

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/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[RH035 trade name][†]
Ethinylestradiol/levonorgestrel

*The warnings and instructions in this leaflet are intended for the person taking the medicine.
If you are a parent or carer responsible for giving the medicine to someone else such as a child,
you will need to apply the instructions accordingly.*

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 is for you only. Do not pass it on to others. It may harm them, even if their illness seems 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 [RH035 trade name] is and what it is used for
2. What you need to know before you take [RH035 trade name]
3. How to take [RH035 trade name]
4. Possible side effects
5. How to store [RH035 trade name]
6. Contents of the pack and other information

1. What [RH035 trade name] is and what it is used for

[RH035 trade name] is a combined oral contraceptive pill ('the Pill'). You take it to stop you getting pregnant.

[RH035 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 your ovaries from releasing an egg
- 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.

[RH035 trade name] does 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 [RH035 trade name]

Before you start taking [RH035 trade name], read the information on 'Blood clots', below. You should know how you can tell if you have a blood clot.

It is important that you understand the benefits and possible harms of taking [RH035 trade name] before you start taking it, or when deciding whether to carry on taking it. [RH035 trade name] is suitable for most healthy women but it may not be suitable for some.

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

**Formerly known as Mylan Laboratories Limited

Do not take [RH035 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 if another form of birth control is more suitable for you.

Do not take [RH035 trade name]:

- If you have, or have ever had, a blood clot in a blood vessel in your legs (deep vein thrombosis, DVT), in your lungs (pulmonary embolism, PE) or in other organs
- If 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 information on ‘Blood clots’, below)
- If you have ever had a heart attack or stroke
- If you have (or have ever had) angina pectoris (which causes chest pain and may be an early 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
 - 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 your health care provider has told you that your liver function test results have not returned to normal
- If you have ever had a tumour (growth) in your liver
- If you are allergic (hypersensitive) to any of the ingredients in [RH035 trade name]

Do not take [RH035 trade name] if you are taking medicines for hepatitis C that contain ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see also ‘Taking other medicines’, below).

Warnings and precautions

Some of the conditions listed may make [RH035 trade name] less suitable for you, and in some cases [RH035 trade name] may make the conditions worse. You may still be able to take [RH035 trade name], but you may need to take extra care and have check-ups more often.

Tell your health care provider if any of the following conditions apply to you, or if the condition begins or gets worse while you are taking [RH035 trade name]:

- symptoms of angioedema such as swollen face, tongue or throat, itchy rash, or you cannot swallow or breathe easily. If you have these symptoms, contact a health care provider immediately. [RH035 trade name] contains an oestrogen that may cause or worsen the symptoms of hereditary and acquired angioedema
- inflammatory bowel disease such as Crohn’s disease or ulcerative colitis
- systemic lupus erythematosus (SLE – a disease that affects your immune system)
- haemolytic uraemic syndrome (a blood clotting disorder that may cause kidney failure)
- sickle cell anaemia
- pancreatitis (inflammation of the pancreas)
 - raised levels of fat in the blood (hypertriglyceridaemia) or a blood relative has this condition. Hypertriglyceridaemia may increase the risk of developing pancreatitis
 - needing an operation or being off your feet for a long time (see ‘Blood clots’, below)

- just given birth, which can increase the chances of blood clots. Ask your health care provider how soon after delivery you can start taking [RH035 trade name]
- inflammation of the veins under the skin (superficial thrombophlebitis)
- varicose veins
- diabetes
- problems with your heart or circulation such as high blood pressure or if a close relative has had such problems
- problems with blood clotting or if a close relative has had such problems
- inherited disease called porphyria
- being overweight or obese
- having migraines
- any illness that got worse during pregnancy or previous use of the contraceptive pill

Blood clots

[RH035 trade name] can increase your risk of developing a blood clot, compared with not taking an oral contraceptive. In rare cases, a blood clot can block vessels and cause serious problems.

