Package leaflet: information for the user

EVRA 203 micrograms/24 hours + 33.9 micrograms/24 hours patchfor transdermal use
norelgestromin/ethinylestradiol

Important things you need to know about combined hormonal contraceptives (CHCs):
- These are among the most reliable reversible contraceptive methods when used correctly.
- The products slightly increase the risk of developing a blood clot in the veins and arteries, especially in the first year of using a CHC or if you restart after a break of 4 weeks or more.
- Pay close attention and contact your doctor if you think you may have symptoms of a blood clot (see section 2 'Blood clots').

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor, pharmacist, or nurse.
- Do not pass this medicine on to others, as it is prescribed only for you. It may harm others, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor, pharmacist, or nurse.

Contents of this leaflet

1. What is EVRA and what is it used for?
EVRA contains two types of sex hormones, a progestogen called norelgestromin and an estrogen called ethinylestradiol.
Because EVRA contains two hormones, it is called a ‘combined hormonal contraceptive’.
It is used to prevent pregnancy.

2. When should you not use this medicine or be extra careful?
General remarks
Before you start using EVRA, read the information about blood clots in section 2. It is especially important that you read what the symptoms of a blood clot are (see section 2 ‘Blood clots’).

When should you not use this medicine?
You should not use this medicine if you have any of the conditions listed below. If you have one or more of the conditions listed below, tell your doctor. Your doctor will discuss with you which other form of birth control is more suitable for you.
- You have a blood clot in a blood vessel in your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolism, PE), or another organ, or you have had this in the past.

You know that you have a disorder that affects your blood clotting – for example, protein C deficiency, protein S deficiency, antithrombin III deficiency, factor V Leiden, or antiphospholipid antibodies.
You need to undergo surgery or you cannot walk for a long time (see section 'Blood clots').
You have ever had a heart attack or stroke.
You have angina pectoris (a condition that causes severe chest pain and can be an early sign of a heart attack) or a transient ischemic attack (TIA – temporary symptoms of a stroke), or you have had this before.
You have one of the following diseases, which can increase the chance of getting a blood clot in your arteries:

- severe diabetes with blood vessel damage
- severely increased blood pressure
- a severely increased fat content in your blood (cholesterol or triglycerides)
- a condition called hyperhomocysteinemia.

You have a type of migraine called 'migraine with aura', or you have had this.
You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.
You have ever been told that you might have breast cancer or cancer of the uterus, cervix, or vagina.
You have ever had liver tumors or a liver disease that caused your liver to not function properly.
You have unexplained vaginal bleeding.
If you have hepatitis C and are using medicines that contain ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir, or sofosbuvir/velpatasvir/voxilaprevir (see also section 'Are you taking any other medicines?').

If any of the above situations apply to you, do not use this medicine. If you are not sure, contact your doctor, pharmacist, or nurse before using this medicine.

When should you be extra careful with this medicine?
When should you contact your doctor?

Call emergency medical help if you notice possible signs of a blood clot, which could mean you have a blood clot in your leg (i.e., deep vein thrombosis), a blood clot in your lung (i.e., pulmonary embolism), a heart attack, or a stroke (see the section below 'Blood clots (thrombosis)').

For a description of the symptoms of these serious side effects, go to 'How do I recognize a blood clot?'.

Warnings and precautions

Before you start using this medicine, you must first see your doctor for a medical examination. Tell your doctor if any of the following situations apply to you.

If the condition develops or worsens while you are using EVRA, you should also tell your doctor.

You have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease).

