

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.

* https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[RH066 trade name][†]
Desogestrel/ethinylestradiol + 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 [RH066 trade name] is and what it is used for
2. What you need to know before you take [RH066 trade name]
3. How to take [RH066 trade name]
4. Possible side effects
5. How to store [RH066 trade name]
6. Contents of the pack and other information

1. What [RH066 trade name] is and what it is used for

[RH066 trade name] is a combined oral contraceptive (COC) pill ('the Pill'). It is taken to prevent pregnancy.

[RH066 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.

[RH066 trade name] is a 28-day Pill. Each pack contains 28 tablets, of which the first 21 contain the active contraceptive and the last 7 contain an inactive placebo. When taking [RH066 trade name] in this formulation, there are no "pill-free" days. There is usually a withdrawal bleed during the last 7 days of the cycle when the placebo tablets are taken. This usually begins 2 or 3 days after finishing the active tablets and can last until taking tablets from the next pack has begun

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.

[RH066 trade name] will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this.

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

2. What you need to know before you take [RH066 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.

Before you start using [RH066 trade name] you should read the information on blood clots in this section.

Before you start taking the Pill:

- Your health care provider will ask about you and your family's medical problems and check your blood pressure. You may also need other checks, such as a breast examination.

While you are on the Pill:

- You will need regular check-ups with your health care provider or family planning nurse, usually when you need another prescription of the Pill.
- You should go for regular cervical smear tests.
- Check your breasts and nipples every month for changes – tell your health care provider if you can see or feel anything unusual, such as lumps or dimpling of the skin.
- If you need a blood test tell your health care provider that you are taking the Pill, because it can affect the results of some tests.
- If you are going to have an operation, make sure your health care provider knows about it. You may need to stop taking the Pill about 4–6 weeks before the operation. This is to reduce the risk of a blood clot. Your health care provider will tell you when you can start taking the Pill again.

Do not take [RH066 trade name]:

You should not use [RH066 trade name] if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your health care provider. Your health care provider will discuss with you what other form of birth control would be more appropriate. See also section 'Warnings and precautions', below.

- 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) a cancer that is affected by sex hormones, such as some cancers of the breast, lining of the womb or ovary
- If you have known or suspected pregnancy
- If you have vaginal bleeding that has not been explained by your health care provider
- 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 have or have had pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood
- If you are allergic (hypersensitive) to any of the ingredients in [RH066 trade name]

If you suffer from any of these conditions, or if you develop them for the first time while taking [RH066 trade name], contact your health care provider as soon as possible and stop taking it.

Do not use [RH066 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:

When should you contact your health care provider?

Seek urgent medical attention

- If you notice signs of a possible blood clot in the leg (deep vein thrombosis), a blood clot in the lungs (pulmonary embolism), a heart attack or a stroke (see section “Blood clots”, below).

Some of the conditions listed below can be made worse by taking [RH066 trade name] or mean that it is less suitable for you. You may still be able to take [RH066 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 [RH066 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. [RH066 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 [RH066 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 [RH066 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 [RH066 trade name] 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?	Possible cause
<ul style="list-style-type: none"> • swelling of one leg or along a vein in the leg or foot especially when accompanied by: <ul style="list-style-type: none"> ○ pain or tenderness in the leg which may be felt only when standing or walking ○ increased warmth in the affected leg ○ change in colour of the skin on the leg e.g. turning pale, red or blue 	Deep vein thrombosis (DVT)
<ul style="list-style-type: none"> • 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 <p>If you are unsure, talk to a health care provider, 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"> • immediate loss of vision or • painless blurring of vision which can progress to loss of vision 	Retinal vein thrombosis (blood clot in the eye)
<ul style="list-style-type: none"> • chest pain, discomfort, pressure, or 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
<ul style="list-style-type: none"> • 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 	Stroke

Are you experiencing any of these signs?	Possible cause
<ul style="list-style-type: none"> • sudden, severe, or prolonged headache with no known cause • loss of consciousness or fainting with or without seizure <p>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.</p>	
<ul style="list-style-type: none"> • swelling and slight blue discolouration of an extremity • severe pain in your stomach (acute abdomen) 	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 [RH066 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 [RH066 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 [RH066 trade name]	About 9 to 12 out of 10,000 women

When you stop [RH066 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 [RH066 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/m²)
- 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. [RH066 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 [RH066 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 [RH066 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 [RH066 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 [RH066 trade name], you are advised to stop smoking. If you are unable to stop smoking and are older than 35 your healthcare provider 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 [RH066 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 healthcare provider.

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 [RH066 trade name] provide the same protective effects. However, 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

- If you are seriously overweight

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 [RH066 trade name].

