**Package leaflet: Information for the user**

**Roxina 3 mg/0.02 mg film-coated tablets**
drospirenone / 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 your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them.
- 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 Roxina is and what it is used for

- Roxina is a contraceptive pill and is used to prevent pregnancy.
- Each tablet contains a small amount of different female hormones, namely drospirenone and ethinylestradiol.
- Contraceptive pills that contain two hormones are called "combination" pills.

## 2. What you need to know before you take Roxina

**General notes**
Before you start using Roxina you should read the information on blood clots in section 2. It is particularly important to read the symptoms of a blood clot - see Section 2 "Blood clots".

Before you begin taking Roxina, 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.

In this leaflet, several situations are described where you should stop using Roxina, or where the reliability of Roxina 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 Roxina alters the monthly changes of the body temperature and of the cervical mucus.

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

If you have any unusual symptoms such as unexplained pains in the chest, abdomen or legs you must consult your doctor immediately.

When you should not use Roxina

You should not use Roxina 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.

**Do not use Roxina**

- if you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs
- if you know you have a disorder affecting your blood clotting - for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies
- if you need 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 a stroke
- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA - temporary stroke symptoms)
- if you have any of the following diseases that may increase your risk of a clot in the arteries: severe diabetes with blood vessel damage very high blood pressure
- a very high level of fat in the blood (cholesterol or triglycerides) a condition known as hyperhomocysteinaemia
- if you have (or have ever had) a type of migraine called 'migraine with aura'
- if you have (or have ever had) a liver disease and your liver function is still not normal
- if your kidneys are not working well (renal failure)
- if you have (or have ever had) a tumour in the liver
- if you have (or have ever had) or if you are suspected of having breast cancer or cancer of the genital organs
- if you have any unexplained bleeding from the vagina
- if you are allergic to ethinylestradiol or drospirenone, or any of the other ingredients of this medicine (listed in section 6.). This may cause itching, rash or swelling.
- Roxina contains soya lecithin. If you are allergic to peanut or soya, do not use this medicine.

Do not use Roxina if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see also in section "Other medicines and Roxina").

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Roxina

When should you contact your doctor?

Seek urgent medical attention

- if you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke (see 'Blood clots' section below).

For a description of the symptoms of these serious side effects please go to "How to recognise a blood clot".

**Tell your doctor if any of the following conditions apply to you.**

In some situations you need to take special care while using Roxina or any other combination pill, and your doctor may need to examine you regularly. If the condition develops, or gets worse while you are using Roxina, you should also tell your doctor.

- if you exerience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Products containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema.
- if a close relative has or has ever had breast cancer;
- if you have a disease of the liver or the gallbladder;
- if you have diabetes;
- if you have depression or mood changes;
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- if you have systemic lupus erythematosus (SLE - a disease affecting your natural defence system);
- if you have haemolytic uraemic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys);
- if you have sickle cell anaemia (an inherited disease of the red blood cells);
- if you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas);
- 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 Roxina;
- if you have varicose veins;
- if you have epilepsy (see "Other medicines and Roxina");
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- if you have a disease that first appeared during pregnancy or earlier use of sex hormones (for example, hearing loss, a blood disease called porphyria, skin rash with blisters during pregnancy (gestational herpes), a nerve disease causing sudden movements of the body (Sydenham's chorea));
- if you have or 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.

**BLOOD CLOTS**

Using a combined hormonal contraceptive such as Roxina 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 Roxina 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:<br>  - pain or tenderness in the leg which may be felt only when standing or walking<br>  - increased warmth in the affected leg<br>  - 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;<br>- sudden cough without an obvious cause, which may bring up blood;<br>- sharp chest pain which may increase with deep breathing;<br>- severe light headedness or dizziness;<br>- rapid or irregular heartbeat;<br>- severe pain in your stomach.<br><br><u>If you are unsure</u>, 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 one eye:<br>- immediate loss of vision or<br>- painless blurring of vision which can progress to loss of vision | Retinal vein thrombosis (blood clot in the eye) |
| - chest pain, discomfort, pressure, heaviness;<br>- sensation of squeezing or fullness in the chest, arm or below the breastbone;<br>- fullness, indigestion or choking feeling;<br>- upper body discomfort radiating to the back, jaw, throat, arm and stomach;<br>- sweating, nausea, vomiting or dizziness;<br>- extreme weakness, anxiety, or shortness of breath;<br>- rapid or irregular heartbeats. | Heart attack |
| - sudden weakness or numbness of the face, arm or leg, especially on one side of the body;<br>- sudden confusion, trouble speaking or understanding;<br>- sudden trouble seeing in one or both eyes;<br>- sudden trouble walking, dizziness, loss of balance or coordination;<br>- sudden, severe or prolonged headache with no known cause;<br>- loss of consciousness or fainting with or without seizure.<br><br>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. | Stroke |
| - swelling and slight blue discolouration of an extremity;<br>- 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 a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung it can cause a pulmonary embolism. Very rarely 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 Roxina 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 Roxina 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, norethisterone, or norgestimate about 5-7 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains drospirenone such as Roxina between about 9 and 12 women 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" below).