You have systemic lupus erythematosus (SLE - a disease that affects your natural defense system).
You have hemolytic uremic syndrome (HUS - a blood clotting disorder that causes kidney failure).
You have sickle cell anemia (an inherited disease of the red blood cells).
You have sickle cell anemia (a hereditary disease of the red blood cells).
You have elevated fat levels in your blood (hypertriglyceridemia), or this condition runs in your family or has occurred in your family. Hypertriglyceridemia has been associated with an increased risk of developing pancreatitis (an inflammation of the pancreas).
You need to undergo surgery or you may be unable to walk for a long time (see 'Blood clots' in section 2).
If you have recently given birth, you have an increased risk of developing blood clots. Ask your doctor how soon after delivery you can start using EVRA.
You have an inflammation in the veins just under the skin (superficial thrombophlebitis).
You have varicose veins.
Contact a doctor immediately if you experience symptoms of angioedema such as swelling of the face, tongue and/or throat and/or difficulty swallowing or hives possibly together with difficulty breathing. Medicines containing estrogens can trigger or worsen symptoms of hereditary or acquired angioedema.

BLOOD CLOTS

If you use a CHC like EVRA, you have a higher chance of developing blood clots than if you do not use a CHC. In rare cases, a blood clot can block a blood vessel and cause serious problems.

Blood clots can occur
in veins (this is called 'venous thrombosis', 'venous thromboembolism' or VTE)in arteries (this is called 'arterial thrombosis', 'arterial thromboembolism' or ATE).
One does not always fully recover from blood clots. In rare cases, there can be long-term serious effects, or in very rare cases, blood clots can be fatal.

It is important for you to know that the overall chance of getting a blood clot that causes harm from EVRA is small.

HOW DO I RECOGNIZE A BLOOD CLOT?

HOW DO I RECOGNIZE A BLOOD CLOT?
Seek emergency medical help if you notice any of the following complaints or symptoms.

Do you experience any of these complaints?	What can you suffer from?
swelling of aleg or along a vein in a leg or foot, especially if accompanied by: - pain or tenderness in the leg that you may only feel when standing or walking; - increased temperature in the affected leg; - discoloration of the skin of the leg, for example, becoming pale, red, or blue.	Deep vein thrombosis

sudden unexplained shortness of breath or rapid breathing; sudden coughing without a clear cause, where you may cough up blood; sharp chest pain, which may worsen when you take a deep breath; severe light-headedness in the head or dizziness; fastle or irregular heartbeat; severe pain in your stomach.	Pulmonary embolism

If in doubt, contact a doctor, as some of these symptoms, such as coughing or shortness of breath, may mistakenly be considered a milder condition, such as a respiratory infection (e.g., cold).

Symptoms that usually occur in one eye: sudden loss of vision or painless blurred vision, which can develop into loss of vision.	Venous thrombosis in the retina (blood clot in the eye)
pain, discomfort, pressure or heavy feeling on the chest; tight or full feeling in the chest, arm or under the breastbone; full feeling, sensation of indigestion or choking; discomfort in the upper body 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
suddenweakness or numbness of 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 lack of coordination; sudden, severe or prolonged headache with no known cause; loss of consciousness or fainting with or without a seizure.	Stroke

The symptoms of a stroke can sometimes be brief and recover almost immediately and completely. However, you should still seek emergency medical help as you may be at risk of having another stroke.

swelling and slight bluediscoloration of an arm or other leg;
Blood clots that block blood vessels block
severe pain in your stomach/abdomen (acute abdomen).

BLOOD CLOTS IN A VEIN

What can happen if a blood clot forms in a vein?

The use of CHCs has been associated with an increased risk of blood clots in a vein (venous thrombosis). However, these side effects are rare. They usually occur in the first year of using a CHC.

If a blood clot forms in a vein in a 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.

It is very rare for a blood clot to form in a vein in another organ, such as the eye (retinal vein thrombosis).

When is the risk of a blood clot forming in a vein the highest?

The risk of developing a blood clot in a vein is highest in the first year a woman first uses a CHC. The risk may also be increased if you restart using a CHC (the same product or a different product than before) after a break of 4 weeks or longer.

After the first year, the risk decreases, but it remains slightly higher than if you do not use a CHC.

If you stop using EVRA, the risk of a blood clot returns to normal within a few weeks.

How high is the risk that I will get a blood clot?

The risk depends on your natural risk of VTE and the type of CHC you use. The risk of developing a blood clot in a leg or lung (DVT or PE) with EVRA is generally low.

