

## **WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET**

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.\**

*The medicine may be authorised for additional or different uses by national medicines regulatory authorities.*

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\*[https://extranet.who.int/prequal/sites/default/files/documents/75%20SRA%20clarification\\_February2017\\_0.pdf](https://extranet.who.int/prequal/sites/default/files/documents/75%20SRA%20clarification_February2017_0.pdf)

## Information for the patient

**[RH071 trade name]**<sup>†</sup>  
ethinylestradiol/levonorgestrel + placebo

**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 questions about the medicine, ask your health care provider.
- 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 seem to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What [RH071 trade name] is and what it is used for
2. What you need to know before you take [RH071 trade name]
3. How to take [RH071 trade name]
4. Possible side effects
5. How to store [RH071 trade name]
6. Contents of the pack and other information

#### 1. What [RH071 trade name] is and what it is used for

[RH071 trade name] is a combined oral contraceptive pill ('the Pill'). It is taken to prevent pregnancy.

[RH071 trade name] 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
- by preventing the lining of your womb thickening enough for an egg to grow in it.

[RH071 trade name] is a 21-day Pill – you take one each day for 21 days, followed by 7 days when you take no pills.

The benefits of taking the Pill include:

- It is one of the most reliable reversible methods of contraception if used correctly
- It doesn't interrupt sex
- It usually makes your periods regular, lighter, and less painful
- It may help with pre-menstrual symptoms.

[RH071 trade name] will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this.

#### 2. What you need to know before you take [RH071 trade name]

It is important that you understand the benefits and risks of taking the Pill before you start taking it, or when deciding whether to carry on taking it. Although the Pill is suitable for most healthy women it isn't suitable for everyone.

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<sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

Do not take [RH071 trade name] if you have any of the conditions listed below. If you have any of these conditions, you must tell your health care provider, who will discuss with you whether another form of birth control may be more appropriate.

**Do not take [RH071 trade name]:**

- If you have, or have ever had, a blood clot in a blood vessel in your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolism, PE) or other organs.
- If you know you have a disorder that makes your blood clot more easily - for example, 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”, below)
- If you have ever had a heart attack or stroke
- If you have (or have ever had) angina pectoris (chest pain that 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:
  - Type 1 or Type 2 diabetes with blood vessel damage
  - Very high blood pressure
  - Very high levels of cholesterol or triglycerides in your blood
  - A condition called hyperhomocysteinaemia
- If you have (or have ever had) a type of migraine called “migraine with aura”
- If you have (or have ever had) breast cancer
- If you have ever had a severe liver disease, and you have been told by your healthcare provider that your liver function test results have not returned to normal
- If you have ever had a tumour in your liver
- If you are allergic (hypersensitive) to any of the ingredients in [RH071 trade name]

Do not use [RH071 trade name] if you have hepatitis C and are taking medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir and sofosbuvir/velpatasvir/voxilaprevir (see also in section “Taking other medicines”, below).

**Warnings and precautions:**

Some of the conditions listed below can be made worse by taking [RH071 trade name] or mean that it is less suitable for you. You may still be able to take [RH071 trade name] but you may need to take extra care and have check-ups more often.

Tell your healthcare provider if any of the following conditions apply to you, or if the condition begins or gets worse while you are taking [RH071 trade name].

- If you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or breathing, contact a healthcare provider immediately. [RH071 trade name] contains oestrogens that may cause or worsen the symptoms of hereditary and acquired angioedema.
- If you have inflammatory bowel disease such as Crohn’s disease or ulcerative colitis.
- If you have systemic lupus erythematosus (SLE – a disease that affects your immune system)
- If you have haemolytic uraemic syndrome (HUS – a blood disorder that may cause kidney failure)
- If you have sickle cell anaemia
- If you have pancreatitis (inflammation of the pancreas)
- 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
- If you need an operation, or you are off your feet for a long time (see “Blood clots”, below)
- If you have just given birth you are at increased risk for blood clots. You should ask your healthcare provider how soon after delivery you can start taking [RH071 trade name]

- If you have inflammation of the veins under the skin (superficial thrombophlebitis)
- If you have varicose veins
- If you have diabetes
- If you or your close family have ever had problems with your heart or circulation such as high blood pressure
- If you or your close family have ever had problems with blood clotting
- If you have the inherited disease called porphyria
- If you are overweight or obese
- If you have migraines
- If you have any illness that got worse during pregnancy or previous use of the contraceptive pill

### **Blood clots:**

Using a combined hormonal contraceptive such as [RH071 trade name] increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block vessels and cause serious problems.

