

## Package leaflet: Information for the user

### EVRA 203 micrograms/24 hours + 33.9 micrograms/24 hours transdermal patch norelgestromin/ethinyl estradiol

#### **Important things to know about combined hormonal contraceptives (CHCs):**

- They are one of the most reliable reversible methods of contraception if used correctly
- They slightly increase the risk of having a blood clot in the veins and arteries, especially in the first year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks
- Please be alert and see your doctor if you get symptoms of a blood clot (see section 2 “Blood clots”)

#### **Read all of this 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.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

#### **What is in this leaflet**

1. What EVRA is and what it is used for
2. What you need to know before you use EVRA
3. How to use EVRA
4. Possible side effects
5. How to store EVRA
6. Contents of the pack and other information

#### **1. What EVRA is and what is it used for**

EVRA contains two types of sex hormones, a progestogen called norelgestromin and an oestrogen called ethinyl estradiol.

Because it contains two hormones, EVRA is called a ‘combined hormonal contraceptive’.

It is used to prevent pregnancy.

#### **2. What you need to know before you use EVRA**

##### **General notes**

Before you start using EVRA you should read the information on blood clots in section 2. It is particularly important to read the symptoms of a blood clot - see Section 2 “Blood clots”.

##### **When you should not use EVRA**

You should not use EVRA if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor. Your doctor will discuss with you what other form of birth control would be more appropriate.

- if you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs;
- if you know you have a disorder affecting your blood clotting - for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies;
- if you need an operation or if you are off your feet for a long time (see section ‘Blood clots’;
- if you have ever had a heart attack or a stroke;
- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA – temporary stroke symptoms);
- if you have a disease that may increase your risk of a clot in the arteries:
  - severe diabetes with blood vessel damage
  - very high blood pressure
  - a very high level of fat in the blood (cholesterol or triglycerides);
  - a condition known as hyperhomocysteinaemia
- if you have (or have ever had) a type of migraine called ‘migraine with aura’;
- if you are allergic to norelgestromin, ethinyl estradiol or any of the other ingredients of this medicine (listed in section 6)
- if you have ever been told you might have breast cancer or cancer of the womb, cervix or vagina
- if you have ever had liver tumours or a liver disease because of which your liver does not function properly
- if you have unexplained vaginal bleeding.

Do not use this medicine if any of the above applies to you. If you are not sure, talk to your doctor, pharmacist or nurse before using this medicine.

### **When to take special care with EVRA**

When should you contact your doctor?

#### Seek urgent medical attention

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

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

### **Warnings and precautions**

Before using this medicine, you will need to see your doctor for a medical check-up.

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

If the condition develops, or gets worse while you are using EVRA, you must tell your doctor.

- if you have Crohn’s disease or ulcerative colitis (chronic inflammatory bowel disease);
- if you have SLE (systemic lupus erythematosus; a disease affecting your natural defence system);
- if you have haemolytic uraemic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys);
- if you have sickle cell anaemia (an inherited disease of the red blood cells);

- if you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas);
- if you need an operation, or you are off your feet for a long time (see in section 2 ‘Blood clots’);
- if you have just given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking EVRA;
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- if you have varicose veins.

## BLOOD CLOTS

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

Blood clots can develop

- in veins (referred to as a ‘venous thrombosis’, ‘venous thromboembolism’ or VTE)
- in the arteries (referred to as an ‘arterial thrombosis’, ‘arterial thromboembolism’ or ATE).

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, they may be fatal.

**It is important to remember that the overall risk of a harmful blood clot due to EVRA is small.**

## HOW TO RECOGNISE A BLOOD CLOT

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

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none"> <li>• swelling of one leg or along a vein in the leg or foot especially when accompanied by:               <ul style="list-style-type: none"> <li>- pain or tenderness in the leg which may be felt only when standing or walking;</li> <li>- increased warmth in the affected leg;</li> <li>- change in colour of the skin on the leg e.g. turning pale, red or blue.</li> </ul> </li> </ul>	Deep vein thrombosis
<ul style="list-style-type: none"> <li>• sudden unexplained breathlessness or rapid breathing;</li> <li>• sudden cough without an obvious cause, which may bring up blood;</li> <li>• sharp chest pain which may increase with deep breathing;</li> <li>• severe light headedness or dizziness;</li> <li>• rapid or irregular heartbeat;</li> <li>• severe pain in your stomach.</li> </ul> <p>If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (eg a ‘common cold’).</p>	Pulmonary embolism
<p>Symptoms most commonly occur in one eye:</p> <ul style="list-style-type: none"> <li>• immediate loss of vision or;</li> </ul>	Retinal vein thrombosis (blood clot in the eye)