- Out of every 10,000 women who do not use any CHC and are not pregnant, about 2 will develop a blood clot in a year.
- Out of every 10,000 women who use a CHC containing levonorgestrel, norethisterone, or norgestimate, 5 to 7 will develop a blood clot in a year.
- Out of every 10,000 women who use a CHC containing etonogestrel or norelgestromin, such as EVRA, between 6 and 12 will develop a blood clot in a year.
- The risk of developing a blood clot depends on your personal medical history (see 'Factors that increase your risk of a blood clot' below).

	The risk of developing a blood clot in a year
Women who do not use combined hormonal pill/patch/ring and are not pregnant	About 2 in every 10,000 women
Women who use a combination pill that contains levonorgestrel, norethisterone, or norgestimate	About 5-7 in every 10,000 women
Women using EVRA	Approximately 6-12 out of every 10,000 women

Factors that increase your risk of a blood clot in a vein

The risk of a blood clot with EVRA is small, but there are certain conditions that increase that risk. You are at greater risk:

if you are severely overweight (BMI [body mass index] over 30 kg/m^2);
if one of your close relatives has had a blood clot in a leg, lung, or other organ at a young age (e.g., before the age of 50). In that case you may be hereditary coagulation disorder have;
if you need to undergo surgery, or if you cannot walk for a long time due to an injury or illness, or if your leg is in a cast. It may be necessary to stop using EVRA a few weeks before surgery, or when you are less mobile; if you need to stop using EVRA, ask your doctor when you can start using it again;
as you get older (particularly over the age of 35);
if you have given birth in the past few weeks.

The risk of developing a blood clot increases the more of these conditions apply to you.

A flight (longer than 4 hours) can temporarily increase the risk of developing a blood clot, especially if some of the mentioned conditions apply to you.

It is important that you tell your doctor if one or more of these conditions apply to you, even if you are unsure. Your doctor may decide that you should stop using EVRA.

If any of the above conditions change while you are using EVRA, for example, if a close relative experiences thrombosis without a known cause, or if you gain a lot of weight, inform your doctor.

BLOOD CLOTS IN AN ARTERY

What can happen if a blood clot forms in an artery?
Like a blood clot in a vein, a blood clot in an artery can cause serious problems. It can, for example, cause a heart attack or a stroke.

Factors that increase your risk of a blood clot in an artery
It is important to know that the risk of a heart attack or stroke from using EVRA is very small, but it can increase:

with increasing age (over about 35 years);
if you smoke. If you use a CHC like EVRA, it is advised that you stop smoking. If you cannot stop smoking and are over 35 years old, your doctor may advise you to use a different type of contraceptive;
if u overweight have;
if you have high blood pressure;
if a member of your immediate family has had a heart attack or stroke at a young age (before the age of 50). In that case, you may also have an increased risk of having a heart attack or stroke;
if you, or a member of your immediate family, have high levels of fat in the blood (cholesterol
or triglycerides);
if you have migraines, especially migraines with aura;
if you have a heart condition (heart valve disorder, or a heart rhythm disorder called atrial fibrillation);
if you have diabetes.

If more than one of these conditions applies to you, or if one of these conditions is particularly severe, the risk of developing a blood clot may be even further increased.

If any of the above conditions change while you are using EVRA, for example, if you start smoking or if an immediate family member develops thrombosis without a known cause, or if you gain a lot of weight, tell your doctor.

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

Additionally, contact your doctor, pharmacist, or nurse before using this medicine if you have any of the following conditions or if they occur or worsen while using EVRA:

- You think you might be pregnant;
- You have headaches that get worse or occur more frequently;
- You weigh 90 kg or more;
- You have high blood pressure or your blood pressure is rising;
- You have a gallbladder condition, including gallstones or inflammation of the gallbladder;
- You have a blood disorder called porphyria;
- You have a nerve disorder with sudden body movements, called 'Sydenham's chorea';
- You had a rash with blisters during pregnancy (called 'herpes gestationis');
- You have hearing loss;
- You have diabetes;
- You have a depression;
- You have epilepsy or another condition that causes seizures or convulsions;
- You have liver problems where the skin and the whites of the eyes turn yellow (jaundice);
- You have (had) 'pregnancy spots'. These are yellow-brown spots, especially on your face (called 'chloasma'). These spots may not completely disappear, even after you stop using EVRA. Protect your skin from sunlight or ultraviolet radiation. This can help prevent you from getting these spots or them worsening.
- You have kidney problems.