| | **Risk of developing a blood clot in a year** |
|---|---|
| Women who are **not using** a combined hormonal pill/patch/ring and are not pregnant | About 2 out of 10,000 women |
| Women using a combined hormonal contraceptive pill containing **levonorgestrel, norethisterone or norgestimate** | About 5-7 out of 10,000 women |
| Women using Roxina | About 9-12 out of 10,000 women |

**Factors that increase your risk of a blood clot in a vein**
The risk of a blood clot with Roxina is small but some conditions will increase the risk.
Your risk is higher:
- if you are very overweight (body mass index or 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 Roxina may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Roxina 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 Roxina needs to be stopped.

If any of the above conditions change while you are using Roxina, for example a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, 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 heart attack or stroke from using Roxina is very small but can increase:
- with increasing age (beyond about 35 years);
- **if you smoke.** When using a combined hormonal contraceptive like Roxina you are advised to stop smoking. If you are unable to stop smoking and are older than 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 then about 50). In this case you could also have a higher risk of having a heart attack or stroke;
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides);
- if you get migraines, especially migraines with aura;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation);
- if you have diabetes.

If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot may be increased even more.

If any of the above conditions change while you are using Roxina, for example you start smoking, a close family member experiences a thrombosis for unknown reason; or you gain a lot of weight, tell your doctor.

**Roxina and cancer**
Breast cancer has been observed slightly more often in women using combination 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 combination pills because they are examined by their doctor more often.

The occurrence of breast tumours becomes gradually less after stopping the combination hormonal contraceptives. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in pill users. In isolated cases, these tumours have led to life-threatening internal bleeding. Contact your doctor if you have unusually severe abdominal pain.

Some studies suggest that long-term use of the pill increases a woman's risk of developing cervical cancer. However, it is not clear to what extent sexual behaviour or other factors such as Human Papilloma Virus (HPV) increases this risk.

**Psychiatric disorders**
Some women using hormonal contraceptives including Roxina have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

**Bleeding between periods**
During the first few months that you are taking Roxina, you may have unexpected bleeding (bleeding outside the tablet-free days). If this bleeding occurs for more than a few 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 4-day tablet-free interval**
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. Continue to take Roxina as usual.

If you have taken the tablets incorrectly, or, if you have taken tablets correctly but the expected bleeding does not happen twice in a row, you may be pregnant. Contact your doctor immediately. Bleeding under treatment with Roxina normally does not occur every 4 weeks but at reduced frequency with intervals of up to 120 days. Unexpected pregnancy may be difficult to recognize. If for some reason you think you may be pregnant, do a pregnancy test. If the test is positive, or you are still unsure contact your doctor.

Do not continue with tablet-taking until you are sure that you are not pregnant. In the meantime, use nonhormonal contraceptive measures. See also under ‘Pregnancy’.

**Children and adolescents**
Roxina is only indicated after menarche (the first menstrual period).

*Elderly*
Roxina is not indicated after menopause.

*Hepatic impairment*
Women with severe liver problems should not take Roxina (see ‘Do not use Roxina’).

*Renal impairment*
Women with severe renal problems should not take Roxina (see ‘Do not use Roxina’).

**Other medicines and Roxina**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Always tell your doctor which medicines or herbal products you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you use Roxina. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long, or, whether the use of another medicine you need must be changed.

Do not use Roxina if you have Hepatitis **C** and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir, as these products may cause increases in liver function blood test results (increase in ALT liver enzyme).
Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicinal products.
Roxina can be restarted approximately 2 weeks after completion of this treatment. See section “Do not use Roxina”.

Some medicines can have an influence on the blood levels of Roxina and can make it **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, felbamate, topiramate),
    tuberculosis (e.g. rifampicin),
  - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efavirenz) fungal infections (griseofulvin, ketoconazole),
  - arthritis, arthrosis (etoricoxib),
  - high blood pressure in the blood vessels in the lungs (bosentan),
- the herbal remedy St. John's Wort *(Hypericum perforatum).* If you want to use herbal products containing St. John's wort while you are already using Roxina you should consult your doctor first.