<ul style="list-style-type: none"> <li>• painless blurring of vision which can progress to loss of vision</li> </ul>	
<ul style="list-style-type: none"> <li>• chest pain, discomfort, pressure, heaviness;</li> <li>• sensation of squeezing or fullness in the chest, arm or below the breastbone;</li> <li>• fullness, indigestion or choking feeling;</li> <li>• upper body discomfort radiating to the back, jaw, throat, arm and stomach;</li> <li>• sweating, nausea, vomiting or dizziness;</li> <li>• extreme weakness, anxiety, or shortness of breath;</li> <li>• rapid or irregular heartbeats.</li> </ul>	Heart attack
<ul style="list-style-type: none"> <li>• sudden weakness or numbness of the face, arm or leg, especially on one side of the body;</li> <li>• sudden confusion, trouble speaking or understanding;</li> <li>• sudden trouble seeing in one or both eyes;</li> <li>• sudden trouble walking, dizziness, loss of balance or coordination;</li> <li>• sudden, severe or prolonged headache with no known cause;</li> <li>• loss of consciousness or fainting with or without seizure.</li> </ul> <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>	Stroke
<ul style="list-style-type: none"> <li>• swelling and slight blue discolouration of an extremity;</li> <li>• severe pain in your stomach (acute abdomen)</li> </ul>	Blood clots blocking other blood vessels

## **BLOOD CLOTS IN A VEIN**

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

- The use of combined hormonal contraceptives has been connected with an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare. Most frequently, they occur in the first year of use of a combined hormonal contraceptive.
- If a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung it can cause a pulmonary embolism.
- Very rarely a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

### **When is the risk of developing a blood clot in a vein highest?**

The risk of developing a blood clot in a vein is highest during the first year of taking a combined hormonal contraceptive for the first time. The risk may also be higher if you restart taking a combined hormonal contraceptive (the same product or a different product) after a break of 4 weeks or more

After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive.

When you stop EVRA your risk of a blood clot returns to normal within a few weeks.

### **What is the risk of developing a blood clot?**

The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you are taking.

The overall risk of a blood clot in the leg or lung (DVT or PE) with EVRA is small.

- Out of 10,000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains levonorgestrel, norethisterone, or norgestimate about 5-7 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains etonorgestrel or norelgestromin such as EVRA between about 6 and 12 women will develop a blood clot in a year.
- The risk of having a blood clot will vary according to your personal medical history (see “Factors that increase your risk of a blood clot” below)

	Risk of developing a blood clot in a year
Women who are <b>not using</b> a combined hormonal pill/patch/ring and are not pregnant	About 2 out of 10,000 women
Women using a combined hormonal contraceptive pill containing <b>levonorgestrel, norethisterone or norgestimate</b>	About 5-7 out of 10,000 women
Women using EVRA	About 6-12 out of 10,000 women

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

The risk of a blood clot with EVRA is small but some conditions will increase the risk. Your risk is higher:

- if you are very overweight (body mass index or BMI over 30 kg/m<sup>2</sup>);
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50). In this case you could have a hereditary blood clotting disorder;
- if you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of EVRA may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop EVRA ask your doctor when you can start using it again;
- as you get older (particularly above about 35 years);
- if you gave birth less than a few weeks ago.

The risk of developing a blood clot increases the more conditions you have.

Air travel (> 4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.

It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that EVRA needs to be stopped.

