PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed with a doctor's prescription only

Medicine name and its form:

EVRA®
Transdermal patch

The active ingredients and their quantities:
Norelgestromin 6 mg
Ethinyl estradiol 600 mcg
Inactive and allergenic ingredients in the preparation - see section 6 - "Further information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.
It is important to know that combined hormonal contraceptives (like EVRA) may slightly increase the risk of development of a blood clot in the veins and arteries, especially in the first year of use or when restarting a combined hormonal contraceptive (like EVRA) following a break of 4 or more weeks. Be alert and refer to a doctor if symptoms of a blood clot occur (see in section 2 "Blood clots").

1. WHAT IS THE MEDICINE INTENDED FOR?

Female contraception. EVRA is intended for women of fertile age.
EVRA is a transdermal patch that contains two types of sex hormones, a progestogen, called norelgestromin, and an estrogen, called ethinyl estradiol.
Since the medicine contains two hormones, it is called a combined hormonal contraceptive used to prevent pregnancy.
Therapeutic group: Combined contraceptive patch.

2. BEFORE USING THE MEDICINE

Before using EVRA, read the information regarding blood clots found in section 2. It is important to carefully read about the symptoms indicative of blood clots (see in section 2 - "Blood clots").

Do not use the medicine if:
- you are sensitive (allergic) to norelgestromin, ethinyl estradiol or to any of the other ingredients of the medicine (listed in section 6 in this leaflet – "Further information").
- you are suffering, or have suffered in the past, from a blood clot in a blood vessel of the legs (Deep Vein Thrombosis or DVT), in the lungs (Pulmonary Embolism or PE), or in other organs.
- you are suffering from a disorder that affects blood clotting - e.g., protein C deficiency, protein S deficiency, antithrombin III deficiency, Factor V Leiden or antiphospholipid antibodies.
- you are due to undergo surgery or if you will be immobile (you will not be able to walk) for a long time (see in section - "Blood clots").
- you have suffered in the past from a heart attack or a stroke.
- you are suffering, or have suffered in the past, from angina pectoris (a condition that causes severe chest pain and may be the first sign of a heart attack) or from transient ischaemic attack (temporary stroke symptoms).
- you are suffering from a disease that may increase the risk of a blood clot in the arteries, such as:
  - Severe diabetes with blood vessel damage.
  - Severe hypertension.
  - Very high levels of fats in the blood (cholesterol or triglycerides).
  - A condition called hyperhomocysteinaemia.
- you are suffering, or have suffered in the past, from a type of migraine called 'Migraine with aura'.
- you have been told that you may be at risk of breast cancer or cancer of the womb, cervix or vagina.
- you have suffered from liver tumours or from liver disease that caused impaired liver function.
- you are suffering from unexplained vaginal bleeding.
- you are suffering from hepatitis C and are taking medicines containing ombitasvir/paritaprevir/ritonavir and dasabuvir (also see in section "**If you are taking or have recently taken other medicines**...").

Do not use EVRA if any of the above-mentioned conditions applies to you. If you are unsure, consult the doctor or pharmacist before using EVRA.

Special warnings regarding use of the medicine:
Seek urgent medical attention if you notice that you are suffering from symptoms that could be indicative of a blood clot in the leg (Deep Vein Thrombosis or DVT), a blood clot in the lungs (Pulmonary Embolism), a heart attack or a stroke (see "Blood clots" section below).
For a description of the symptoms of these serious side effects, please see the "How to recognize formation of blood clots" section later in the leaflet.

Warnings and precautions
Before starting to use EVRA, see a doctor for a medical check-up.

Consult a doctor before using EVRA if you suffer from the following conditions:
Tell the doctor if you are suffering from any of the following conditions, or if any of the following conditions develops or worsens during the course of treatment with EVRA.
- Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease).
- systemic lupus erythematosus (SLE), an autoimmune disease that affects the immune system.
- a blood clotting problem that causes kidney failure, called Haemolytic Uraemic Syndrome (HUS).
- sickle cell anaemia (an inherited disease of the red blood cells).
- high levels of fats in the blood (hypertriglyceridaemia) or a family history of this condition. Hypertriglyceridaemia is found to be associated with increased risk of developing pancreatitis.
- If you are due to undergo surgery, or if you will be immobile (you will not be able to walk) 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. Consult the doctor regarding how soon after delivery you can start using EVRA.
- inflammation in the veins under the skin (Superficial thrombophlebitis).
- varicose veins.