Blood clots can develop in a vein (a blood vessel taking blood to the heart) or in an artery (a blood vessel taking blood away from the heart):

- In veins, where it causes ‘venous thrombosis’ or ‘venous thromboembolism’ (VTE)
- In arteries, where it causes ‘arterial thrombosis’ or ‘arterial thromboembolism’ (ATE)

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, people can die from these effects. But the overall risk of having a serious blood clot due to [RH035 trade name] is small.

How to recognise a blood clot

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

| Sign or symptom | Possible cause |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <ul style="list-style-type: none"> • swelling of one leg or along a vein in the leg or foot especially if you also have: <ul style="list-style-type: none"> ○ pain or tenderness in the leg which may occur only when standing or walking ○ increased warmth in the affected leg ○ change in the colour of the leg skin e.g. turning pale, red or blue | Deep vein thrombosis (DVT) |
| <ul style="list-style-type: none"> • sudden breathlessness or rapid breathing for no good reason • sudden cough without an obvious cause, which may bring up blood • sharp chest pain which may increase with deep breathing • severe lightheadedness or dizziness • rapid or irregular heartbeat • severe pain in your belly <p>If you are unsure, talk to a health care provider as 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) |
| <ul style="list-style-type: none"> • Symptoms most commonly occur in one eye: <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) |

| Sign or symptom | Possible cause |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| <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 spreading to the back, jaw, throat, arm and stomach sweating, nausea (feeling sick), 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 sudden, severe or prolonged headache with no known cause loss of consciousness or fainting with or without seizure (fit) <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 have another stroke.</p> | Stroke |
| <ul style="list-style-type: none"> swelling and slight blue discoloration around hands and feet severe pain in your belly (acute abdomen) | Blood clot blocking other blood vessels |

If you have any of these signs or symptoms, see your health care provider as soon as possible. Stop taking [RH035 trade name] until your health care provider says you can. Use another method of contraception, such as condoms, in the meantime.

Blood clots in a vein

The use of a combined hormonal contraceptive, such as [RH035 trade name], may increase the risk of blood clots in the vein (venous thrombosis). However, this side effects is 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 gets stuck 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 [RH035 trade name] for the first time. The risk may also be higher if you restart a combined hormonal contraceptive (the same one or a different one) after a break of 4 weeks or more. After the first year, the risk gets smaller but remains slightly higher than if you were not using a combined hormonal contraceptive.

When you stop [RH035 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 [RH035 trade name] is small, but some conditions can 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 years. If this is the case, you could have a hereditary blood clotting disorder
- If you need 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. [RH035 trade name] may need to be stopped at least 4 weeks before your operation or while you are less mobile. Your health care provider will advise you when you can restart [RH035 trade name]
- If you gave birth less than a few weeks ago
- As you get older (particularly above about 35 years of age)

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. Talk with your health care provider if you are planning travel that involves sitting down for a long time.

If any of the above conditions develop or change while you are using [RH035 trade name], for example a close family member has thrombosis for no known reason, or you gain a lot of weight, tell your health care 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 [RH035 trade name] is very small, but the following conditions can increase the risk:

- increasing age (above about 35 years)
- **smoking.** When using a combined hormonal contraceptive like [RH035 trade name], you should try to stop smoking. If you cannot stop smoking and you are older than 35 years, your health care provider may advise a different type of contraceptive
- being overweight
- high blood pressure
- a member of your immediate family has had a heart attack or stroke at a young age (less than about 50 years). In this case you could also have a higher risk of having a heart attack or stroke
- you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides)
- migraines, especially migraines with aura
- a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation)
- 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 increase even more.

If any of the above conditions change while you are using [RH035 trade name], for example you start smoking, a close family member has thrombosis for no known reason, or you gain a lot of weight, tell your health care provider.

[RH035 trade name] and cancer

Although high-dose combined hormonal contraceptives reduce the risk of cancer of the ovary and womb if used for a long time, it is not clear if lower dose combined hormonal contraceptives, such as [RH035 trade name], reduce the risk of these cancers.