If you are not sure whether the above applies to you, consult your doctor or pharmacist before using EVRA.

Sexually transmitted diseases
This medicine does not provide protection against HIV infection (AIDS) or other sexually transmitted diseases. These include chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, syphilis. Always use condoms to protect yourself against these diseases.

Medical examination

- If your blood or urine needs to be tested, tell your doctor or the person taking your blood or receiving the urine that you are using EVRA. This is because hormonal contraceptives can affect the results of certain tests.

Children and adolescents up to 18 years
EVRA has not been tested in children and adolescents under 18 years. EVRA should not be used by children and adolescents who have not yet had their first menstruation.

Are you using any other medicines?
Are you using any other medicines besides EVRA, have you done so recently, or is there a possibility that you will use other medicines soon? Tell that then your doctor or pharmacist.

Do not use EVRA if you have hepatitis C and are taking medicines containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir, or sofosbuvir/velpatasvir/voxilaprevir, as these medicines can cause an increase in liver function test results (increase in the liver enzyme alanine aminotransferase (ALT)). Your doctor will prescribe another type of contraceptive before starting treatment with these medicines. EVRA can be restarted approximately 2 weeks after finishing this treatment. See section 'When should you not use this medicine?'.

Some medicines and herbal therapies can prevent EVRA from working properly. If this happens, you could become pregnant or experience unexpected bleeding. This includes medicines used for the treatment of:

- some antiretroviral medicines used to treat HIV/AIDS and hepatitis C virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efavirenz)
- medicines for infections (such as rifampicin and griseofulvin)
- medicines for seizures (such as barbiturates, topiramate, phenytoin, carbamazepine, primidone, oxcarbazepine, and felbamate)
- bosentan (a medicine for high blood pressure in the lung blood vessels)
- St. John's wort, an herbal therapy used for depression.

If you are using any of these medicines, you may need to use another reliable contraceptive method (such as a condom, diaphragm, or spermicide). The disruptive effect of some of these medicines can last up to 28 days after you stop using them. Discuss with your doctor or pharmacist the use of another method of contraception if you are using EVRA and any of the above medicines simultaneously.

EVRA can make some other medicines less effective, such as:

- medicines that contain ciclosporin contain
- seizures]. seizures (convulsions) increase].

Your doctor may need to adjust the dosage of the other medication. Ask your doctor or pharmacist for advice before using any medication.

Pregnancy and breastfeeding

- Do not use this medicine if you are pregnant or think you might be pregnant.
- Stop using this medicine immediately if you become pregnant.
- Do not use this medicine if you are breastfeeding or planning to breastfeed.

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medication.

Driving and using machines
You may drive a vehicle or use machines while using this medicine.

Risks of using a combined hormonal contraceptive
The information below is based on data about combination contraceptive pills (combination pills). Since EVRA transdermal patches contain the same hormones as those used in combination pills, it is likely that EVRA carries the same risks. All combined contraceptives carry risks that could lead to disability or death.
It has not been shown that a transdermal patch like EVRA is safer than a combination contraceptive pill taken orally.

Combined hormonal contraceptives and cancer

Cervical cancer
Cervical cancer appears to occur more frequently in women who use combined hormonal contraceptives. However, this may have other causes, including sexually transmitted infections.

Breast cancer
Breast cancer appears to occur more frequently in women who use combined hormonal contraceptives. However, it is possible that the combined hormonal contraceptive is not the cause of the increased occurrence of breast cancer. Women who use combined hormonal contraceptives may be examined more often. This could mean that there is a greater chance of breast cancer being detected. The increased risk gradually decreases after stopping combined hormonal contraceptives. After 10 years, the risk is the same as for people who have never used combined hormonal contraceptives.

