/Ethinylestradiol, you should also tell to your doctor.
- if you smoke
- if you are diabetic
- if you are overweight
- if you have high blood pressure
- if you have a heart valve condition or heart rhythm disorder
- if you suffer from migraines
- if you have epilepsy
- if you or someone in your immediate family has or has ever had high blood cholesterol
- if someone in your immediate family has had breast cancer
- if you have liver or gallbladder disease
- if you have Crohn's disease or ulcerative colitis (inflammatory bowel disease)
- if you have systemic lupus erythematosus (SLE) (a disease that affects your natural defence system)
- if you have haemolytic uraemic syndrome (HUS) (a blood clotting disorder which causes kidney failure)
- if you have sickle cell disease (an inherited disease affecting red blood cells)
- if you have high levels of fats in the blood (hypertriglyceridaemia) or a family history of this disorder. Hypertriglyceridaemia has been associated with an increased risk of pancreatitis (inflammation of the pancreas)
- if you need an operation, or you are off your feet for a long time (see section 2, '*Blood clots*')
- if you have just given birth, you are at increased risk of blood clots. You should ask your doctor how soon you can start taking Levonorgestrel/Ethinylestradiol after giving birth
- if you have inflammation of the veins under the skin (superficial thrombophlebitis)
- if you have varicose veins
- if you have a condition which first appeared or which worsened during pregnancy, or previous use of sex hormones (e.g., hearing loss, a metabolic disease called porphyria, a skin disease called herpes gestationis, a nerve condition called Sydenham's chorea)
- if you have or have had chloasma (patches of yellow-brown pigmentation on the skin, especially on the face); if so, avoid excessive exposure to sunlight or ultraviolet radiation
- if you develop symptoms of angioedema, such as swelling of the face, tongue and/or throat and/or difficulty swallowing or hives with possible breathing difficulties, see your doctor immediately. Products containing oestrogen may trigger or worsen symptoms of hereditary or acquired angioedema.

Blood clots
Using a combined hormonal contraceptive such as Levonorgestrel/Ethinylestradiol 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 form:
- in the veins (this is called "venous thrombosis" or "venous thromboembolism" [VTE]);

- in the arteries (this is called “arterial thrombosis” or “arterial thromboembolism” [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 Levonorgestrel/ Ethinylestradiol 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?	These could be:
• swelling of one leg or along a vein in the leg or foot, especially when accompanied by: o pain or tenderness in the leg, which may only be felt when standing or walking o increased warmth in the affected leg o 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 shortness of breath, may be mistaken for a milder condition, such as a respiratory tract infection (e.g., common cold).	Pulmonary embolism
Symptoms most commonly occur in one eye: • immediate loss of vision, or • painless blurring of vision, which can progress to loss of vision.	Retinal vein thrombosis (blood clot in the eye)
• chest pain, discomfort, pressure, heaviness • sensation of squeezing or fullness in the chest, arm or below the breastbone • fullness, indigestion or choking feeling • upper body discomfort radiating to the back, jaw, throat, arm and stomach • sweating, nausea, vomiting or dizziness • extreme weakness, anxiety or shortness of breath • rapid or irregular heartbeat.	Heart attack
• sudden weakness or numbness of the face, arm or leg, especially on one side of the body • sudden confusion, trouble speaking or understanding • sudden trouble seeing in one or both eyes • sudden trouble walking, dizziness, loss of balance or coordination • sudden, severe or prolonged headache with no known cause • loss of consciousness or fainting with or without seizure.	Stroke

Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.	
• swelling and slight blue discolouration of an extremity • severe pain in your stomach (acute abdomen).	Blood clots blocking other blood vessels

BLOOD CLOTS IN A VEIN

What can happen if a blood clot forms in a vein?
- The use of combined hormonal contraceptives has been connected with an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare. Most frequently, they occur in the first year of use of a combined hormonal contraceptive.
- If a blood clot forms in a vein in the leg or foot, it can cause deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung, it can cause a pulmonary embolism.
- In very rare cases, a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

When is the risk of developing a blood clot in a vein highest?
The risk of developing a blood clot in a vein is highest during the first year of taking a combined hormonal contraceptive for the first time. The risk may also be higher if you restart taking a combined hormonal contraceptive (the same product or a different product) after a break of 4 weeks or more.
After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive.