It also seems that taking a combined hormonal contraceptive slightly increases your risk of cancer of the cervix. This type of cancer is caused by certain types of human papillomavirus (HPV), which you can catch from your sexual partner.

Breast cancer

If you have breast cancer, or have had it in the past, you should not take [RH035 trade name]. It slightly increases your risk of breast cancer. This risk goes up the longer you are on the combined hormonal contraceptive but returns to normal within about 10 years of stopping it. Breast cancer is rare in women under the age of 40 years and the extra cases of breast cancer in users of a combined hormonal contraceptive (or in those who have used it recently) is small.

Risk of developing breast cancer by age 35 and 45 years

- Of 10 000 women who have **never taken a combined hormonal contraceptive**, about **16** will have breast cancer by the time they are 35 years old.
- Of 10 000 women who **take a combined hormonal contraceptive for 5 years in their early 20s**, about **17–18** will have breast cancer by the time they are 35 years old.
- Of 10 000 women who have **never taken a combined hormonal contraceptive**, about **100** will have breast cancer by the time they are 45 years old.
- Of 10 000 women who **take a combined hormonal contraceptive for 5 years in their early 30s**, 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 health care 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 a combined hormonal contraceptive has also been linked to liver diseases, such as jaundice and non-cancer liver tumours, but this is rare. Very rarely, women taking a combined hormonal contraceptive for a long time have developed some forms of liver cancer.

See your health care 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 [RH035 trade name].

Psychiatric disorders

Some women using hormonal contraceptives including [RH035 trade name] have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you get mood changes and depressive symptoms contact your health care provider for medical advice as soon as possible.

Taking other medicines

If you need to take another medicine while you are taking [RH035 trade name], tell your health care provider that you are taking [RH035 trade name]. You should also read the leaflets that come with your medicine to check if you can take it with hormonal contraceptives.

Some medicines can change the amount of [RH035 trade name] in your blood and stop it working properly. For example:

- Some medicines used to treat epilepsy
- Some medicines used to treat HIV and hepatitis C
- Griseofulvin (an antifungal medicine)
- Some antibiotics
- Some sedatives (barbiturates)
- St. John's wort (a herbal remedy)

If you need to take one of these medicines, [RH035 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.

[RH035 trade name] can also affect how well other medicines work. Your health care provider may need to adjust the dose of your other medicine.

[RH035 trade name] can also interfere with the results of some blood tests, so always tell your health care provider that you are taking [RH035 trade name] if you have a blood test.

Do not use [RH035 trade name] if you have hepatitis C and are taking medicines containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir and sofosbuvir/velpatasvir/voxilaprevir, as they may affect the results of blood tests to check how well your liver is working (increase in ALT liver enzyme). Your health care provider will prescribe another type of contraceptive before you start treatment with these hepatitis C medicines. [RH035 trade name] can be restarted about 2 weeks completing this treatment.

Taking [RH035 trade name] with food or drink

There are no special instructions about food and drink while on [RH035 trade name].

Pregnancy and breast-feeding

Do not take [RH035 trade name] if you are pregnant. If you think you might be pregnant, do a pregnancy test to check that you are pregnant before you stop [RH035 trade name].

Talk to your health care provider about when to start [RH035 trade name] while you are breast-feeding your baby.

Driving and using machines

[RH035 trade name] has no effect on your ability to drive or use machines.

Important information about some of the ingredients of [RH035 trade name]

[RH035 trade name] contains lactose and sucrose contact your health care provider before taking this medicinal product if you have intolerance to some sugars or a disease called diabetes mellitus

3. How to take [RH035 trade name]

To prevent pregnancy, always take [RH035 trade name] as described below. Check with your health care provider or family planning nurse if you are not sure.

Take [RH035 trade name] every day

[RH035 trade name] comes in packs of 28 tablets, each marked with arrows.