Roxina may **influence the effect** of other medicines, e.g.

- medicines containing ciclosporin,
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures),
- theophylline (used to treat breathing problems),
- tizanidine (used to treat muscle pain and/or muscle cramps).

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

**Roxina with food and drink**
Roxina 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 hormone contraceptives can affect the results of some tests.

**Pregnancy and breast-feeding**
Pregnancy
If you are pregnant, do not take Roxina. If you become pregnant while taking Roxina stop immediately and contact your doctor.

If you want to become pregnant, you can stop taking Roxina at any time (see also "If you want to stop taking Roxina").

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

Breast-feeding
Use of Roxina is generally not advisable when a woman is breast-feeding. 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 Roxina affects driving or use of machines.

**Roxina contains lactose and soya lecithin**
Roxina film-coated tablet contains 46.106 mg lactose (as 48.53 mg of lactose monohydrate). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
Roxina film-coated tablet contains 0.07 mg soya lecithin. If you are allergic to peanut or soya, do not use this medicinal product.

## 3. How to take Roxina

**General advice**
Before you start using Roxina for the first time you should discuss with your doctor how to use this product during the different phases.

Always use Roxina, exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Each blister contains 24 tablets.
Take one tablet of Roxina, every day, if necessary with a small amount of water. You may take the tablets with or without food, but you should take the tablets every day around the same time.

**Tablet intake**

*1) Mandatory phase (day 1-24):*
Start by taking a pill marked with the correct day of the week. When starting Roxina tablets must be taken continuously for a minimum of 24 days, after which you can either:
- stop taking tablets for a 4-day tablet-free interval during which your period will start, or continue to take them for up to 120 days (see flexible phase) by which you delay your period.

*2) Flexible phase (day 25-120):*

The tablets can be taken continuously up to a maximum of 120 days (when all the blisters included in this package will be finished). Within this time interval, you may decide yourself if you want to delay your period or take the 4-day tablet-free interval. With the 4-day tablet-free interval you will start your period. This will usually cause bleeding.
In the event of continued bleeding (three consecutive days) during tablet-taking in the flexible phase (days 25-120), it is advisable to start a 4-day table-free interval which will induce your period. This 4-day tablet-free interval will reduce the total number of days with bleeding.

**Tablet-free interval**
A tablet-free interval should not be longer than 4 days and it should only be started if tablet taking has been continuous for 24 days.

**During the 4-day tablet-free interval** bleeding usually occurs and may not have finished before you start the next tablet intake cycle. On the 5th day you have to continue taking the pills as specified, even if the bleeding did not stopped during the tablet-free interval.

**After each 4-day tablet-free interval,** you will start a new intake cycle of a <u>minimum of 24 days</u> to a maximum of 120 days. After the mandatory phase of 24 days of continuous tablet taking, you again may choose when to have the tablet-free 4 day interval between days 25 and 120.

<u>You must start a new blister, which contains 24 tablets,</u> for the mandatory phase and after a 4-day tablet free interval, in order to help you to correctly follow the product administration. After the mandatory phase, you must use the partial blister pack (if available) at the beginning of the flexible phase immediately following the mandatory phase started after your last 4-day tablet-free interval.

**General dosing rules:**
- Any 4-day tablet free interval can only be started if tablet taking has been continuous for 24 days, i.e. after the completion of the mandatory phase.
- After any 4-day tablet free interval, a new mandatory phase starts, i.e. tablets must be taken for a minimum of 24 days before any new break can be scheduled.

**Preparation of the strip**
To help you keep track, there are 5x7 weekdays stickers with 7 strips marked with the 7 days of the week. Choose the week-days sticker strip that starts with the day you begin taking the tablets. For example, if you start on a Wednesday, use the week-days sticker strip that starts with “Wed”.

Fit the "=>" symbol on the strip to the same symbol on the blister card and place the strip into the area bordered with black line. Each day will line up with a row of pills.
There is now a day shown above every tablet and you can see whether you have taken a pill on a particular day.

If you use Roxina in this manner, you are protected against pregnancy also during the 4 days when you are not taking tablets.

***If you are not sure what to do, ask your doctor or pharmacist.***

The prescription of the next blister pack should be issued in time i.e. prior to the use of the last blister in the pack to ensure that you do not run out of tablets.