Blood clots can develop:

- In veins (referred to as a “venous thrombosis”, “venous thromboembolism” or VTE)
- In an artery (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. However, it is important to remember that the overall risk of having a serious blood clot due to [RH071 trade name] is small.

### **How to recognise a blood clot**

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

<b>Are you experiencing any of these signs?</b>	<b>Possible cause</b>
<ul style="list-style-type: none"> <li>• swelling of one leg or along a vein in the leg or foot especially when accompanied by:                             <ul style="list-style-type: none"> <li>○ pain or tenderness in the leg which may be felt only when standing or walking</li> <li>○ increased warmth in the affected leg</li> <li>○ change in colour of the skin on the leg e.g. turning pale, red or blue</li> </ul> </li> </ul>	Deep vein thrombosis (DVT)
<ul style="list-style-type: none"> <li>• sudden unexplained breathlessness or rapid breathing</li> <li>• sudden cough without an obvious cause, which may bring up blood</li> <li>• sharp chest pain which may increase with deep breathing</li> <li>• severe light headedness or dizziness</li> <li>• rapid or irregular heartbeat</li> </ul> <p>If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a ‘common cold’).</p>	Pulmonary embolism (PE)
<p>Symptoms most commonly occur in one eye:</p> <ul style="list-style-type: none"> <li>• immediate loss of vision or</li> <li>• painless blurring of vision which can progress to loss of vision</li> </ul>	Retinal vein thrombosis (blood clot in the eye)
<ul style="list-style-type: none"> <li>• chest pain, discomfort, pressure or heaviness</li> <li>• sensation of squeezing or fullness in the chest, arm or below the breastbone</li> <li>• fullness, indigestion or choking feeling</li> <li>• upper body discomfort radiating to the back, jaw, throat, arm</li> </ul>	Heart attack

Are you experiencing any of these signs?	Possible cause
and stomach <ul style="list-style-type: none"> <li>• sweating, nausea, vomiting or dizziness</li> <li>• extreme weakness, anxiety, or shortness of breath</li> <li>• rapid or irregular heartbeat</li> </ul>	
<ul style="list-style-type: none"> <li>• sudden weakness or numbness of the face, arm or leg, especially on one side of the body</li> <li>• sudden confusion, trouble speaking or understanding</li> <li>• sudden trouble seeing in one or both eyes</li> <li>• sudden trouble walking, dizziness, loss of balance or coordination</li> <li>• sudden, severe or prolonged headache with no known cause</li> <li>• loss of consciousness or fainting with or without seizure</li> </ul> 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
<ul style="list-style-type: none"> <li>• swelling and slight blue discolouration of an extremity</li> <li>• severe pain in your stomach (acute abdomen)</li> </ul>	Blood clot blocking other blood vessels

**If you have any of these signs or symptoms, see your healthcare provider as soon as possible. Do not take any more [RH071 trade name] until your healthcare provider says you can. Use another method of contraception such as condoms in the meantime.**

### **Blood clots 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.

- 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).

The risk of developing a blood clot in a vein is highest during the first year of taking a combined hormonal contraceptive such as [RH071 trade name] 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 four 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.

### **Risk of developing a blood clot over a one-year period:**

Women who are not using a combined hormonal pill and are not pregnant	About 2 out of 10,000 women
Women taking [RH071 trade name]	About 5-7 out of 10,000 women

When you stop [RH071 trade name] your risk of a blood clot returns to normal within a few weeks.