When you stop taking Levonorgestrel/Ethinylestradiol, your risk of a blood clot returns to normal within a few weeks.

What is the risk of developing a blood clot?
The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you are taking.

The overall risk of a blood clot in the leg or lung (DVT or PE) with Levonorgestrel/Ethinylestradiol is small.
- Out of 10,000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains levonorgestrel, such as Levonorgestrel/Ethinylestradiol, about 5-7 will develop a blood clot in a year.
- The risk of having a blood clot will vary according to your personal medical history (see '*Factors that increase your risk of a blood clot in a vein*' below).

	Risk of developing a blood clot in a year
Women who are **not using** a combined hormonal pill and are not pregnant	About 2 out of 10,000 women
Women using a combined hormonal contraceptive pill containing **levonorgestrel**	About 5-7 out of 10,000 women
Women using Levonorgestrel/Ethinylestradiol	About 5-7 out of 10,000 women

Factors that increase your risk of a blood clot in a vein
The risk of a blood clot with Levonorgestrel/Ethinylestradiol is small but some conditions will increase the risk. Your risk is higher:

- if you are very overweight (body mass index [BMI] over 30 kg/m^2)
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g., below the age of about 50). In this case, you could 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, or you have your leg in a cast. The use of Levonorgestrel/Ethinylestradiol may need to be stopped at least 4 weeks before surgery or while you are less mobile. If you need to stop Levonorgestrel/Ethinylestradiol, ask your doctor when you can start using it again.
- as you get older (particularly above about 35 years)
- if you gave birth less than a few weeks ago.

The risk of developing a blood clot increases the more conditions you have.

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

It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that Levonorgestrel/Ethinylestradiol needs to be stopped.

If any of the above conditions change while you are using Levonorgestrel/Ethinylestradiol, e.g., a close family member experiences a thrombosis for no known reason, or you gain a lot of weight, tell your doctor.

3. How to take Levonorgestrel/Ethinylestradiol

Always take this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

When taken correctly, combined oral contraceptives have a failure rate of approximately 1% per year. The failure rate can increase if tablets are missed or taken incorrectly.

When and how do you take the tablets?
The Levonorgestrel/Ethinylestradiol blister pack contains 21 tablets. The blister pack indicates the day of the week on which each tablet should be taken. Take your tablet every day at approximately the same time, with some liquid if necessary.
Follow the direction of the arrows until you have taken all 21 tablets. Do not take any tablets during the next 7 days. Menstruation (withdrawal bleeding) should start during these 7 days. This usually begins on the 2nd or 3rd day after the last Levonorgestrel/Ethinylestradiol. Start your next blister pack on the 8th day, even if your menstruation is still ongoing. This means that you always start a new blister pack on the same day of the week, and also that your withdrawal bleeding falls on approximately the same days every 4 weeks.

Starting the first pack
You have not used a hormonal contraceptive in the past month.
Start taking Levonorgestrel/Ethinylestradiol on the first day of your cycle, which is the first day of your menstrual bleeding. Take one tablet on the respective day of the week.
For example, if your period starts on a Friday, take a tablet marked “FRI”. Then follow the day indications in the direction of the arrows. Levonorgestrel/Ethinylestradiol will work immediately, it is not necessary to use an additional contraceptive method. You can also start on day 2 to day 5 of your cycle. In this case, however, during the first cycle, you must ensure that you use an additional contraceptive method (barrier method) during the first 7 days that you taje the tablet.

Changing to Levonorgestrel/Ethinylestradiol from another combined pill, a vaginal ring or a (contraceptive) patch for use on the skin (transdermal).
You can start taking Levonorgestrel/Ethinylestradiol on the day following the last day of taking your previous pill pack (this means no pill-free interval). If your previous pill pack also contains hormone-free tablets, you can start Levonorgestrel/Ethinylestradiol the day after you have taken the last tablet

containing hormones (if you do not know which one, ask your doctor or pharmacist). You can also start later, but never later than the day following the pill-free period of your previous pill (or the day after the last hormone-free tablet of your previous pill).