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

Within a few days of starting the inactive tablets from the strip, you should have a bleed like a period. This bleed may not have finished when it is time to start your next strip of tablets.

You do not need to use extra contraception during these 7 days when you take the inactive tablets – as long as you have taken your tablets correctly and start the next strip of tablets on time.

Starting [RH035 trade name]

If you are a new user or starting a combined oral contraceptive again after a break, you can start taking [RH035 trade name] in the first 5 days after the start of your monthly bleeding. This will give you contraceptive protection straight away.

If it is more than 5 days after the start of your monthly bleeding, you can still start [RH035 trade name] if you are reasonably sure that you are not pregnant. You should use additional contraceptive protection (such as male and female condoms) or not have sex for the next 7 days.

If you are not having monthly bleeding

You can start [RH035 trade name] at any time if you are reasonably sure that you are not pregnant. You should use additional contraceptive protection (such as male and female condoms), or not have sex for the next 7 days.

Switching from another contraceptive tablet

- **If you are taking a 21-day tablet:** start [RH035 trade name] the day after the end of the previous strip. You will have contraceptive protection straight away. You will not have a bleed until after your first strip of [RH035 trade name]
- **If you are taking a 28-day tablet:** start taking [RH035 trade name] the day after your last active tablet. You will have contraceptive protection straight away. You will not have a bleed until after you have taken all the active tablets (first 21 days).
- **If you are taking a progestogen-only pill (POP or 'mini Pill'):** start [RH035 trade name] on the first day of your monthly bleeding, even if you have already taken the progestogen-only pill for that day. You will have contraceptive protection straight away.

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

- You can start [RH035 trade name] within 5 days after the start of your monthly bleeding. You will have contraceptive protection straight away. The IUD can be removed at this time.
- If it is more than 5 days since the start of your monthly bleeding, you can still start [RH035 trade name] if you are reasonably sure that you are not pregnant. The IUD can be removed at the time of your next monthly bleeding.
- If you do not have monthly bleeding, or irregular monthly bleeding, you can start [RH035 trade name] at any time if you are reasonably sure that you are not pregnant. You should use additional contraceptive protection (such as male and female condoms), or not have sex for the next 7 days.

Switching from another non-hormonal contraceptive method

- You can start [RH035 trade name] within 5 days after the start of your monthly bleeding. You will have contraceptive protection straight away.
- If it is more than 5 days since the start of your monthly bleeding, you can still start [RH035 trade name] if you are reasonably sure that you are not pregnant. You should use additional contraceptive protection (such as male and female condoms), or not have sex for the next 7 days.

Starting [RH035 trade name] after using an emergency contraceptive pill

- If you have used an emergency contraceptive pill containing a **progestogen such as levonorgestrel**, start [RH035 trade name] immediately after taking the emergency contraceptive pill. You will have contraceptive protection straight away. If you do not start immediately, follow the instructions described under 'Starting [RH035 trade name]'.
- If you have used an emergency contraceptive pill containing **ulipristal acetate**, start [RH035 trade name] 5 days afterwards. You should use additional contraceptive protection (such as male and female condoms), or not have sex from the time you took the emergency use contraceptive pill until you have taken [RH035 trade name] for 7 days. If more than 5 days have passed since you used the emergency contraceptive pill, you can still start [RH035 trade name] at any time if you are reasonably sure that you are not pregnant. In this case, follow the instructions described under 'Starting [RH035 trade name]'.

Starting [RH035 trade name] after a miscarriage or abortion

- You can start taking [RH035 trade name] within 7 days of an abortion or a miscarriage during the first 6 months of your pregnancy. You will have contraceptive protection straight away.
- If it is more than 7 days after an abortion or miscarriage during the first 6 months of pregnancy, you can start taking [RH035 trade name] at any time if you are reasonably sure that you are not pregnant. You should use additional contraceptive protection (such as male and female condoms), or not have sex for the next 7 days.