Blood clots
Using a combined contraceptive, such as EVRA, increases the risk of formation of blood clots compared with the risk in women who do not use such preparations. In rare cases, a blood clot can block blood vessels and cause serious problems.
Blood clots can develop:
- in veins (venous thrombosis, venous thromboembolism)
- in the arteries (arterial thrombosis or arterial thromboembolism)

Sometimes, recovery from blood clots is not complete. Rarely, there may be lasting effects and, very rarely, there may be fatal effects.
It is important to remember that the overall risk of formation of harmful blood clots due to use of EVRA is small.

How to recognize formation of blood clots?
Seek urgent medical attention if you notice that you are suffering from any of the following signs or symptoms:

Are you experiencing any of the following signs?	**What are you likely to be suffering from?**
• swelling of one leg or along a vein in the leg or foot, especially when accompanied by: ✓ pain or tenderness in the leg which may only be felt when standing or walking ✓ increased warmth in the swollen leg ✓ change in colour of the skin of the leg, e.g., turning pale, red or blue	Deep vein thrombosis
• sudden unexplained breathlessness or rapid breathing • sudden cough without an obvious cause, which may bring up blood • sharp chest pain which can worsen with deep breathing • severe dizziness • rapid or irregular heartbeat • severe stomach pain If you are unsure, please refer to the doctor, as symptoms such as coughing or shortness of breath may be mistaken for a milder condition of respiratory tract infection (e.g., a common cold).	Pulmonary embolism
Symptoms that most commonly occur in one eye: • immediate loss of vision • painless blurring of vision which may progress to loss of vision	Retinal vein thrombosis (blood clot in the eye)
• chest pain, discomfort, pressure or heaviness • sensation of squeezing or fullness in the chest, arm or below the breastbone • feeling of fullness, indigestion or choking feeling • upper body discomfort radiating to the back, jaw, throat, arm and stomach • sweating, nausea, vomiting or dizziness • extreme weakness, anxiety, or shortness of breath • rapid or irregular heartbeat	Heart attack
• sudden weakness or numbness of the face, leg or hand, 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 Sometimes, the symptoms of stroke are brief, with immediate and full recovery, but you should still seek immediate medical attention for fear of an additional stroke.	Stroke
• swelling, slight blue discolouration of the extremities • severe stomach pain (acute abdomen)	Blood clots blocking other blood vessels

Blood clots in a vein
What can happen when a blood clot forms in a vein?
- The use of combined hormonal contraceptive has been associated with an increased risk of formation of blood clots in a vein (venous thrombosis). However, these side effects are rare. Mostly, these side effects occur in the first year of use of this type of preparation.
- If a blood clot forms in a vein in the leg or foot, it may cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and reaches the lungs, it may cause a pulmonary embolism.
- Very rarely, a blood clot may form in the vein of other organs, 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 preparation (the same preparation or a different preparation from the same group) after a break of 4 weeks or more.
After the first year, the risk gets smaller, but is always slightly higher than in the population who is not taking a combined hormonal contraceptive.
When you stop using EVRA, the risk of developing blood clots returns to normal within a few weeks.

What is the risk of developing a blood clot?
The risk depends on your natural risk of venous thromboembolism (VTE) and on the type of combined hormonal contraceptive you are taking.
The overall risk of developing a blood clot in the leg or lung (deep vein thrombosis or pulmonary embolism) with EVRA is low.
- About 2 out of 10,000 women who are not taking a combined hormonal contraceptive and are not pregnant will develop a blood clot in a year.
- About 5-7 out of 10,000 women who are taking a combined hormonal contraceptive that contains levonorgestrel, norethisterone or norgestimate will develop a blood clot in a year.
- About 6-12 out of 10,000 women who are taking a combined hormonal contraceptive that contains etonogestrel or norelgestromin, such as EVRA, will develop a blood clot in a year.
- The risk of developing a blood clot varies according to your medical history (see "Factors that increase the risk of developing a blood clot" further on in this section).

	The risk of developing a blood clot in a year
Women **who are not using** a combined hormonal contraceptive (pill, patch, ring) and are not pregnant	About 2 out of 10,000 women
Women using a combined hormonal contraceptive pill containing **levonorgestrel, norethisterone or norgestimate**	About 5-7 out of 10,000 women
Women using EVRA	About 6-12 out of 10,000 women

Factors that increase the risk of developing a blood clot in a vein
The risk of developing a blood clot in women using EVRA is low, but some conditions increase this risk. Your risk is higher:
- if you are very overweight (body mass index [BMI] over 30 kg/m^2).
- if a member of your immediate family has had a blood clot in the leg, lung or other organ at a young age (below the age of 50). In this case you may have a hereditary blood clotting disorder.
- if you need to undergo surgery, or if you will be immobile (unable to walk) for a long time because of an injury, illness, or if your leg is in a cast. The use of EVRA may need to be stopped several weeks before the surgery or during the period when you are less mobile. If you need to stop treatment with EVRA, please consult the doctor on when you can start treatment with EVRA again.
- as you get older (particularly above about the age of 35).
- if you have given birth within the past few weeks.