Liver cancer
In rare cases, non-cancerous liver tumors have been found in women using combined hormonal contraceptives. Even rarer was the discovery of liver tumors that were cancerous. These can cause internal bleeding leading to severe pain around the stomach. If this occurs, contact your doctor immediately.

3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you.

If you do not, you may increase the risk of pregnancy.
Are you unsure about the correct use? Then contact your doctor or pharmacist.
Make sure you always have non-hormonal contraceptives (such as condoms or spermicidal foam or gel) on hand as backup if you have used the patch incorrectly.

How many patches do you need to
Week 1, 2 & 3: Apply one patch and leave it on for exactly seven days.
Week 4: Do not apply a patch this week.

If you have not used a hormonal contraceptiveduring your previous cycle
You can start this medicine on the first day of your next period.
If one or more days have passed since the start of your period, discuss with your doctor the temporary use of a non-hormonal contraceptive.

If you switch from an oral contraceptive pill to EVRA When you switch from an oral contraceptive pill to this medicine:
Wait until your bleeding ('menstruation') has started.
Apply your first patch during the first 24 hours of your menstruation.

If the patch is applied after day 1 of your menstruation, you should:
use a non-hormonal contraceptive until day 8, when you replace your patch.

If you have not had bleeding within 5 days after taking the last contraceptive pill, contact your doctor before starting this medicine.

If you switch from a progestogen-only contraceptive pill, an implant, or an injectable contraceptive to EVRA
You can start this medicine any day after stopping a progestogen-only contraceptive pill or on the day of removal of an implant or when the next injection would take place.
Apply the patch the first day after stopping a progestogen-only contraceptive pill or the removal of the implant or when your next injection would take place.
Use a non-hormonal contraceptive until day 8, when you replace your patch.

After a miscarriage or abortionbefore 20 weeks of pregnancy
Discuss this with your doctor.
You may start this medicine immediately.

If one or more days have passed since your miscarriage or abortion when you start this medicine, discuss with your doctor the temporary use of a non-hormonal contraceptive.

After a miscarriage or abortion after 20 weeks ofpregnancy
Discuss this with your doctor.

You may start this medicine on day 21 after the abortion or miscarriage, or on the first day of your next menstruation, whichever comes first.

After one delivery
Discuss this with your doctor.
If you have given birth and are not breastfeeding, you should not start this medication earlier than 4 weeks after delivery.
If you start more than 4 weeks after delivery, use another non-hormonal contraceptive in addition to this medication for the first 7 days.

If you have had intercourse since the birth of your baby, wait for your first period or contact your doctor to ensure you are not pregnant before starting this medication.

If you breastfeeding are
Discuss this with your doctor.
Do not use this medication if you are breastfeeding or plan to breastfeed (see also section 2, Pregnancy and breastfeeding).

Important information to follow when using the patches
Replace EVRA every week on the same day. This is because the patch is designed to work for 7 days.
There should not be more than 7 patch-free days in a row.
You may only wear one patch at a time.
Do not cut or tamper with the patch.
Do not apply the patch to skin that is red or irritated or has a cut.
To work properly, the patch must adhere firmly to your skin.
The patch should be pressed firmly until the edges stick well.
Do not apply cream, oil, lotion, powder, or makeup on the skin where you want to apply a patch or near a patch you are wearing. The patch could therefore come loose ..
Check every day to see if the patch is still securely attached.
Continue using the patches, even if you do not have intercourse often.
How to use the patch:

If you are using EVRA for the first time, wait until the day your period starts.

Apply the first patch within the first 24 hours of your period.

If the patch is applied after the first day of your period, use a non-hormonal contraceptive until day 8, when you replace your patch.
The day you apply your first patch is day 1. Your 'patch change day' is the same day of the week every week.
Choose a place on your body to apply the patch.