If any of the above conditions change while you are using EVRA, for example a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

### BLOOD CLOTS IN AN ARTERY

#### What can happen if a blood clot forms in an artery?

Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

## Factors that increase your risk of a blood clot in an artery

It is important to note that the risk of a heart attack or stroke from using EVRA is very small but can increase:

- with increasing age (beyond about 35 years);
- **if you smoke.** When using a combined hormonal contraceptive like EVRA you are advised to stop smoking. If you are unable to stop smoking and are older than 35 your doctor may advise you to use a different type of contraceptive;
- if you are overweight;
- if you have high blood pressure;
- if a member of your immediate family has had a heart attack or stroke at a young age (less than about 50). In this case you could also have a higher risk of having a heart attack or stroke;
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides);
- if you get migraines, especially migraines with aura;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation);
- if you have diabetes.

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

If any of the above conditions change while you are using EVRA, for example you start smoking, a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

Additionally, talk to your doctor, pharmacist or nurse before using EVRA if you have any of the following or they happen or get worse while using EVRA:

- You think you might be pregnant;
- You have headaches that get worse or happen more often;
- You weigh 90 kg (which is 14 stone 2 lb) or more;
- You have high blood pressure or your blood pressure gets higher;
- You have gallbladder disease including gallstones or inflammation of the gallbladder;
- You have a blood problem called porphyria;
- You have a problem of the nervous system involving sudden movements of the body called 'Sydenham's chorea';
- You had a skin rash with blisters during pregnancy (called 'herpes gestationis');
- You have a hearing loss;
- You have diabetes;
- You have depression;
- You have epilepsy or any other problem that can cause fits (convulsions);
- You have liver problems including yellowing of the skin and whites of the eye (jaundice);
- You have or have had 'pregnancy spots'. These are yellowish-brown patches or spots, especially on your face (called 'chloasma'). These spots may not go away completely, even after you stop using EVRA. Protect your skin from sunlight or ultraviolet radiation. This may help prevent you from getting these spots or help prevent them from getting worse.
- You have kidney problems

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using EVRA.

## **Sexually transmitted disease**

This medicine will not protect you against HIV infection (AIDS) or any other sexually transmitted disease. These include chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, syphilis. Always use condoms to protect yourself from these diseases.

## **Medical tests**

- If you need a blood or urine test, tell your doctor or the laboratory staff that you are taking EVRA, because hormonal contraceptives can affect the results of some tests.

## **Children and adolescents**

EVRA has not been studied in children and adolescents under 18 years of age. EVRA must not be used in children and adolescents who have not yet had their first menstrual period.

## **Other medicines and EVRA**

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

Certain medicines and herbal therapies may stop EVRA from working properly. If this happens you could get pregnant.

Tell your doctor if you are taking:

- some antiretroviral medicines used to treat HIV/AIDS (such as nelfinavir, ritonavir, nevirapine, efavirenz)
- medicines for infection (such as rifampicin, rifabutin and griseofulvin, penicillins and tetracycline)
- anti-seizure medicines (such as topiramate, phenobarbital, phenytoin, carbamazepine, primidone, oxcarbamazepine, felbamate, eslicarbazepine acetate and rufinamide are some examples)
- (fos)aprepitant (a medicine to treat nausea)
- bosentan (a medicine for high blood pressure in the blood vessels in the lungs)
- St. John's wort (an herbal therapy used for depression). St. John's wort should not be taken when you are using EVRA.

If you take any of these medicines, you may need to use another method of birth control (such as a condom, diaphragm or foam). The interfering effect of some of these medicines can last for up to 28 days after you have stopped taking them. Talk to your doctor or pharmacist about using another method of birth control if you use EVRA and any of the above medicines concomitantly.

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

- medicines containing ciclosporin
- lamotrigine used for epilepsy [This can increase the risk of fits (seizures)].

Your doctor may need to adjust the dose of the other medicine. Ask your doctor or pharmacist for advice before taking any medicine.

## **Pregnancy and breast-feeding**

- Do not use this medicine if you are pregnant or think you may be pregnant

- Stop using this medicine right away if you become pregnant
- Do not use this medicine if you are breast-feeding or planning to breast-feed.

If you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

You can drive or use machines while using this medicine.