If you have used a vaginal ring or a transdermal patch, you should preferably start using Levonorgestrel/Ethinylestradiol on the day the last ring or patch is removed from the pack, but at the latest on the day when the next application is due. was fitted with the ring or patch. If you follow these guidelines, it is not necessary to use additional contraception.

Changing to Levonorgestrel/Ethinylestradiol from a progestin-only pill (mini-pill).
You can stop taking the minipill any day. You will then start taking Levonorgestrel/Ethinylestradiol the next day, at the same time as when you took your previous mini-pill. During the first 7 days that you are taking the tablets, you must also use an additional contraceptive method (a barrier method) when you have sexual intercourse.

Changing to Levonorgestrel/Ethinylestradiol from an injection, an implant or a progestogen-releasing intrauterine system (IUS or IUD).
Start taking Levonorgestrel/Ethinylestradiol on the day scheduled for your next injection or on the day your implant or IUS is removed. During the first 7 days of taking the tablets, you must also use an additional contraceptive method (a barrier method) when you have sex.

Starting Levonorgestrel/Ethinylestradiol after childbirth or miscarriage or abortion
After the delivery.
If you have just given birth, your doctor may advise you to wait until your first normal menstrual period before you start taking Levonorgestrel/Ethinylestradiol. It is sometimes possible to start earlier. Your doctor will advise you. If you are breast-feeding and wish to take Levonorgestrel/Ethinylestradiol, you should first discuss this with your doctor.

After a miscarriage or an abortion.
Follow your doctor's advice.

If you take more of this medicine than you should
There are no reports of serious harmful effects from taking too many Levonorgestrel/Ethinylestradiol tablets at the same time. If you have taken a number of tablets at once, you may feel sick, vomit or lose blood from the vagina. Even girls who have not yet had periods and have accidentally taken this medicine may experience such bleeding. If you discover that a child has taken Levonorgestrel/Ethinylestradiol, ask your doctor for advice.

If you have used or taken too much of Levonorgestrel/Ethinylestradiol, immediately contact your doctor, pharmacist or the Anti-Poison Center (070/245.245).

If you forget to take this medicine

If you are **less than 12 hours** late taking a tablet, the reliability of the pill is maintained. Take the tablet as soon as you remember and take the following tablets at the usual times.

If you are **more than 12 hours** late taking a tablet, the reliability of the pill may be reduced. The more tablets you have forgotten in a row, the greater the risk that the contraceptive effect is reduced. The risk of becoming pregnant is particularly high if you miss tablets at the beginning or near the end of the blister pack. Therefore, you should follow the rules below (see also the schedule below).

Forgetting more than one tablet forgotten in a blister pack.
Ask your doctor for advice.

1 tablet forgotten in week 1.

Take the missed tablet as soon as you remember, even if this means taking two tablets at the same time. Take the next tablets at the usual time. Use additional contraceptive measures (a barrier method such as a condom) for the next 7 days.

If you had sexual intercourse in the week before skipping the tablet, there is a possibility that you could become pregnant. Therefore, contact your doctor immediately.

1 tablet forgotten in week 2.

Take the missed tablet as soon as you remember, even if this means taking two tablets at the same time. Take the next tablets at the usual time. The reliability of the pill remains unchanged. You do not need to take any additional contraceptive precautions.

1 tablet forgotten in week 3.
You can choose one of the following options without the need for additional contraceptive precautions:

1. Take the missed tablet as soon as you remember, even if this means taking two tablets at the same time. Take the next tablets at the usual time. Start the next blister pack as soon as the previous one is empty, **without a break between blister packs.** You may not experience withdrawal bleeding before the end of the second blister pack.
However, you may experience spotting or breakthrough bleeding during the days you take tablets.

2. Stop taking the tablets from the opened blister pack; wait an interval of 7 days or less without tablets (**including the day on which you forgot a tablet)**, and continue with the next blister pack. With this method, you can always start your next blister pack on the same day of the week as you are used to.

• If you have forgotten tablets in a blister pack and you do not have your expected period during the next normal tabletfree interval, you may be pregnant. Consult your doctor before starting the next blister pack.