Always apply your patch to clean, dry, hairless skin.

Apply it to the buttock, abdomen, outer arm, or upper back; these are areas where it cannot be rubbed off by tight clothing.
Never apply a patch to your breasts.
Never apply a patch to your breasts.

Open the foil-lined pouch with your fingers.

Tear it open along the edge (do not use scissors).
Firmly grasp a corner of the patch and carefully remove it from the foil-lined pouch.
The patch has a transparent protective layer.
Sometimes a patch can stick to the inside of the pouch – be careful not to accidentally remove the transparent layer while taking the patch out of the pouch.
Then pull off half of the transparent protective layer from the patch (see the drawing).
Do not touch the sticky surface do not touch.

Apply the patch to your skin.

Then remove the other half of the protective layer.
Press firmly with your palm on the patch for 10 seconds.
Ensure the edges are well adhered.

Wear the patch for 7 days (one week).
Remove the used patch on the first 'patch replacement day', day 8.
Immediately apply a new patch.
On day 15 (week 3), you must remove the used patch again.
Apply a new patch.

At the end of this week, you will have worn a patch for a total of 3 weeks.

To prevent irritation, do not apply the new patch to exactly the same spot on your skin where the previous patch was.

Do not wear a patch in week 4 (from day 22 to day 28).

During this period, bleeding is expected to occur.
During this week, you are only protected against pregnancy if you apply the next patch on time.

For the next four-week cycle.

Apply a new patch on the usual 'patch change day', the day after day 28.
You must do this regardless of when the bleeding starts or ends.

If you want to shift the 'patch change day' to another day of the week, discuss this with your doctor.
You will need to complete the current cycle and remove the third patch on the correct day.
During week 4, you can choose a new 'patch change day' and apply the first patch on that day. Make sure you never go more than 7 days without a patch.

If you wish to delay your menstruation, apply a patch at the beginning of week 4 (day 22) instead of not wearing a patch in week 4. You may experience light bleeding or breakthrough bleeding. Do not wear more than 6 patches (i.e., for 6 consecutive weeks) in a row. If you have worn 6 patches in a row (i.e., for 6 consecutive weeks), do not apply a patch in week 7. After 7 days without a patch, apply a new patch and restart the cycle with this day as day 1. Contact your doctor before deciding to delay your menstruation.

Daily activities while wearing the patch

Normal activities such as bathing, showering, using the sauna, and exercising should not affect the patch's effectiveness.
The patch is designed to stay in place during such activities.
However, you should check that the patch has not fallen off after these types of activities.

If you need to apply the patch to a new area of your body on a different day than your 'patch change day'

If the patch causes irritation or discomfort:

you can remove it and replace it with a new patch on a different site until your next patch change day.
But you should only wear one patch at a time.

If you find it difficult to remember when to change your patch

Contact your doctor, pharmacist, or nurse. He or she may be able to make changing the patch easier for you. He or she can also discuss with you whether another contraceptive method might be more suitable for you.

If your patch becomes loose, lifts at the edges, or falls off

Within one day (maximum 24 hours):

Try to reapply it or apply a new patch immediately.
You do not need any additional contraceptive.
Your 'patch change day' should remain the same.
Do not try to reapply a patch if:

- it does not stick
- it has stuck to itself or another surface
- other material is stuck to it
- it is the second time it has come loose or fallen off.

Do not use tape or bandages to keep the patch in place.
If you cannot reapply the patch, apply a new patch immediately.

After one day (24 hours or more) or if you are unsure how long:

Immediately start a new four-week cycle by applying a new patch.
You now have a new day 1 and a new 'patch change day'.
For the first week of the new cycle, you must also use an additional non-hormonal contraceptive for safety.

If you do not follow these instructions, you may become pregnant.

If you have forgotten to replace a patch

At the start of a patch cycle (week 1 (day 1)):
If you forget to apply your patch, you are at a very high risk of becoming pregnant.
- You must use an additional non-hormonal contraceptive for one week.
- Apply the first patch of the new cycle as soon as you remember.
- You now have a new 'patch change day' and a new day 1.