### **Risks of using combined hormonal contraceptives**

The following information is based on information about combined birth control pills. As the EVRA transdermal patch contains similar hormones to those used in combined birth control pills, it is likely to have the same risks. All combined birth control pills have risks, which may lead to disability or death.

It has not been shown that a transdermal patch like EVRA is safer than a combined birth control pill taken by mouth.

### **Combined hormonal contraceptives and cancer**

#### **Cervical cancer**

Cervical cancer has been found more often in women taking combined hormonal contraceptives. However, this may be due to other causes including sexually-transmitted disease.

#### **Breast cancer**

Breast cancer has been found more often in women who take combined hormonal contraceptives. However, it is possible that the combined hormonal contraceptive is not the cause of more women having breast cancer. It may be that women taking the combined hormonal contraceptive are examined more often. This might mean that there is a better chance of the breast cancer being noticed. The increased risk gradually goes down after stopping the combined hormonal contraceptive. After 10 years, the risk is the same as for people who have never used the combined hormonal contraceptive.

#### **Liver cancer**

In rare cases, liver tumours which are not cancer have been found in women taking combined hormonal contraceptives. Even more rarely, liver tumours which are cancer have been found. This can cause bleeding inside the body with very bad pain in the stomach area. **If this happens to you, talk to your doctor immediately.**

## **3. How to use EVRA**

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

- If you do not, you may increase your risk of getting pregnant
- Check with your doctor or pharmacist if you are not sure
- Always keep non-hormonal contraceptives (such as condoms, foam or sponge) as a back-up in case you make a mistake when using the patch.



### **How many patches to use**

- Weeks 1, 2 & 3: Put on one patch and leave it on for exactly seven days
- Week 4: Do **not** put on a patch this week.

### **If you have not used a hormonal contraceptive during your previous cycle**

- You may start this medicine on the first day of your next period.
- If one or more days have elapsed since the start of your period, talk to your doctor about temporarily using a non-hormonal contraceptive.

### **If you switch from the oral contraceptive pill to EVRA**

If you are switching from an oral contraceptive pill to this medicine:

- Wait until you get your menstrual period
- Put on your first patch during the first 24 hours of your period.

If the patch is applied after Day 1 of your period, you should:

- Use a non-hormonal contraceptive until Day 8 when you change your patch.

If you do not get your period within 5 days of taking the last contraceptive pill, check with your doctor before starting this medicine.

### **If you switch from the progestogen-only pill, an implant or an injectable to EVRA**

- You may start this medicine any day after stopping the progestogen-only pill or on the day of removal of an implant or when the next injection would be due
- The first day after stopping the progestogen-only pill, removing the implant or when your next injection would be due, put on a patch
- Use a non-hormonal contraceptive until Day 8, when you change your patch.

### **After miscarriage or abortion *before* 20 weeks of pregnancy**

- Talk to your doctor
- You may start this medicine right away

If one or more days have elapsed since your miscarriage or abortion when you start this medicine, talk to your doctor about temporarily using a non-hormonal contraceptive.

### **After miscarriage or abortion *after* 20 weeks of pregnancy**

- Talk to your doctor

You may start this medicine on Day 21 following the abortion or miscarriage, or on the first day of your next period, whichever comes first

### **After delivery**

- Talk to your doctor
- If you've had a baby and are not breast-feeding, you should not start using this medicine sooner than 4 weeks after delivery

- If you start more than 4 weeks after delivery, use another non-hormonal contraceptive in addition to this medicine for the first 7 days

If you've had sex since delivery of your baby, wait for your first period or see your doctor to make sure you are not pregnant before starting this medicine

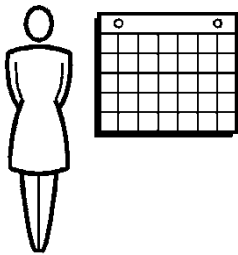
### If you are breast-feeding

- Talk to your doctor
- Do not use this medicine if you are breast-feeding or planning to breast-feed (see also section 2 Pregnancy and breast-feeding).