Psychiatric disorders:

Some women using hormonal contraceptives including [RH066 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:

Tell your health care provider if you are using, have recently used, or might use any other medicines or herbal products, even those not prescribed. Also tell any other health care provider who prescribes another medicine (or your pharmacist) that you use [RH066 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 [RH066 trade name] and can stop it from working properly. For example:

- Some medications used to treat epilepsy
- Rifampicin (used to treat tuberculosis)
- Some medications used to treat HIV and Hepatitis C Virus infections
- Griseofulvin (an anti-fungal medicine)
- Bosentan (used to treat high blood pressure in the lungs)
- St. John's Wort

If you need to take one of these medicines, [RH066 trade name] may not be suitable for you or you may need to use extra contraception for a while. Your health care provider can tell you if this is necessary and for how long.

[RH066 trade name] can also affect how well other medicines work. Your healthcare provider may need to adjust the dose of your other medicine.

[RH066 trade name] can also interfere with the results of some blood tests, so always tell your healthcare provider that you are taking [RH066 trade name] if you have a blood test.

Do not use [RH066 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. [RH066 trade name] can be restarted approximately 2 weeks after completion of this treatment. See section "Do not take [RH066 trade name]", above.

Taking [RH066 trade name] with food or drink:

There are no special instructions about food and drink while on [RH066 trade name].

Pregnancy and breastfeeding:

Do not use [RH066 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 [RH066 trade name].

If you are breast-feeding, your healthcare provider may advise you not to take [RH066 trade name]. They will be able to suggest alternative contraception. Breast-feeding may not stop you getting pregnant.

Driving and using machines:

[RH066 trade name] has no known effect on the ability to drive or use machines.

[RH066 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 [RH066 trade name]

To prevent pregnancy, always take [RH066 trade name] as described below. Check with your healthcare provider or family planning nurse if you are not sure.

Take [RH066 trade name] every day

[RH066 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

Within a few days after you have taken the 21 active pills in the strip, you should have a withdrawal bleed like a period. This bleed may not have finished before you start the next strip of pills. Continue with the next strip of pills even if you are still bleeding.

Starting [RH066 trade name]:

If you are a new user or starting the Pill again after a break:

You can start [RH066 trade name] within five days of the start of your period. No additional contraceptive protection is needed.

If it is more than five days since the start of your period, you can still start [RH066 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:

[RH066 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.

Contraception after having a baby:

If you are breastfeeding:

- If you are less than 6 weeks postpartum, you should not use [RH066 trade name].
- If you are between 6 weeks and 6 months postpartum, you should only restart [RH066 trade name] if other contraceptive methods are not available or not acceptable.
- If you are more than 6 months postpartum, you can start [RH066 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 postpartum, you should only restart [RH066 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 [RH066 trade name]:
 - If your period has not returned, [RH066 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, [RH066 trade name] can be started as advised for other women having menstrual cycles (see above).

Starting [RH066 trade name] after a miscarriage or abortion:

If you have had a miscarriage or an abortion, you may start taking [RH066 trade name] straight away. No additional contraceptive protection is needed.

Switching from another hormonal contraceptive:

- If you have been using your hormonal method consistently and correctly or if you are reasonably certain that you are not pregnant, [RH066 trade name] can be started immediately; there is no need to wait for her next menstrual period.
- If your previous method was an injectable contraceptive, [RH066 trade name] should be started when the next injection would be given. No additional contraceptive protection is needed.

Switching from a non-hormonal contraceptive (other than an IUD):

- You can start [RH066 trade name] within five days after the start of your period. No additional contraceptive protection is needed.
- If it is more than five days after the start of your period, you can start [RH066 trade name] 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.

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

- You can start [RH066 trade name] within five days of the start of your period. No additional contraceptive protection is needed. The IUD can be removed at this time.
- If it is more than five days after the start of your period, you can start [RH066 trade name] if you are reasonably certain that you are not pregnant.
 - If you are sexually active in this menstrual cycle, it is recommended that the IUD be removed at the time of your next menstrual period.
 - If you are not sexually active in this menstrual cycle, you will need to abstain from sex or use additional contraceptive protection for the next seven days. If that additional protection is to be provided by the IUD that you are using, it is recommended that the IUD be removed at the time of your next menstrual period.
- If you are not having periods, or if you have irregular bleeding, you can start [RH066 trade name] as advised for other amenorrhoeic women.

What to do if you miss doses:

If you miss 1 or 2 active (hormonal) pills in a row, or start a pack 1 or 2 days late

- You should take an active pill as soon as possible and then continue to take one pill per day.
 - If you miss two or more active (hormonal) pills in a row, you can take the first missed pill and then either continue taking the rest of the missed pills (one each day) or discard them to stay on schedule.
 - Depending on when you remember that you missed the pill(s), you may take two pills on the same day (one when you remember, and the other at the regular time) or even at the same time.
- No additional contraceptive protection is needed.