Contraception after having a baby

If you are breast-feeding (or mainly breast-feeding)

- You can start [RH035 trade name] 6 months after your baby is born, or earlier if the baby's main food is no longer breast milk.
- If it is longer than 6 months after your baby was born and your monthly bleeding has not started, you can start [RH035 trade name] at any time if you are reasonably sure that you are not pregnant. You should use additional contraceptive protection (such as male and female condoms), or not have sex for the next 7 days.
- If your monthly bleeding has returned, you can start [RH035 trade name] during the first 5 days of your monthly bleeding.
- If it is more than 5 days after the start of your monthly bleeding, you can still start [RH035 trade name] if you are reasonably sure that you are not pregnant. You should use additional contraceptive protection (such as male and female condoms), or not have sex for the next 7 days.

If you are partially breast-feeding

- You can start taking [RH035 trade name] 6 weeks after your baby is born. If your monthly bleeding has returned during these 6 weeks, you should use another contraception protection (such as male and female condoms), or not have sex until you start taking [RH035 trade name].
- If your monthly bleeding has not returned and more than 6 weeks have passed after your baby is born, you can start taking [RH035 trade name] immediately. You should use additional contraception (such as male and female condoms), or not have sex for the first 7 days.
- If your monthly bleeding has returned and more than 6 weeks have passed after your baby is born:
 - you can start [RH035 trade name] in the first 5 days after the start of your monthly bleeding. This will give you contraceptive protection straight away.
 - if more than 5 days have passed after the start of your monthly bleeding, you can still start [RH035 trade name] if you are reasonably sure that you are not pregnant. You should use additional contraception protection (such as male and female condoms), or not have sex for the next 7 days.

If you are not breast-feeding

- You can start taking [RH035 trade name] between 21 to 28 days after your baby is born.
- If it is longer than 28 days after your baby is born and your monthly bleeding has not returned, you can start taking [RH035 trade name] at any time if you are reasonably sure that you are not pregnant. You should use another contraception protection (such as male and female condoms), or not have sex for 7 days.
- If it is longer than 28 days after your baby is born and your monthly bleeding has returned:
 - you can start taking [RH035 trade name] in the first 5 days after the start of your monthly bleeding. This will give you contraceptive protection straight away.
 - if more than 5 days have passed after the start of your monthly bleeding, you can still start [RH035 trade name] if you are reasonably sure that you are not pregnant. You should use additional contraceptive protection (such as male and female condoms), or not have sex for the next 7 days.

If you miss a dose of [RH035 trade name]

If you missed one or two tablets or started a new pack one or two days late, you should take the most recently missed tablet right away and take the next tablet in the strip at the usual time. This may mean taking two tablets in one day or even taking two tablets at the same time. Do not worry, your contraception protection is not likely to be reduced.

If you missed more than two tablets, what you do depends on whether the missed tablets were from the first 21 days, or the last 7 days of the tablet strip.

Tablets from the first 21 days of the strip contain the contraceptive and are called active tablets. Tablets from the last 7 days do not contain any active ingredient and are called inactive tablets.

If you missed at least 3 tablets from the first 21 days

Tablets from the first 21 days of the pack contain the active contraceptive. If you miss 3 or more of the active tablets in a row (or start your new pack at least 3 days late):

- Take the most recently missed tablet right away.
- Leave any earlier missed tablets in the strip.
- Take your next tablet at the usual time. This may mean taking two tablets in one day or even taking two tablets at the same time.
- Check how many tablets from the first 21 days are left after the most recently missed tablet. Follow the instructions below according to how many tablets are left.

If at least 7 active tablets are left in the strip

- Take extra contraceptive precautions (e.g. condoms), or not have sex for the next 7 days.
- When you finish all the active tablets, take the 7 days of inactive tablets as usual.
- If you had sex in the past 5 days, you could be pregnant. Contact your health care provider for advice as soon as possible. The health care provider may recommend you use emergency protection.