### Important information to follow when using the patch

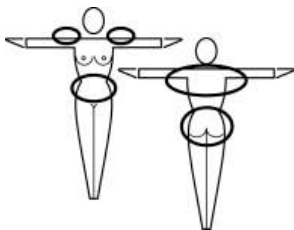
- Change EVRA on the same day of each week. This is because it is designed to work over 7 days
- Never go without wearing a patch for more than 7 days in a row
- Only wear one patch at a time
- Do not cut or tamper with the patch in any way
- Do not put the patch on skin that is red, irritated or cut
- To work properly the patch must stick firmly to your skin
- Press the patch down firmly until the edges stick well
- Do not use creams, oils, lotions, powder or makeup on the skin where you are placing a patch or near a patch you are wearing. This may make the patch come loose
- Do not put a new patch on the same area of skin as the old patch. If you do you are more likely to cause irritation
- Check each day to make sure the patch has not fallen off
- Keep using the patches even if you do not have sex very often.

### How to use the patch:



If this is the first time you are using EVRA, wait until the day you get your menstrual period.

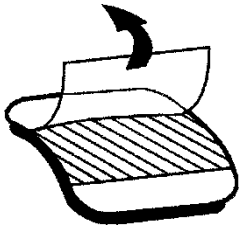
- Apply your first patch during the first 24 hours of your period
- If the patch is put on after the first day of your period, use a non-hormonal contraceptive until Day 8, when you change your patch
- **The day you apply your first patch will be Day 1. Your "Patch Change Day" will be on this day of the week every week.**



Choose a place on your body to put the patch.

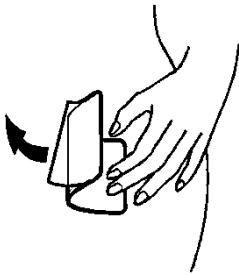
- Always put your patch on clean, dry, hairless skin
- Put it on the buttock, abdomen, upper outer arm or upper back - places where it won't be rubbed by tight clothing
- **Never put the patch on your breasts.**

Using your fingers, open the foil sachet



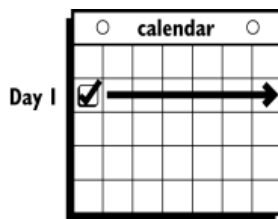
- Open it by tearing it along the edge (do not use scissors)
- Firmly grasp a corner of the patch and gently take it from the foil sachet
- There is a clear protective covering on the patch
- **Sometimes patches can stick to the inside of the sachet – be careful not to accidentally remove the clear covering as you remove the patch**
- Then peel away half of the clear protective covering (see picture). Try not to touch the sticky surface.

Put the patch on your skin



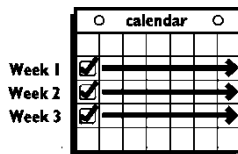
- Then take off the other half of the covering
- Press down firmly on the patch with the palm of your hand for 10 seconds
- Make sure that the edges stick well.

Wear the patch for 7 days (one week)



- On the first “Patch Change Day”, Day 8, take off the used patch
- Put on a new patch immediately.

- On Day 15 (Week 3), take off the used patch
- Put on another new one.



This makes a total of three weeks with the patches.

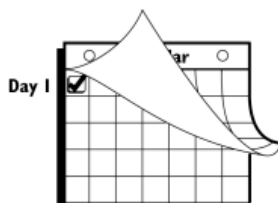
**To help stop irritation, do not put the new patch on exactly the same area of your skin as your last patch.**

Do not wear a patch on Week 4 (Day 22 through Day 28).



- **You should have your period during this time**
- During this week you are protected from getting pregnant only if you start your next patch on time.

For your next four week cycle



- Put on a new patch on your normal “Patch Change Day”, the day after Day 28
- **Do this no matter when your period begins or ends.**

If you want to change your “Patch Change Day” to a different day of the week talk to your doctor. You will need to complete the current cycle and remove the third patch on the correct day. During Week 4, you may pick a new Change Day and apply the first patch on that day. You should never go more than 7 days in a row without wearing a patch.

If you want to delay your period, apply a patch at the beginning of Week 4 (Day 22) instead of not wearing a patch on Week 4. You may experience light or breakthrough bleeding. Do not wear more than 6 patches (so not more than 6 weeks) in a row. When you have worn 6 patches in a row (so for 6 consecutive weeks), do not put on a patch in week 7. After 7 days of not wearing a patch, apply a new patch and restart the cycle using this as Day 1. Talk with your doctor before deciding to delay your period.