The risk of developing a blood clot increases as the number of the above-mentioned factors you are suffering from increases.
Air travel for over 4 hours may temporarily increase the risk of developing a blood clot, particularly if you are suffering from some of the above-mentioned factors.
Please inform the doctor if you are suffering from any of the above-mentioned factors, even if you are unsure. The doctor may decide that you must stop treatment with EVRA.
If any of the above-mentioned factors changes during the course of treatment with EVRA, for example, a member of your immediate family experiences a thrombosis for an unknown reason, or if you gain a lot of weight, tell the 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. For example, a heart attack or a stroke.

Factors that increase the risk of developing a blood clot in an artery
It is important to note that the risk of a heart attack or stroke due to use of EVRA is very low but can increase:
- with increasing age (above the age of 35).
- **if you smoke.** When using a combined hormonal contraceptive like EVRA, it is recommended to stop smoking. If you are unable to stop smoking and you are above the age of 35, the doctor may advise you to use a different contraceptive.
- if you are overweight.
- if you suffer from hypertension.
- if a member of your immediate family had a heart attack or a stroke at a young age (below the age of 50). In this case, you could also have a higher risk of 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 suffer from migraines, especially migraines with aura.
- if you suffer from a heart problem (a valve problem, a heart rhythm disturbance called atrial fibrillation).
- if you suffer from diabetes.

If you suffer from more than one of the above-mentioned factors, or if any of them are particularly severe, the risk of developing a blood clot is higher.
If any of the above-mentioned factors changes during the course of treatment with EVRA, for example, if you start smoking, a member of your immediate family experiences a thrombosis for an unknown reason, or if you gain a lot of weight, tell the doctor.

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

In addition, refer to the doctor, pharmacist or nurse before using EVRA if you suffer from any of the following conditions or if they worsen during the course of treatment with EVRA:
- you might be pregnant.
- headaches that got worse or happen more often.
- you weigh 90 kg or more.
- you suffer from hypertension or your blood pressure gets higher.
- you suffer from gallbladder disease including gallstones or inflammation of the gallbladder.
- you suffer from porphyria (a blood disease).
- you suffer from Sydenham's chorea, a problem of the nervous system involving sudden movements of the body.
- you have suffered from herpes gestationis, a skin rash with blisters during pregnancy.
- you suffer from a decrease in hearing.
- you suffer from diabetes.
- you suffer from depression.
- you suffer from epilepsy or any other condition that causes convulsions.
- you suffer from liver problems, including yellowing of the skin and eyes (jaundice).
- you suffer or have suffered from "pregnancy spots". These are yellowish-brown patches, primarily on the face (called chloasma). These spots may not go away completely, even after you stop using EVRA. Protect the skin from sunlight or ultraviolet radiation to help prevent you from getting these spots or prevent existing spots from getting worse.
- you suffer from kidney problems.

If you are not sure if any of the above-mentioned conditions applies to you, consult the doctor or pharmacist before using EVRA.

Sexually transmitted diseases
EVRA does not protect against infection with HIV (AIDS) or other sexually transmitted diseases. These diseases include: chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B (jaundice), syphilis. Always use a condom to protect yourself from these diseases.

Medical tests
If you undergo any blood or urine tests, tell the doctor/laboratory staff that you are using EVRA, because the results of some laboratory tests can be affected by it.

Children and adolescents
EVRA has not been tested in young and adolescent girls under 18 years of age. EVRA must not be used in young and adolescent girls who have not yet had their first menstrual period.