If you stop taking this medicine
You can stop taking Levonorgestrel/Ethinylestradiol, whenever you want. If you wish to stop because you want to become pregnant, it is generally recommended that you wait until you have had a natural menstrual period before trying to conceive. This makes it easier to calculate when the delivery is expected.

If you do not wish to become pregnant, ask your doctor for advice on other methods of birth control.

Do you have any other questions about the use of this medicine? Please contact your doctor or pharmacist.

What to do if…

…you suffer from gastrointestinal disorders (e.g. vomiting, severe diarrhea)
If you vomit or have severe diarrhea, it is possible that the active ingredients of your Levonorgestrel/Ethinylestradiol tablet were not fully absorbed by the body. If you vomit within 3 to 4 hours of taking your tablet, this amounts to missing a tablet. Therefore, follow the advice for missed tablets. If you have severe diarrhea, contact your doctor.

…if you wish to postpone your period
You can postpone your period if you start using the next Levonorgestrel/Ethinylestradiol blister pack immediately after the previous blister pack has been used up. You can continue with this blister pack for as long as you wish, until it is empty. If you wish for your period to start, you only need to stop taking the tablets. While using the second blister pack, you may experience some breakthrough

bleeding or spotting on the days you take tablets. Start your subsequent blister pack after the usual tabletfree interval of 7 days.

…if you wish to shift the start day of your period.
If you take your tablets as directed, your period will start on approximately the same day every 4 weeks. If you wish to change this day, you only need to shorten the normal tablet-free period between two blister packs (but never extend it). For example, if your period normally starts on Friday and you want to shift it to Tuesday in the future (3 days earlier), you must now start the new blister pack 3 days earlier than usual. If you make the tablet-free period very short (for example, 3 days or less), it is possible that you will not experience bleeding during this tablet-free period. You may experience breakthrough bleeding or spotting during the next blister pack.

…you experience unexpected bleeding.
With all pills, you may experience irregular vaginal bleeding (spotting or breakthrough bleeding) between periods during the first few months. You may need a sanitary pad, but continue taking your tablets as usual. Irregular vaginal bleeding usually stops once your body has adjusted to the pill (usually after taking tablets for about 3 cycles). If the bleeding lasts longer, becomes heavy, or starts again, ask your doctor for advice.

…you miss a monthly bleeding.
If you have taken all your tablets at the correct time and have not vomited, had severe diarrhea, or taken other medicines, then it is very unlikely that you are pregnant. Continue taking Levonorgestrel/Ethinylestradiol as usual.

If your period is missed twice in a row, you may be pregnant. Consult your doctor immediately. Do not start the next Levonorgestrel/Ethinylestradiol blister pack until your doctor has checked that you are not pregnant.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
If you get any side effects, particularly if severe and persistent, or notice any change to your medical condition that you think may be due to Levonorgestrel/ Ethinylestradiol, please inform your doctor.

There is an increased risk of blood clots in the veins (venous thromboembolism [VTE]) or arteries (arterial thromboembolism [ATE]) in all women taking combination hormonal contraceptives. For more details on the various risks associated with taking combined hormonal contraceptives, see section 2, '*What you need to know before you take Levonorgestrel/ Ethinylestradiol'*.

Serious side effects
Seek immediate medical attention if you develop any of the symptoms of angioedema, such as swelling of the face, tongue and/or throat, and/or difficulty swallowing or hives with possible breathing difficulties (see also '*Warnings and precautions*').

Serious side effects associated with the use of the pill, as well as the symptoms concerned, are described in the sections '*Warnings and precautions*', '*Blood clots*' and '*The Pill and cancer*'. See also the section '*Do not take Levonorgestrel/Ethinylestradiol*'. For more information, please read these sections and, if necessary, consult your doctor immediately.

Other possible side effects
The following side effects have been reported during treatment with Levonorgestrel/ Ethinylestradiol.

Common (may affect up to 1 in 10 people)
- nausea, abdominal pain (pain in the stomach)
- weight gain
- headache
- depressed mood, mood swings

- breast pain, breast tenderness.