If fewer than 7 active tablets are left in the strip

- Take extra contraceptive precautions (e.g. condoms), or not have sex for the next 7 days
- When you finish all the active tablets, do not take the inactive tablets. Instead, start the next strip from the beginning the next day.
- If you do not have a bleed after you have taken the 21 active tablets from the next strip, during the week you take inactive tablets, do a pregnancy test before starting another strip.
- If you had sex in the past 5 days, you could be pregnant. Contact your health care provider for advice as soon as possible. The health care provider may recommend you use emergency protection.

If you lose an active tablet

Either take the last active tablet of the strip in place of the lost tablet. Then take all the other tablets on their proper days. Your cycle will be one day shorter than normal, but your contraceptive protection won't be reduced. After your 7 inactive tablet 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 tablet from a spare strip if you have one. Then take all the other tablets from your current strip as usual. You can then keep the opened spare strip in case you lose any more tablets.

If you vomit or have diarrhoea

If you are sick (vomit) or have bad diarrhoea within 4 hours of taking [RH035 trade name], you may not get the usual dose of hormones from that tablet. If you are better within 1 day of taking [RH035 trade name], follow the instructions under 'If you lose an active tablet', which describes how to take another tablet.

If you are still sick or have diarrhoea lasting more than 1 day after taking [RH035 trade name], follow the instructions under 'If you miss a dose of [RH035 trade name]'.

Talk to your health care provider if your stomach upset carries on or gets worse. The health care provider may recommend another form of contraception.

Missed a period could you be pregnant?

Occasionally, you may miss a bleed. This could mean that you are pregnant, but that is very unlikely if you have taken your tablets correctly. Start your next strip at the normal time. If you think that you could have become pregnant (for example, by missing tablets or taking medicines that reduce the effect of [RH035 trade name]), or if you miss a second bleed, you should do a pregnancy test. You may need to visit your family

planning clinic or your health care provider to arrange a pregnancy test. If you are pregnant, stop taking [RH035 trade name] and see your health care provider.

If you take more than one tablet as a single dose

It is unlikely that taking more than one tablet will do you any harm, but you may feel sick, vomit, or have some vaginal bleeding. Even girls who have not yet started their monthly bleeding but have accidentally taken this medicine may bleed. Talk to your health care provider if you have any concerns or you feel ill after taking extra tablets.

4. Possible side effects

Like all medicines, [RH035 trade name] can cause side effects, although not everybody gets them. If you get any side effects, particularly if severe and persistent, or if you think [RH035 trade name] has caused any changes to your health, you should speak to your health care provider.

All women who use a combined hormonal contraceptive have an increased risk of blood clots. Clots can occur in the veins (venous thromboembolism, VTE) or in the arteries (arterial thromboembolism, ATE). For details on the different risks from taking combined hormonal contraceptives see section 2 ‘What you need to know before you use [RH035 trade name]’.

Serious side effects – see a health care provider straight away

Rare serious side effects (may occur in between 1 in 1000 and 1 in 10 000 women who take a combined hormonal contraceptive):

- Blood clots in a vein or artery, such as:
 - in a leg or calf (deep vein thrombosis, DVT)
 - in a lung (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 a blood clot may be higher if you have any other conditions that increase this risk (see section 2 for conditions that increase the risk for blood clots and for symptoms of a blood clot).

- Severe allergic reaction
 - swelling of the hands, face, lips, mouth, tongue or throat. A swollen tongue or throat may make it difficult to swallow and breathe. Contact a health care provider immediately if you have any of these symptoms
 - a bumpy red rash (hives) and itching
- Skin reactions also affecting the body (erythema multiforme and erythema nodosum)
 - rash usually on hands and feet, which spreads to your belly, chest, back or face and can be itchy
 - high temperature
 - headache
 - body aches and pains
 - feeling generally unwell
- 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 or contains blood
 - unusual vaginal bleeding

- pelvic pain
- painful sex
- Signs of serious liver problems may include:
 - pain in your abdomen (belly), especially on the upper 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 health care provider. The health care provider may tell you to stop taking [RH035 trade name].