Drug Interactions:

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Do not use EVRA if you have hepatitis C and are taking the medicines containing ombitasvir/paritaprevir/ritonavir and dasabuvir as this may increase liver function blood test results (increase in ALT liver enzyme). Your doctor will prescribe another type of contraceptive prior to starting treatment with these medicines. You can take EVRA again approximately 2 weeks after completion of this treatment. See section "Do not use the medicine if".
In particular, inform the doctor or pharmacist if you are taking:
Certain medicines and herbal therapies may impair the effectiveness of EVRA. When EVRA does not work, you may become pregnant or experience unexpected bleeding.
These include medicines used for the treatment of:
- certain medicines for the treatment of HIV infection (AIDS) and hepatitis C virus infections (called protease inhibitors and non-nucleoside analog reverse transcriptase inhibitors e.g., ritonavir, nevirapine and efavirenz)
- medicines for the treatment of infections (e.g., rifampicin and griseofulvin)
- anti-seizure medicines (e.g., barbiturates, topiramate, phenytoin, carbamazepine, primidone, oxcarbazepine, and felbamate)
- a medicine to treat pulmonary hypertension (bosentan)
- St. John's wort (an herbal therapy).

If you are taking any of the above-mentioned medicines, you may need a different contraceptive method (e.g., condom, diaphragm or foam). The interfering effect of some of the above-mentioned medicines may last for up to 28 days after discontinuing taking them. Consult the doctor or pharmacist about using a different contraceptive if you use EVRA and are concomitantly taking any of the above-mentioned medicines.
EVRA may affect the effectiveness of the following medicines:
- medicines containing ciclosporin
- lamotrigine for the treatment of epilepsy (may increase the risk of convulsions).

The doctor may need to adjust the dosage of the additional medicine. Consult the doctor or pharmacist before taking any medicine.

Pregnancy and breastfeeding
- Do not use the preparation if you are pregnant or may be pregnant.
- Stop using EVRA immediately if you become pregnant.
- Do not use the preparation if you are breastfeeding or are planning to breastfeed.

If you may be pregnant or are planning to become pregnant, consult the doctor or pharmacist before using the medicine.

Driving and use of machines
You can drive and operate machines when using EVRA.

Risks in using combined hormonal contraceptives
The information provided below is based on data about combined birth control pills. Since EVRA is a transdermal patch containing hormones similar to those used in combined birth control pills, it is likely to have the same risks. All combined birth control pills have risks, that may lead to disability or death. It has not been shown that a transdermal patch like EVRA is safer than combined birth control pills taken by mouth.

Cancer and combined hormonal contraceptives
Cervical cancer:
The prevalence of cervical cancer has been found to be higher in women who used combined hormonal contraceptives. However, this increased prevalence may be associated with other causes including sexually transmitted disease.

Breast cancer:
The prevalence of breast cancer has been found to be higher in women who used combined hormonal contraceptives. However, it is possible that the combined hormonal contraceptives are not the cause of more women having breast cancer; rather, it may be that women using combined hormonal contraceptives are examined more often, and there is therefore a greater chance of diagnosing breast cancer. The increased risk gradually declines after discontinuing use of combined hormonal contraceptives. After 10 years, the risk is the same as for women who have never used combined hormonal contraceptives.

Liver cancer:
In rare cases, liver tumours which are not cancerous have been found in women who used combined hormonal contraceptives. More rarely, cancerous liver tumours have been found. Such a tumour can cause internal bleeding with strong pain in the stomach area.
If this happens, report to your doctor immediately.

3. HOW SHOULD EVRA BE USED?

Always use EVRA according to the doctor's or pharmacist's instructions.
Check with the doctor or pharmacist if you are uncertain about the medicine dosage and treatment regimen.
The dosage and treatment regimen will be determined by the doctor only.
Do not exceed the recommended dose.
Do not swallow!
This medicine is intended for external use only.
- If you do not use it as per the instructions, you increase the risk of getting pregnant.
- Ask the doctor or pharmacist if you are uncertain.
- Always keep non-hormonal contraceptives (e.g., condoms, foam or contraceptive sponge) as a back-up in case of any 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:
- Start using EVRA on the first day of your next period.
- If one or more days have elapsed since the start of your period, please refer to the doctor about temporarily using a non-hormonal contraceptive.

If you switch from an oral contraceptive pill to EVRA:
If you are switching from an oral contraceptive pill to EVRA
- 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:
- Use a non-hormonal contraceptive until Day 8, on which you change the patch.

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

Switching from a progestogen-only pill, an implant or a contraceptive injection to EVRA:
- You may start using EVRA any day after stopping the progestogen-only pill or on the day of removal of the implant or on the day you are supposed to inject the contraceptive preparation.
- Put on the patch the first day after stopping the progestogen-only pill, the day of removing the implant or when you were supposed to inject the contraceptive preparation.
- Use a non-hormonal contraceptive until Day 8, on which you change a patch.