### *Factors that increase your risk of a blood clot in a vein:*

The risk of developing a blood clot with [RH071 trade name] is small, but some conditions will increase the risk. Your risk will be higher if any of the following are present:

- If you are very overweight (body mass index or BMI more than 30 kg/m<sup>2</sup>)
- If one of your immediate family has had a blood clot in the leg, lung or other organ before the age of 50. If this is the case, you could have a hereditary blood clotting disorder
- If you need to have surgery, 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. [RH071 trade name] may need to be stopped at least 4 weeks before

surgery or while you are less mobile. Your healthcare provider will advise you when you can restart [RH071 trade name]

- 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 for more than 4 hours may temporarily increase your risk of developing a blood clot, particularly if you have one or more of the other factors listed above.

If any of the above conditions change while you are using [RH071 trade name], for example a close family member experiences a thrombosis for no known reason, or you gain a lot of weight, tell your healthcare provider.

### **Blood clots in an artery:**

A blood 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:*

The risk of a heart attack or stroke from using [RH071 trade name] is very small, but can increase with the following conditions:

- with increasing age (beyond about 35 years)
- **if you smoke.** When using a combined hormonal contraceptive like [RH071 trade name], 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 than 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 [RH071 trade name], for example you start smoking, a close family member experiences a thrombosis for no known reason, or you gain a lot of weight, tell your doctor.

### **The Pill and Cancer:**

Although high dose Pills reduce your risk of cancer of the ovary and womb if used in the long term, it is not clear whether lower dose Pills such as [RH071 trade name] provide the same protective effects. It also seems that taking the Pill slightly increases your risk of cancer of the cervix. This might be due to having sex without a condom, rather than an effect of the Pill itself. All women should have regular smear tests.

*Breast cancer:*

If you have breast cancer, or have had it in the past, you should not take the Pill. The Pill slightly increases your risk of breast cancer. This risk goes up the longer you are on the Pill but returns to normal within about 10 years of stopping it. Because breast cancer is rare in women under the age of 40, the extra cases of breast cancer in current and recent Pill users is small.

*Risk of developing breast cancer by age 35 and 45 years:*

- Of 10,000 women who have **never taken the Pill**, about **16** will have breast cancer by the time they are 35 years old.

- Of 10,000 women who **take the Pill for 5 years in their early twenties**, about **17–18** will have breast cancer by the time they are 35 years old.
- Of 10,000 women who have **never taken the Pill**, about **100** will have breast cancer by the time they are 45 years old.
- Of 10,000 women who **take the Pill for 5 years in their early thirties**, about **110** will have breast cancer by the time they are 45 years old.

Your risk of breast cancer is higher:

- If you have a close relative (mother, sister, or grandmother) who has had breast cancer

**See your healthcare provider as soon as possible if you notice any changes in your breasts, such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.**

#### *Liver cancer:*

Taking the Pill has also been linked to liver diseases, such as jaundice and non-cancer liver tumours, but this is rare. Very rarely, the Pill has also been linked with some forms of liver cancer in women who have taken it for a long time.

**See your healthcare provider as soon as possible if you get severe pain in your stomach, or yellow skin or eyes (*jaundice*).** You may need to stop taking [RH071 trade name].

#### **Psychiatric disorders:**

Some women using hormonal contraceptives including [RH071 trade name] 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 healthcare provider for further medical advice as soon as possible.

#### **Taking other medications:**

If you need to take another medication while you are taking [RH071 trade name], you should tell your doctor, dentist, or pharmacist that you are taking [RH071 trade name]. You should also check the leaflets that come with your medication to see if they can be taken with hormonal contraceptives.

Some medications can change the blood levels of [RH071 trade name] and can stop it from working properly. For example:

- Some medications used to treat epilepsy
- Some medications used to treat HIV and Hepatitis C Virus infections
- Griseofulvin (an anti-fungal medicine)
- Some antibiotics
- Some sedatives (barbiturates)
- St. John's Wort

If you need to take one of these medicines, [RH071 trade name] may not be suitable for you or you may need to use extra contraception for a while. Your doctor, pharmacist or dentist can tell you if this is necessary and for how long.