**When can you start with Roxina**

- *If you have not used a contraceptive with hormones in the previous month*

Begin with Roxina on the first day of the cycle (that is, on the first day of your period). If you start Roxina on the first day of your period you are immediately protected against pregnancy. You may also begin on day 2-5 of the cycle, but then you must use extra protective measures (for example, a condom) for the first 7 days.

- *Changing from another combined hormonal contraceptive, or combined contraceptive vaginal ring or patch*

You can start Roxina preferably on the day after the last tablet-free interval or after the last hormone-free tablet of your previous pill. When changing from a combined contraceptive vaginal ring or patch, follow the advice of your doctor.

- *Changing from a progestogen-only method (progestogen-only pill, injection, implant or a progestogen-releasing IUD)*

You may switch any day from the progestogen-only pill (from an implant or an IUD 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 miscarriage*

Follow the advice of your doctor.

- *After having a baby*

You can start Roxina between 21 and 28 days after having a baby. If you start later than day 28, use a so-called barrier method (for example, a condom) during the first seven days of Roxina use.
If, after having a baby, you have had sex before starting Roxina (again), be sure that you are not pregnant or wait until your next period.

- *If you are breast-feeding and want to start Roxina (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.

**If you take more Roxina than you should**
There are no reports of serious harmful results of taking too many Roxina tablets. If you take several tablets at once then you may have symptoms of nausea or vomiting or you may bleed from the vagina. Even young girls who have not had their first period yet may have bleeding from the vagina, if they accidentally take this medicine.

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

**If you forget to take Roxina**
If you forget a tablet (one of the 24 tablets of your blister pack) you must do the following:

- If you are **less than 24 hours** late taking a tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and then continue taking the tablets again at the usual time.
- If you are **more than 24 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.

The risk of incomplete protection against pregnancy is greatest if you forget a tablet at the beginning or at the end of the blister pack. Therefore, you should keep the following rules:

**More than one tablet forgotten**
Contact your doctor.

**One tablet forgotten between days 1-7**
Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time and use **extra precautions** for the next 7 days, for example, a condom. If you have had sex in the week before forgetting the tablet you must realize that there is a risk of pregnancy. In that case, contact your doctor.

**One tablet forgotten between days 8-24**
Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. The protection against pregnancy is not reduced, and you do not need to take extra precautions. If you have taken your tablets correctly in the 7 days preceding the first missed tablet, there is no need to use extra contraceptive precautions. However, if this is not the case or if you have missed more than 1 tablet, use extra precautions until you have taken the tablets continuously, without interruption for at least 7 days. If you are unsure what to do, ask your doctor for advice.

**One tablet forgotten between days 25-120**
You may choose either of the following options, without the need for extra contraceptive precautions.
1. Take the missed tablet as soon as you remember, even if that means that you have to take two tablets at the same time, and take the next tablets at the usual time until you have taken at least 7 tablets without interruption.

2. Stop taking tablets, have a 4-day tablet-free interval (also count the day you missed your tablet) and continue with a new intake cycle of Roxina.

If you have forgotten any of the tablets in a blister, and you do not have a bleeding during your 4-day tablet-free interval, this may mean that you are pregnant. You must contact your doctor before you start the next blister pack.

**What to do in the case of vomiting or severe diarrhoea**
If you vomit within 3-4 hours after taking the tablet or you have severe diarrhoea, there is a risk that the active substances in the pill will not be fully taken up by your body. This 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 24 hours* of when you normally take your pill. If that is not possible or 24 hours have passed, use extra protection (e.g. a condom) for the next 7 days.

**If you want to stop taking Roxina**
You can stop taking Roxina 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 Roxina and wait for a 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 medicine, ask your doctor or pharmacist.

## 4. Possible side effects

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

If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be due to Roxina, please talk to your doctor.

Serious side effects
Contact a doctor immediately if you experience any of the following symptoms of angioedema: swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also section “Warnings and precautions”).

An increased risk of blood clots in your veins (venous thromboembolism [VTE]) or blood clots in your arteries (arterial thromboembolism [ATE]) is present for all women taking combined hormonal contraceptives. For more detailed information on the different risks from taking combined hormonal contraceptives please see section 2 "What you need to know before you use Roxina".

The following is a list of the side effects that have been linked with the use of Roxina.

**Common side effects** (may affect up to 1 in 10 people)
- mood swings, depression, decreased interest in or loss of interest in sex,
- headache,
- migraine,
- nausea,
- breast pain, problems with your periods, such as irregular periods, absence of periods.