In the middle of your patch cycle (week 2 or week 3):
If you have forgotten to replace a patch for one or two days (maximum 48 hours):
- You must apply a new patch as soon as you remember.
- Apply your next patch on your normal 'patch change day'.

No additional contraceptive is needed then.

For more than 2 days (48 hours or more):
If you forget to change your patch for more than 2 days, you may become pregnant.
Start a new four-week cycle as soon as you remember by applying a new patch.
You now have a different 'patch change day' and a new day 1.
You must use an additional contraceptive for the first week of the new cycle.

At the end of your patch cycle (week 4):
If you forgot to remove a patch:
Remove it as soon as you remember.
Start the next cycle on the usual 'patch change day', the day following day 28. There is then no extra contraceptive needed.

If your bleeding is absent or irregular while using EVRA
This medicine can cause unexpected bleeding or spotting from the vagina during the weeks you wear the patches.
This usually stops after the first few cycles.
Incorrect use of the patches can also cause spotting and light bleeding.
Continue using this medicine and if the bleeding persists after the first three cycles, consult your doctor or pharmacist.

If you do not have bleeding during the EVRA-free week (week 4), you should still apply a new patch on your usual 'patch change day'.
If you have used this medicine correctly and do not experience bleeding, it does not necessarily mean you are pregnant.
However, if you miss bleeding twice in a row, contact your doctor or pharmacist, as you may be pregnant.

Have you used too much of this medicine (more than one EVRA patch at a time)? Remove the patches and contact a doctor immediately.

Using too many patches can result in the following consequenceand have:
nausea and vomiting
vaginal bleeding.

If you stop using this medicine
You may experience irregular or very light or no menstruation. This usually occurs in the first 3 months and especially if your menstrual cycle was not regular before you started using this medicine.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them. If you experience a side effect, especially if it is severe and persistent, or if there is a change in your health condition that you think may be caused by EVRA, contact your doctor.
Contact a doctor immediately if you experience any of the following symptoms of angioedema: swelling of the face, tongue and/or throat and/or difficulty swallowing or hives possibly with difficulty breathing (see also section 'Warnings and precautions').
All women using CHCs have an increased risk of blood clots in the veins [venous thromboembolism (VTE)] or blood clots in the arteries [arterial thromboembolism (ATE)]. For more information on the different risks of using CHCs, see section 2 'When should you not use this medicine or be extra careful?'.

Very common side effects (may occur in more than 1 in 10 women):
- Headache
- Nausea
- Tender breasts.

Common side effects (may occur in up to 1 in 10 women):
- Vaginal yeast infection, sometimes candida called
- Mood problems such as depression, mood changes or mood swings, anxiety, crying
- Dizziness
- Migraine
- Stomach pain or bloated feeling
- Vomiting or diarrhea
- Pimples (acne), skin rash, itchy skin or irritated skin
- Muscle twitches
- Breast problems such as pain, enlargement, or lumps in the breast
- Changes in menstrual pattern, uterine cramps, painful menstruations, vaginal discharge
- Problems where the patch has been on the skin such as rednessd, irritation, itching, or rash
- Fatigue or feeling unwell
- Weight gain.

Sometimes occurring side effects (may occur in up to 1 in 100 women):
- Allergic reaction, hives
- Swelling due to fluid retention
- High levels of fats in the blood (such as cholesterol or triglycerides)
- Sleep problems (insomnia)
- Less interest for sex
- Eczema, red skin
- Unusual milk discharge
- Premenstrual syndrome
- Dry vagina
- Other problems where the patch has been on the skin
- Swelling
- High blood pressure or increase in blood pressure
- Increased appetite
- Hair loss
- Sensitivity to sunlight.

Rare side effects (may occur in up to 1 in 1,000 women):

harmful blood clots in a vein or artery, for example:
- in a leg or foot (i.e. DVT)
- in a lung (i.e. PE)
- heart attack
- stroke
- 'mini-stroke' or temporary symptoms similar to a stroke, known as TIA (transient ischemic attack)
- blood clots in the liver, stomach/intestines, kidneys, or eyes.