[RH071 trade name] can also affect how well other medicines work. Your healthcare provider may need to adjust the dose of your other medicine.

[RH071 trade name] can also interfere with the results of some blood tests, so always tell your healthcare provider that you are taking [RH071 trade name] if you have a blood test.

Do not use [RH071 trade name] if you have hepatitis C and are taking medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir and sofosbuvir/velpatasvir/voxilaprevir, as these products may cause increases in liver function blood test results (increase in ALT liver enzyme).

Your healthcare provider will prescribe another type of contraceptive prior to start of the treatment with these medicinal products. [RH071 trade name] can be restarted approximately 2 weeks after completion of this treatment. See section "Do not take [RH071 trade name]", above.

### **Taking [RH071 trade name] with food or drink:**

There are no special instructions about food and drink while on [RH071 trade name].

### **Pregnancy and breastfeeding:**

Do not use [RH071 trade name] if you are pregnant. If you think you might be pregnant, do a pregnancy test to confirm that you are before you stop taking [RH071 trade name].

If you are breast-feeding, your healthcare provider may advise you not to take [RH071 trade name]. They will be able to suggest alternative contraception. Breast-feeding may not stop you getting pregnant.

### **Driving and using machines:**

[RH071 trade name] has no known effect on the ability to drive or use machines.

### **[RH071 trade name] contains lactose**

If you have been told by your health care provider that you have an intolerance to some sugars, contact your health care provider before taking this medicinal product.

## **3. How to take [RH071 trade name]**

To prevent pregnancy, always take [RH071 trade name] as described below. Check with your healthcare provider or family planning nurse if you are not sure.

### **Take [RH071 trade name] every day**

[RH071 trade name] comes in packs of 28 pills, each marked with a day of the week.

- Take your pill at the same time every day.
- Start by taking a pill marked with the correct day of the week.
- The first 21 pills contain the active contraceptive and the remaining 7 pills are inactive placebo pills.
- Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 28 pills.
- Swallow each pill whole, with water if necessary. Do not chew the pill.
- After you have finished a pack, you will begin a new pack right away. There are no 'pill-free' days

### **Starting [RH071 trade name]:**

If you are a new user or starting the Pill again after a break, it is best to take your first [RH071 trade name] pill on the first day of your next period, but you can take the first pill up to five days after the start of your period. By starting this way, you will have contraceptive protection with your first dose.

If it is more than five days since the start of your period, you can still start [RH071 trade name] provided you are reasonably certain that you are not pregnant. You will need to abstain from sex or use additional contraceptive protection for the next seven days.

*If you are not having periods:*

[RH071 trade name] can be started at any time provided you are reasonably certain that you are not pregnant. You will need to abstain from sex or use additional contraceptive protection for the next seven days.

### **Switching to [RH071 trade name] from another contraceptive Pill:**

- **If you are currently taking a 21-day Pill:** start [RH071 trade name] the next day after the end of the previous strip. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of [RH071 trade name]
- **If you are taking a 28-day Pill:** start taking [RH071 trade name] the day after your last active pill. You will have contraceptive protection with your first pill. You will not have a bleed until after you have taken all the active pills (first 21 days).
- **If you are taking a progestogen-only Pill (POP or 'mini Pill'):** start [RH071 trade name] on the first day of bleeding, even if you have already taken the progestogen-only Pill for that day. You will have contraceptive protection straight away.



**Switching to [RH071 trade name] from a non-hormonal contraceptive method (other than an IUD):**

- You can start [RH071 trade name] within five days after the start of menstrual bleeding. No additional contraceptive protection is needed.
- If it is more than five days since the start of your menstrual period, you can start [RH071 trade name] provided you are reasonably certain that you are not pregnant. You will need to abstain from sex or use additional contraceptive protection for the next seven days.