### **Everyday activities while using the patches**

- Normal activities such as having a bath or shower, using a sauna and exercising should not affect how well the patch works
- The patch is designed to stay in place during these types of activities
- However, you should check that the patch has not fallen off after doing these activities.

### **If you need to place the patch on a new area on your body on a day other than your “Patch Change Day”**

If the patch causes irritation or you become uncomfortable wearing it:

- You can take it off and replace it with a new patch in a different place on your body until your next “Patch Change Day”
- You may only use one patch at a time.

### **If you have trouble remembering to change your patch**

- Talk to your doctor, pharmacist or nurse. He/she may be able to make patch changing easier for you. He/she may also talk about whether you need to use another method of contraception.

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

**For less than one day** (up to 24 hours):

- Try to put it on again or put on a new patch immediately
- Back-up contraception is not needed
- Your “Patch Change Day” should remain the same
- Do not try to put a patch back on if:
  - it is no longer sticky
  - it has become stuck to itself or another surface
  - it has other material stuck to it
  - it is the second time it has become loose or has fallen off
- Do not use tapes or wrapping to keep the patch in place
- If you cannot get a patch back on, put on a new patch immediately.

**For more than one day** (24 hours or more) or if you are not sure for how long:

- Start a new four week cycle immediately by putting on a new patch
- You now have a new Day 1 and a new “Patch Change Day”
- You must use non-hormonal contraception as back up for the first week of your new cycle.

You may get pregnant if you do not follow these instructions.

### **If you forget to change your patch**

#### **At the start of any patch cycle (Week 1 (Day 1)):**

If you forget to put on your patch, you may be at particularly high risk of becoming pregnant.

- You must use non-hormonal contraception as back up for one week
- Put on the first patch of your new cycle as soon as you remember
- You now have a new “Patch Change Day” and new Day 1.

#### **In the middle of your patch cycle (Week 2 or 3):**

If you forget to change your patch for one or two days (up to 48 hours):

- You must put on a new patch as soon as you remember
- Put on your next patch on your normal “Patch Change Day”.

No back up contraception is needed.

#### **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
- You must start a new four week cycle as soon as you remember by putting on a new patch
- You now have a different “Patch Change Day” and a new Day 1
- You must use back-up contraception for the first week of your new cycle.

#### **At the end of your patch cycle (Week 4):**

If you forget to take off your patch:

- Take it off as soon as you remember
- Start your next cycle on your normal “Patch Change Day”, the day after Day 28.

No back-up contraception is needed.

### **If you have absent or irregular bleeding with EVRA**

This medicine may cause unexpected vaginal bleeding or spotting during the weeks when you are wearing the patch

- This usually stops after the first few cycles
- Mistakes in using your patches can also cause spotting and light bleeding
- Continue using this medicine and if the bleeding lasts more than the first three cycles, talk to your doctor or pharmacist.

If you do not get your period during the EVRA patch-free week (Week 4), you should still use a new patch on your usual “Patch Change Day”.

- If you have been using this medicine correctly and you do not have a period, this does not necessarily mean that you are pregnant
- However, if you miss two periods in a row, talk to your doctor or pharmacist as you may be pregnant.

### **If you use more EVRA than you should (more than one EVRA patch at any one time)**

Take the patches off and talk to a doctor immediately.

Using too many patches may cause you to have the following:

- Feeling sick (nausea) and being sick (vomiting)
- Bleeding from the vagina.

### **If you stop using EVRA**

You may get irregular, little or no menstruation. This usually happens in the first 3 months and especially if your periods were not regular before you started using this medicine.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## **4. Possible side effects**

Like all medicines, EVRA can cause side effects, although not everybody gets them. If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be due to EVRA, please talk to your doctor.

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

### **Very common side effects (may affect more than 1 in 10 women):**

- Headache
- Nausea
- Breast tenderness.