The risk of developing a blood clot is higher if other conditions apply to you that increase this risk (see section 2 for more information on the conditions that increase the risk of blood clots and the symptoms of a blood clot)
Breast-, cervical- or liver cancer
Problems where the patch has been on the skin, such as rash with blisters or sores
Benign tumors (non-cancerous) in your breast or liver
Fibrosis in the uterus
Anger or frustrated feeling
Increased interest in sex
Abnormal taste
Problems with wearing contact lenses
Sudden severe increase in blood pressure (hypertensive crisis)
Inflammation of the gallbladder or the colon
Abnormal cells in the cervix
Brown spots or patches on the face
Gallstones or blockage of the bile duct
Yellowing of the skin and the whites of the eyes
Abnormal levels of sugar or insulin in the blood
A severe allergic reaction that may include swelling of the face, lips, mouth, tongue, or throat which can lead to difficulty swallowing or breathing
Skin rash with tender red nodules on the shins and legs
Itchy skin
Scaly, flaky, itchy and red skin
Reduced amount breastfeeding
Vaginal discharge
Fluid retention in the legs
Fluid retention
Swelling in the arms, legs or feet.

If you have stomach problems
- The amount of hormones you get from EVRA is usually not affected by vomiting or diarrhea.
- You do not need to use additional contraception if you have stomach problems.

During the first 3 cycles, you may experience spotting or light bleeding, tender breasts, or nausea. The problem usually resolves on its own, but if it does not, contact your doctor or pharmacist.

Reporting side effects
If you experience side effects, contact your doctor, pharmacist, or nurse. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the

national reporting system as mentioned in Appendix V. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How do you store this medicine?

Keep out of the sight and reach of children.
Do not use this medicine after the expiry date. You can find it on the label after "EXP". It includes a month and a year. The last day of that month is the expiry date.
Store in the original package to protect from light and moisture.
Do not store in the refrigerator or freezer.

Used patches still contain some active hormones. To protect the environment, they must be disposed of carefully. To dispose of a used patch you must: peel off the disposal sticker on the outside of the pouch

peel off the disposal sticker on the outside of the sachet
place the used patch on the disposal sticker so that the adhesive side is on the dark surface
fold the sticker so that the patch is inside and dispose of it, out of the reach of children.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed responsibly and do not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?
The active substances in this medicine are norelgestromin and ethinylestradiol.
Each 20 cm² patch contains 6 mg norelgestromin and 600 micrograms ethinylestradiol. The active substances are released over 7 days, with an average of 203 micrograms norelgestromin and 34 micrograms ethinylestradiol released every 24 hours.

The other substances in this medicine are: top layer: a pigmented low-density polyethylene outer layer, polyester inner layer; middle layer: polyisobutylene/polybutene adhesive, crospovidone, non-woven polyester fabric, lauryl lactate; third layer: polyethylene terephthalate (PET) film, polydimethylsiloxane coating.

What does EVRA look like and what is in a package?
EVRA is a thin, beige, plastic patch for transdermal use with the imprint EVRA. After removing the transparent plastic protective layer, the adhesive side should be applied to the skin.
EVRA is available in boxes of 3, 9, or 18 patches. Each patch is in an individually foil-lined sachet. These sachets are wrapped in groups of three in a transparent, perforated plastic film.

Not all mentioned package sizes are marketed.

Marketing authorization holder and manufacturer Marketing authorization holder:
Gedeon Richter Plc.
Gyömrői út 19-21.
1103 Budapest
Hungary

Manufacturer:
Gedeon Richter Plc.
Gyömrői út 19-21.
1103 Budapest
Hungary

This leaflet was last approved in MM/YYYY.

Other sources of information
More information about this medicine is available on the website of the European Medicines Agency http://www.ema.europa.eu.
This leaflet is available in all EU/EEA languages on the website of the European Medicines Agency.