**Switching from an IUD (including the levonorgestrel-releasing IUD):**

- You can start [RH071 trade name] within five days after the start of menstrual bleeding. No additional contraceptive protection is needed. The IUD can be removed at this time.
- If it is more than five days since the start of your menstrual period, you can start [RH071 trade name] provided you are reasonably certain that you are not pregnant. The IUD can be removed at the time of your next menstrual period.
- If you have no periods, or irregular menstrual bleeding, you can start [RH071 trade name] as advised for other amenorrhoeic women (see above).

**Starting [RH071 trade name] after a miscarriage or abortion:**

If you have had a miscarriage or an abortion during the first two trimesters, you may start taking [RH071 trade name] straight away. This means that you will have contraceptive protection with your first pill.

**Contraception after having a baby:**

*If you are breastfeeding:*

- If you are less than 6 weeks post-delivery you should not use [RH071 trade name].
- If you are between 6 weeks and 6 months post-delivery, you should only restart [RH071 trade name] if other contraceptive methods are not available or not acceptable.
- If you are more than 6 months post-delivery you can start [RH071 trade name] as advised for women who have not been on the Pill or have taken a break from the Pill (see above).

*If you are not breastfeeding:*

- If you are less than 21 days post-delivery you should only restart [RH071 trade name] if other contraceptive methods are not available or not acceptable. It is very unlikely that you will ovulate and be at risk of pregnancy during the first 21 days post-delivery. However, if national, regional, or local programme protocols require it, other contraceptive methods may be used during this time.
- If you are more than 21 days post-delivery with no other risk factors for venous thromboembolism, you can restart [RH071 trade name]:
  - If your period has not returned, [RH071 trade name] can be started immediately if you are reasonably certain that you are not pregnant. You will need to abstain from sex or use additional contraceptive protection for the next seven days.
  - If your periods have returned, [RH071 trade name] can be started as advised for other women having menstrual cycles (see above).

**If you miss a dose of [RH071 trade name]:**

If you were due to take the missed pill less than 12 hours ago, you should take the delayed pill right away and continue taking the rest of the pills in the pack as usual. Do not worry, your contraception should not be affected.

If you were due to take your missed pill more than 12 hours ago, or if you have missed more than one pill, what you do depends on whether the missed pill was from the first 21 days, or the last 7 days of the pill pack. Pills from the first 21 days of the pack contain the contraceptive and are called active pills. Pills from the last 7 days do not contain any active ingredient and are called placebo pills.

**If the missed pill was from the first 21 days:**

Pills from the first 21 days of the pack contain the active contraceptive. Missing one or more of the active pills will reduce your protection against becoming pregnant.

- Take the most recently missed pill right away
- Leave any earlier missed pills in the strip
- Take your next pill at the usual time. This may mean taking two pills in one day.
- Check how many pills from the first 21 days are left after the most recently missed pill.

**If there are 7 or more active pills left from the first 21 days:**

- Do not forget to take extra precautions for the next 7 days
- When you finish all the active pills, take the 7 days of placebo pills as usual.
- If you missed one or more active pills during the first week of the pack, and you had sex that week, you could be pregnant. Contact your healthcare provider for advice as soon as possible. They may recommend you use emergency protection.

**If there are less than 7 active pills left from the first 21 days:**

- Do not forget to take extra precautions for the next 7 days
- When you finish all the active pills, do not take the placebo pills. Instead, you should start the next pack from the beginning.
- If you do not have a bleed after you have taken the 21 active pills from the next pack, during the placebo week, do a pregnancy test before starting another pack.
- If you missed one or more active pills during the first week of the pack, and you had sex that week, you could be pregnant. Contact your healthcare provider for advice as soon as possible. They may recommend you use emergency protection.

**If you start a new pack of pills late following the placebo week, you may not be protected from pregnancy. If you had sex in the last seven days, ask your healthcare provider for advice. You may need to consider emergency contraception. You should also use extra contraception, such as a condom, for seven days.**

**If you have missed any of the pills from the first 21 days, and you do not bleed during the placebo (sugar pill) week, you may be pregnant. Contact your healthcare provider or family planning clinic or do a pregnancy test yourself.**

**Other situations that may arise:**

*If you lose a pill:*

**Either** take the last pill of the strip in place of the lost pill. Then take all the other pills on their proper days. Your cycle will be one day shorter than normal, but your contraceptive protection won't be affected. After your seven placebo pill days you will have a new starting day, one day earlier than before.