### **Common side effects (may affect up to 1 in 10 women):**

- Vaginal yeast infection, sometimes called thrush
- Mood problems such as depression, change in mood or mood swings, anxiety, crying
- Dizziness
- Migraine
- Stomach ache or bloating
- Vomiting or diarrhoea
- Acne, skin rash, skin itching or skin irritation
- Muscle spasms
- Breast problems such as pain, enlargement or lumps in the breast
- Changes in menstrual bleeding pattern, uterine cramps, painful periods, vaginal discharge
- Problems where the patch has been on the skin such as redness, irritation, itching or rash
- Feeling tired or generally unwell
- Weight gain.

### **Uncommon side effects (may affect up to 1 in 100 women):**

- Allergic reaction, hives
- Swelling due to water retention in the body
- High levels of fats in the blood (such as cholesterol or triglycerides)
- Problems sleeping (insomnia)
- Less interest in sex
- Eczema, redness of the skin
- Abnormal breast milk production
- Premenstrual syndrome
- Vaginal dryness
- Other problems where the patch has been on the skin
- Swelling
- High blood pressure or rise in blood pressure
- Increased appetite
- Hair loss
- Sensitivity to sunlight.

**Rare side effects (may affect 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 stroke-like symptoms, known as a transient ischaemic attack (TIA)
  - blood clots in the liver, stomach/intestine, kidneys or eye.

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

- Breast, cervical or liver cancer
- Problems where the patch has been on the skin such as skin rash with blisters or ulcers
- Non-cancerous (benign) tumours in your breast or liver
- Fibroids in the womb (uterus)
- Anger or feeling frustrated
- Increased interest in sex
- Abnormal taste
- Problems when wearing contact lenses
- Sudden sharp increase in blood pressure (hypertensive crisis)
- Inflammation of the gall bladder or colon
- Abnormal cells in your cervix
- Brown spots or patches on the face
- Gallstones or blockage of the bile duct
- Yellowing of the skin and whites of the eyes
- Abnormal blood sugar or insulin levels
- Swelling of face, mouth, throat, or tongue
- Skin rash with tender red nodules on the shins and legs
- Itchy skin
- Scaly, flaky, itchy and red skin
- Suppressed lactation
- Vaginal discharge
- Fluid retention in legs
- Fluid retention

- Swelling in the arms, hands, legs or feet.

### **If you have an upset stomach**

- The amount of hormones you get from EVRA should not be affected by being sick (vomiting) or diarrhoea
- You do not need to use extra contraception if you have an upset stomach.

You may have spotting or light bleeding or breast tenderness or may feel sick during the first 3 cycles. The problem will usually go away but if it doesn't, check with your doctor or pharmacist.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

## **5. How to store EVRA**

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

Do not use this medicine after the expiry date, which is stated on the label after "EXP". The expiry date refers to the last day of that month.

Store in the original container to protect from light and moisture.

Do not refrigerate or freeze.

Used patches still contain some active hormones. To protect the environment, the patches should be disposed of with care. To discard the used patch, you should:

- Peel back the disposal label on the outside of the sachet
- Place the used patch within the open disposal label so that the sticky surface covers the shaded area
- Close the label sealing the used patch within and discard, keeping out of reach of children.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What EVRA contains**

The active substances are norelgestromin and ethinyl estradiol. Each 20 cm<sup>2</sup> transdermal patch contains 6 mg norelgestromin and 600 micrograms ethinyl estradiol. The active substances are released over 7 days with an average of 203 micrograms norelgestromin and 34 micrograms ethinyl estradiol being released each 24 hours.

The other ingredients are: backing layer: low-density pigmented 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 EVRA looks like and contents of the pack**



EVRA is a thin, beige, plastic transdermal patch stamped “EVRA”. The sticky adhesive side is stuck to the skin after removal of the clear, plastic, protective covering.

EVRA is available in the following pack sizes: Cartons containing 3, 9 or 18 patches in individual foil-lined sachets, wrapped per three in a transparent perforated plastic film.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder: Janssen-Cilag International N.V. Turnhoutseweg, 30, B-2340 Beerse, Belgium.

Manufacturer: Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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**Other sources of information**

Detailed information on this medicine is available on the European Medicines Agency web site:  
<http://www.ema.europa.eu>.