**Uncommon: side effects** (may affect up to 1 in 100 people)
- nervousness, sleepiness,
- dizziness,‘pins and needles',
- varicose veins, increased blood pressure,
- stomach ache, vomiting, indigestion, intestinal gas, inflammation of the stomach, diarrhoea,
- acne, itching, rash,
- aches and pains, e.g. back pain, limb pain, muscle cramps,
- vaginal fungal infection, pelvic pain, breast enlargement, benign breast lumps, uterine/vaginal bleeding (which usually subsides during continued treatment), genital discharge, hot flushes, inflammation of the vagina (vaginitis), problems with your periods, painful periods, reduced periods, very heavy periods, vaginal dryness, abnormal cervical smear,
- lack of energy, increased sweating, fluid retention, weight increase.

**Rare side effects** (may affect up to 1 in 1,000 people)
- candida (fungal infection),
- anemia, increase in the number of platelets in the blood,
- allergic reaction,
- hormonal (endocrine) disorder,
- increased appetite, loss of appetite, abnormally high concentration of potassium in the blood, abnormally low concentration of sodium in the blood,
- failure to experience an orgasm, insomnia,
- giddiness, tremor,
- eye disorders, e.g. inflammation of the eyelid, dry eyes,
- abnormally rapid heartbeat,
- inflammation of a vein, fainting,
- enlarged abdomen, bowel disorder, feeling bloated, stomach hernia, fungal infection of the mouth, constipation, dry mouth,
- pain of bile ducts or the gallbladder, inflammation of the gallbladder,
- yellow brown patches on the skin, eczema, hair loss, acne-like inflammation of the skin, dry skin, lumpy inflammation of the skin, excessive hair growth, skin disorder, stretch marks on the skin, skin inflammation, light-sensitive skin inflammation, skin nodules,

- difficult or painful sex, inflammation of the vagina (vulvovaginitis), bleeding following intercourse, withdrawal bleeding, breast cyst, increased number of breast cells (hyperplasia), malignant lumps in the breast, abnormal growth on the mucosal surface of the neck of the womb, shrinkage or wasting of the lining of the womb, ovarian cysts, enlargement of the womb,
- feeling generally unwell,
- weight loss,
- harmful blood clots in a vein or artery for example:
  - in a leg or foot (i.e. DVT),
  - in a lung (i.e. PE),
  - heart attack,
  - stroke,
  - mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA) .
  - blood clots in the liver, stomach/intestine, kidneys or eye.

  The chance of having a blood clot may be higher if you have any other conditions that increase this risk (See section 2 for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot).

The following side effects have also been reported, but their frequency is not known (cannot be estimated from the available data):
- hypersensitivity
- erythema multiforme (rash with target-shaped reddening or sores).

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie: E-mail:medsafety@hpra,ie. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Roxina

Keep this medicine out of the sight and reach of children.

Store below 25°C. Store in the original package in order to protect from light.
The partially used blister should be removed from the etui bag and stored back inside the carton protected from light until ready for use.

Do not use this medicine after the expiry date which is stated on the blister and 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 Roxina contains**
- The active substances are drospirenone and ethinylestradiol. Each tablet contains 3 mg drospirenone and 0.02 mg ethinylestradiol.

- The other ingredients are:

  *Tablet core:*
  lactose monohydrate
  maize starch

pregelatinised maize starch
macrogol polyvinyl alcohol grafted copolymer
magnesium stearate

*Film-coating'.*
polyvinyl alcohol
titanium dioxide (El71)
talc
macrogol 3350
lecithin (soya)

**What Roxina looks like and contents of the pack?**
Roxina film-coated tablet is white or almost white, round, biconvex film-coated tablet, diameter about 6 mm. Engraving on one side: “G73”, other side is without engraving.

Roxina 3 mg/0.02 mg film-coated tablets are packed in transparent PVC/PE/PVDC-Aluminium blister packs. The blisters are packed into a cardboard box with a patient information leaflet, an etui storage bag and 5×7 weekdays stickers enclosed in each box.

Pack sizes:
5×24 film-coated tablets

**Marketing Authorisation Holder and Manufacturer**
Gedeon Richter Plc.
1103 Budapest, Gyömrői út 19-21.
Hungary

**This medicinal product is authorised in the Member States of the EEA** and in the United Kingdom (Northern Ireland) **under the following names:**

| | |
|---|---|
| Hungary | Fragotella |
| United Kingdom (Northern Ireland) | Roxina |
| Ireland | Roxina |

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