**Or** if you do not want to change the starting day of your cycle, take a pill from a spare strip if you have one. Then take all the other pills from your current strip as usual. You can then keep the opened spare strip in case you lose any more pills.

*If you vomit or have diarrhoea:*

If you are sick (vomit) or have bad diarrhoea within 4 hours of taking [RH071 trade name], you may not get the usual dose of hormones from that pill. If you are better within 12 hours of taking [RH071 trade name], follow the instructions in the section above, *A lost pill*, which describes how to take another pill.

If you are still sick or have diarrhoea more than 12 hours after taking [RH071 trade name], follow the instructions in the section above, *A missed pill*.

Talk to your healthcare provider if your stomach upset carries on or gets worse. He or she may recommend another form of contraception.

*Missed a period – could you be pregnant?*

Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you have taken your pills correctly. Start your next strip at the normal time. If you think that you might have put yourself at risk of pregnancy (for example, by missing pills or taking other medicines), or if you miss a second bleed, you should do a pregnancy test. You can buy these from the chemist or get a free test at your family planning clinic or from your healthcare provider. If you are pregnant, stop taking [RH071 trade name] and see your healthcare provider.

*If you take more than one pill as a single dose:*

It is unlikely that taking more than one pill will do you any harm, but you may feel sick, vomit, or have some vaginal bleeding. Even girls who have not yet started to menstruate but have accidentally taken this medicine may experience such bleeding. Talk to your healthcare provider if you have any of these symptoms.

#### **4. Possible side effects**

Like all medicines, [RH071 trade name] can cause side effects, although not everybody gets them. If you get any side effects, particularly if severe and persistent, or have any change to your health that you think may be due to [RH071 trade name], you should speak to your healthcare provider.

An increased risk of blood clots in the veins (venous thromboembolism (VTE)) or blood clots in the arteries (arterial thromboembolism (ATE)) is present for all women using 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 [RH071 trade name]”.

#### **Serious side effects – see a healthcare provider straight away:**

Rare serious side effects (between 1 in 1000 and 1 in 10,000 users may be affected):

- Blood clots in a vein or artery, such as:
  - In a leg or calf (i.e. deep vein thrombosis, DVT)
  - In a lung (i.e. pulmonary embolus, PE)
  - Heart attack
  - Stroke
  - Mini-stroke or temporary stroke-like symptoms, known as transient ischemic attack (TIA)
  - Very rarely, blood clots in the liver, 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).

- Severe allergic reaction:
  - Swelling of the hands, face, lips, mouth, tongue or throat. A swollen tongue or throat may lead to difficulty swallowing and breathing. Contact a healthcare provider immediately if you have any of these symptoms.
  - A bumpy red rash (hives) and itching
- Signs of breast cancer may include
  - A lump in the breast that you can feel or see
  - Dimpling of the breast skin
  - Changes in the shape or texture of the nipple
- Signs of cancer of the cervix may include:
  - Vaginal discharge that smells and/or contains blood
  - Unusual vaginal bleeding
  - Pelvic pain
  - Painful sex.

- Signs of serious liver problems may include:
  - Pain in your upper abdomen (stomach area or on the right-hand side)
  - Yellowing of the skin or of the whites of your eyes (jaundice)
  - Itching all over your body

If you have any of these signs or symptoms, you should see your healthcare provider. He or she may also tell you to stop taking [RH071 trade name].