If you miss 3 or more active (hormonal) pills in a row, or start a pack 3 or more days late

- You should take an active pill as soon as possible and then continue to take one pill per day.

- If you miss three or more active (hormonal) pills in a row, you can take the first missed pill and then either continue taking the rest of the missed pills (one each day) or discard them to stay on schedule.
- Depending on when you remember that you missed the pill(s), you may take two pills on the same day (one when you remember, and the other at the regular time) or even at the same time.
- You will need to abstain from sex or use additional contraceptive protection until you have taken active (hormonal) pills for seven days in a row.
- If you missed the pills in the third week, you should finish the active (hormonal) pills in your current pack and start a new pack the next day. You should not take the seven inactive pills.
- If you missed the pills in the first week and had unprotected sex, you may wish to consider the use of emergency contraception.
- 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 miss some inactive (placebo) pills

- You should discard the inactive placebo pills that you missed, and then continue taking one pill each day

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 will not 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 [RH066 trade name], you may not get the usual dose of hormones from that pill. If you are better within 12 hours of taking [RH066 trade name], follow the instructions in the section above, “*If you lose a pill*”, which describes how to take another pill.

If you are still sick or have diarrhoea more than 12 hours after taking [RH066 trade name], follow the instructions in the section above, “*What to do if you miss doses*”.

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 [RH066 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.

If you want to delay a period:

If you want to delay having a period, finish the strip of active pills that you are taking. Start the next active strip the next day without taking any of the placebo pills. After the second strip, take the seven placebo pills

as usual, then start your next strip of active pills in the normal way. When you use the second strip, you may have some unexpected bleeding or spotting on the days that you take the pill.

When you want to get pregnant:

If you are planning a baby, it is best to use another method of contraception after stopping [RH066 trade name] until you have had a proper period. Your healthcare provider or midwife relies on the date of your last natural period to tell you when your baby is due. However, it will not cause you or the baby any harm if you get pregnant straight away.

4. Possible side effects

Like all medicines, [RH066 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 [RH066 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 [RH066 trade name]”.

Serious side effects – see a healthcare provider straight away:

Rare serious side effects (between 1 in 1,000 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 [RH066 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 1,000 users may be affected):

- Stomach upsets and vomiting
- Fluid retention
- Migraine (see your healthcare provider if this is your first migraine, or if it is worse than usual)
- Loss of interest in sex
- Breast enlargement
- Skin rashes that may be itchy

Rare side effects (between 1 in 1,000 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 [RH066 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 [RH066 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 [RH066 trade name]. Also tell them if any existing conditions get worse while you are taking [RH066 trade name].

Bleeding between periods:

A few women have a little unexpected bleeding or spotting while they are taking [RH066 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 [RH066 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 [RH066 trade name] for a while
- carries on even after you have stopped taking [RH066 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 [RH066 trade name]

Do not store above 25°C. Store in the original package in order to protect from light.

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 [RH066 trade name] contains

Active film-coated tablet (white)

- The active ingredients are desogestrel 0.15mg and ethinylestradiol 0.03mg
- The other ingredient(s) of [RH067 trade name] are:

Core tablet: Lactose monohydrate, maize starch, povidone, D-alpha-tocopherol, soybean oil, silica colloidal hydrated, silica colloidal anhydrous, stearic acid

Film coat: Hypromellose, triacetin, polysorbate, titanium dioxide

Placebo film-coated tablet (green)

Core tablet: Lactose monohydrate, maize starch, povidone, silica colloidal anhydrous, magnesium stearate

Film coat: Hypromellose, triacetin, polysorbate, titanium dioxide, FD&C blue #2 aluminium lake, yellow iron oxide (E172)

What [RH066 trade name] looks like and contents of the pack

Active tablet

White, round, biconvex film-coated tablet with **C** and **7** debossed on opposite sides.

Placebo tablet

Green, round, film-coated tablet with a diameter of approximately 5mm.

The tablets are packaged in PVC/PVDC-aluminium blisters. Each blister card contains 21 active (white) tablets plus 7 placebo (green).

Pack sizes: 1, 3 or 6 blister cards packed in a carton box.

Supplier and Manufacturer

Supplier

Laboratorios Leon Farma SA
La Vallina s/n
Poligono Industrial Navatejera
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Manufacturer

Laboratorios Leon Farma SA
C/La Vallina s/n
Poligono Industrial Navatejera
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Leon 24008
Spain

For any information about this medicine, contact the local representative of the supplier.

This leaflet was last revised in January 2021

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