Uncommon (may affect up to 1 in 100 people)
- vomiting, diarrhoea
- fluid retention (slower elimination of fluids)
- migraine
- low libido
- mammary hypertrophy (enlargement of the breasts)
- skin rash, hives.

Rare (may affect up to 1 in 1,000 people)
- contact lens intolerance
- hypersensitivity
- weight loss
- increased libido
- vaginal secretions, breast secretions
- erythema nodosum (reddish swelling under the skin), erythema multiforme (reddish ring-shaped rash)
- blood clots in a vein or artery, for example:
    - in a leg or foot (deep vein thrombosis, DVT)
    - in a lung (pulmonary embolism, PE)
    - heart attack
    - stroke
    - mini-stroke or temporary stroke-like symptoms, known as transient ischaemic attack (TIA)
    - blood clots in the liver, stomach/gut, kidneys, or eye.

Your risk of developing a blood clot may be higher if you have certain other factors which increase this risk (see section 2 for more information on factors which increase the risk of blood clots and symptoms of a blood clot).
Side effects which occur infrequently or with symptoms that do not appear immediately and which are thought to be related to the combination pills are listed below (see also sections '*Do not take Levonorgestrel/Ethinylestradiol*' and '*Warnings and precautions*'.)

Tumours
- Breast cancer is diagnosed slightly more often among pill users. Since breast cancer is rare in women under 40, the increase is small compared to the general risk of breast cancer. It is not known whether the combined pill is the cause.
- Liver tumours (benign or malignant).

Other conditions
- Women who suffer from hypertriglyceridemia (high amount of fat in the blood) are at an increased risk of pancreatitis (inflammation of the pancreas) when using a combination pill.
- High blood pressure.
- Onset or worsening of conditions with a link to combined pill use that has not been established with certainty: jaundice and/or itching associated with obstruction of the flow of bile (cholestasis); formation of gallstones; metabolic disorder known as porphyria; systemic lupus erythematosus (chronic disease that affects the immune system); haemolytic uraemic syndrome (clotting disease); Sydenham's chorea (nerve disorder); herpes gestationis (a type of skin disease that occurs during pregnancy); hearing loss due to otosclerosis (abnormal bone formation in the ear).
- Impaired liver function.
- Changes in glucose tolerance or effect on peripheral insulin resistance.
- Crohn's disease, ulcerative colitis (inflammatory bowel disease).
- Chloasma (yellow-brown pigmentation spots that appear on the skin, mainly on the face).

Interactions
Unexpected bleeding and/or contraceptive failure may result from interactions between other medicines and the contraceptive pill (e.g., St. John's wort – a medicinal plant – or medicines for epilepsy, tuberculosis, HIV infections and other infections). See section '*Other medicines and Levonorgestrel/Ethinylestradiol*'.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Levonorgestrel/Ethinylestradiol

Keep out of the sight and reach of children.
This medicine does not require any special storage conditions.
Do not use this medicine after the expiry date which is stated on the blister/carton after EXP. The expiry date refers to the last day of that month.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Levonorgestrel/Ethinylestradiol contains
- The active substances are levonorgestrel and ethinylestradiol.
- The other ingredients are:

Core: maize starch, pregelatinized starch, povidone, lactose (as monohydrate), colloidal anhydrous silica, magnesium stearate.
Coating: polyvinyl alcohol, partially hydrolysed (E1203), titanium dioxide (E171), talc (E553b), macrogol (E1521), lecithin (soya), sucrose, acacia gum, maize starch, calcium carbonate, povidone, polysorbate 80, ferric oxide – yellow, carnauba wax.

What Levonorgestrel/Ethinylestradiol looks like and contents of the pack
Levonorgestrel/Ethinylestradiol 150 micrograms/30 micrograms coated tablets contain 150 micrograms of the progestogen levonorgestrel and 30 micrograms of the oestrogen ethinylestradiol.
Each carton contains either one or three blister strips of 21 tablets.

Marketing Authorisation Holder
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This medicine is authorised in the Member States of the European Economic Area under the following names:

Ireland	Levonorgestrel/Ethinylestradiol 150 micrograms/30 micrograms coated tablets
Belgium	Levonorgestrel / Ethinylestradiol Renata 0,15 mg / 0,03 mg comprimés enrobés

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