**Less serious side effects:**

Common side effects (between 1 in 10 and 1 in 100 users may be affected):

- Feeling sick (nausea)
- Stomach ache
- Weight gain
- Headaches
- Depressed moods or mood swings
- Sore or painful breasts

Uncommon side effects (between 1 in 100 and 1 in 1000 users may be affected):

- Stomach upsets and vomiting
- Fluid retention
- Migraine
- Loss of interest in sex
- Breast enlargement
- Skin rashes that may be itchy

Rare side effects (between 1 in 1000 and 1 in 10,000 users may be affected):

- Weight loss
- Increased interest in sex
- Vaginal or breast discharge
- Poor tolerance of contact lenses

**Other side effects that have been reported:**

- Bleeding and spotting between your periods can sometimes occur for the first few months but this usually stops once your body has adjusted to [RH071 trade name]. If it continues, becomes heavy or starts again, contact your healthcare provider
- Chloasma (yellow brown patches on the skin). This may happen even if you have been using [RH071 trade name] for several months. Chloasma may be reduced by avoiding too much sunlight and/or UV lamps
- Development or deterioration of the movement disorder chorea
- Crohn's disease or ulcerative colitis
- Conditions that may worsen during pregnancy or use of the Pill:
  - yellowing of the skin (jaundice)
  - persistent itching (pruritus)
  - kidney or liver problems
  - gall stones
  - certain rare medical conditions such as systemic lupus erythematosus
  - blister-like rash (herpes gestationis) whilst pregnant
  - an inherited form of deafness (otosclerosis)
  - a personal or family history of a form of sickle cell disease

- swelling of body parts (hereditary angioedema)
- an inherited disease called porphyria
- cancer of the cervix

Tell your healthcare provider if you are worried about any side effects which you think may be due to [RH071 trade name]. Also tell them if any existing conditions get worse while you are taking [RH071 trade name].

### **Bleeding between periods:**

A few women have a little unexpected bleeding or spotting while they are taking [RH071 trade name], especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking [RH071 trade name] as usual. The problem should disappear after the first few strips.

You may also have unexpected bleeding if you are not taking your pills regularly, so try to take your pill at the same time every day. Also, unexpected bleeding can sometimes be caused by other medicines.

Make an appointment to see your healthcare provider if you get breakthrough bleeding or spotting that:

- carries on for more than the first few months
- starts after you have been taking [RH071 trade name] for a while
- carries on even after you have stopped taking [RH071 trade name]

### **Reporting of side effects**

If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects you can help improve understanding about the safety of this medicine.

## **5. How to store [RH071 trade name]**

Do not store above 30°C.

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

Do not use this medicine after the expiry date stated on the pack. The expiry date refers to the last day of that month.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider 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 [RH071 trade name] contains**

#### ***Active film-coated tablet (yellow)***

The active substances are 0.03 mg ethinylestradiol and 0.15 mg levonorgestrel.

The other ingredients are:

*Core tablet:* Lactose monohydrate, povidone, crospovidone, magnesium stearate.

*Film coat:* Polyvinyl alcohol, titanium dioxide, macrogol, talc, iron oxide yellow.

#### ***Placebo film-coated tablet (white)***

*Core tablet:* Lactose monohydrate, povidone, magnesium stearate.

*Film coat:* Polyvinyl alcohol, titanium dioxide, macrogol, talc.

### **What [RH071 trade name] looks like and contents of the pack**

#### **Active tablet**

Yellow, round, biconvex film-coated tablet and plain on both sides with a diameter of 6 mm and thickness less than 4 mm.

#### **Placebo tablet**

White, round, film-coated tablet and plain on both sides with a diameter of 6 mm and thickness of 3-4 mm.

The tablets are packaged in a PVC/PVD-aluminium blister card. Each blister card contains 21 active (yellow) tablets plus 7 placebo (white) tablets.

### **Supplier and Manufacturer**

#### ***Supplier***

Laboratorios Leon Farma SA  
La Vallina s/n  
Poligono Industrial Navatejera, Villaquilambre  
Leon 24008, Spain  
Telephone: +34 987 878 000  
E-mail: Silvia.Posado@chemogroup.com

#### ***Manufacturer***

Laboratorios Leon Farma SA  
La Vallina s/n  
Poligono Industrial Navatejera, Villaquilambre  
Leon 24008, Spain  
Telephone: +34 987 878 000  
E-mail: Silvia.Posado@chemogroup.com

For any information about this medicine, contact the supplier.

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*Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/prequal/>*