Less serious side effects:

Common side effects (may occur in between 1 in 10 and 1 in 100 women who take a combined hormonal contraceptive):

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

Uncommon side effects (may occur in between 1 in 100 and 1 in 1000 women who take a combined hormonal contraceptive):

- Vomiting and diarrhoea
- Fluid retention
- Migraine
- Loss of interest in sex
- Increased breast size
- Skin rashes that may be itchy

Rare side effects (may occur in between 1 in 1000 and 1 in 10 000 women who take a combined hormonal contraceptive):

- Weight loss
- Increased interest in sex
- Vaginal or breast discharge
- Uncomfortable to wear contact lenses

Other side effects that can occur:

- Reduced monthly bleeding and temporary lack of monthly bleeding after stopping a combined hormonal contraceptive
- Chloasma (yellow brown patches on the skin). This may happen even if you have been using [RH035 trade name] for several months. Chloasma may be reduced by staying out of strong sunlight
- Worsening of a certain movement disorder (chorea)
- Crohn's disease or ulcerative colitis
- High blood levels of triglycerides, a type of fat
- Conditions that may worsen during pregnancy or while you take [RH035 trade name]:
 - 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)
- sickle cell disease
- swelling of body parts (hereditary angioedema)
- an inherited disease called porphyria
- cancer of the cervix

Tell your health care provider if you are worried about any side effects which you think may be due to [RH035 trade name]. Also tell them if any existing conditions get worse while you are taking [RH035 trade name].

Bleeding between periods

You may have a little unexpected bleeding or spotting while taking [RH035 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 [RH035 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.

See your health care provider if you get breakthrough bleeding or spotting that:

- carries on for more than the first few months
- starts after you have been taking [RH035 trade name] for a while
- carries on even after you have stopped taking [RH035 trade name]

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [RH035 trade name]

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

Store below 30°C. Store in the original package. Protect from light.

Do not use this medicine after the expiry date stated on the label or carton after “EXP”. The expiry date refers to the last day of that month.

Do not use this medicine if you notice signs of deterioration or if the medicine looks different from the description below.

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 [RH035 trade name] contains

- The active ingredients are ethinylestradiol 30 µg and levonorgestrel 150 µg.
- The other ingredients of [RH035 trade name] are

White active tablets

Tablet core: Lactose monohydrate, magnesium stearate, maize starch, povidone, talc

Tablet coating: Calcium carbonate, carnauba wax, glycerol, macrogol, povidone, sucrose, talc, titanium dioxide

Yellow placebo tablets

Tablet core: Lactose, magnesium stearate, maize starch, povidone, talc

Tablet coating: Calcium carbonate, carnauba wax, glycerol, macrogol, povidone, sucrose, talc, titanium dioxide, yellow oxide of iron

What [RH035 trade name] looks like and contents of the pack

Active tablets (21)

White, round, sugar-coated tablets. They are biconvex (rounded on top and bottom) with a round edge.

Placebo tablets (7)

Yellow, round, sugar-coated tablets. They are biconvex (rounded on top and bottom) with a round edge.

[RH035 trade name] are provided in clear transparent plastic (PVC/PVdC) on aluminium foil blister cards each containing 28 tablets. The blister cards are available in cartons containing 1, 3, 6 or 100 blister cards.

Supplier and Manufacturer

Supplier

Senador Laboratories Private Limited
Plot 2B & 2C, Biotech Park, Phase II, Lalgadi
Malakpet, Medchal Malkajgiri
Hyderabad,
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India
tel: +91 9819262203
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Manufacturer

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e-mail: regulatory_senador@senadorlabs.es

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Taluka: Sanand Ahmedabad
Gujarat – 382 213
India
tel: (+91) 2717 681603
e-mail: regulatory_senador@senadorlabs.es

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

Country: India
Ms. Yogita Ritesh Attarde
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Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>