After a miscarriage or abortion *before* 20 weeks of pregnancy
- Please consult the doctor.
- You may start treatment with EVRA right away.

If one or more days have elapsed since your miscarriage or abortion until you start using EVRA, consult the doctor about temporarily using a non-hormonal contraceptive.

After miscarriage or abortion *after* 20 weeks of pregnancy
- Please consult the doctor.

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

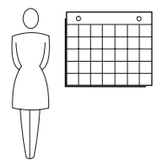
After delivery
- Please consult the doctor.
- If you have had a baby and are not breastfeeding, EVRA can only be used after 4 weeks from the delivery have passed.
- If you start using EVRA more than 4 weeks after delivery, please use another non-hormonal contraceptive in addition to EVRA for the first 7 days.

If you have had sex since the delivery, please wait for your first period or see your doctor to make sure you are not pregnant before you start using EVRA.

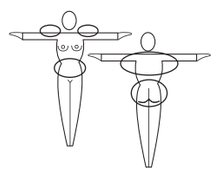
If you are breastfeeding
- Please consult the doctor.
- Do not use this preparation if you are breastfeeding or are planning to breastfeed (see also section 2 - "Pregnancy and breastfeeding").

Important information to follow when using the patch:
- Change the EVRA patch on the same day of the week, since the patch is designed to work over 7 days.
- Do not stop using the EVRA patch and remove it for more than 7 days in a row (in the week without a patch).
- Always put on only one patch at a time.
- Do not cut or tamper with the patch.
- 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 make-up on the skin where you are placing the patch or near a patch you are already wearing, since this may make the patch fall off the skin.
- Do not put a new patch on the same area of skin from which you removed the old patch. If you put on the patch on the same area, you may cause irritation.
- Check each day that the patch has not fallen off.
- Keep using the patches even if you do not have sex very often.

How to use EVRA:
If this is the first time you are using EVRA, wait until the day you get your menstrual period.
- Apply the 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, on which you change the patch.
- ***The day you apply the first patch will be Day 1. The "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 the patch on clean, dry and hairless skin.
- The patch can be put on the buttock, abdomen, upper outer arm or upper back only, in places where the patch will not be rubbed by tight clothing.
- **Never put the patch on the chest.**



Using your fingers, open the aluminium 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 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 protective covering as you remove the patch.***

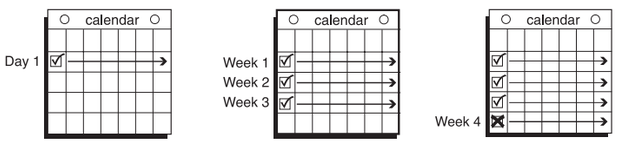
- Take off half of the clear protective covering (see picture).

Avoid touching the sticky surface of the patch.

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

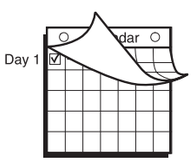
Leave the patch on for 7 days (one week).
- On the first "Patch Change Day", Day 8, take off the used patch.
- Put on a new patch immediately.
- On Day 15 (Week 3), take off the used patch.
- Put on a new patch immediately.

This makes a total of 3 weeks using the patches.



To avoid irritation, do not put a new patch on exactly the same area of the skin as the last patch.
Do not put on a patch in Week 4 (Day 22 through Day 28).
- **You should have your period during this week.**
- During this week you are protected from getting pregnant only if you put on the next patch on time.

The next four-week cycle
- Put on a new patch on your normal "Patch Change Day", which is the day after Day 28.
- ***Do this no matter when your period begins or ends.***



If you want to change the "Patch Change Day" to a different day of the week, consult your doctor. You should complete the treatment cycle and remove the third patch on the regular Change Day. During Week 4 (without a patch), you may pick a new Patch Change Day and apply the first patch on that day. In any case, you should never go more than 7 days in a row without a patch.

If you want to delay your period, please apply a fourth patch at the start of Week 4 (Day 22) instead of not wearing a patch that week. You may experience light or breakthrough bleeding. Do not continue treatment beyond 6 patches in a row (6 consecutive weeks of treatment) . If you have worn 6 patches in a row (6 consecutive weeks of treatment), do not put on another patch in week 7. After a break of 7 days without a patch, apply a new patch and start a new treatment cycle, using this as Day 1 of the treatment. Please consult the doctor before you delay your period.

Everyday activity while using the patches
- Normal activities such as having a bath, shower, sauna and exercising should not affect the patch action.
- The patch was designed to stay in place during these activities.
- However, you should check that the patch has not fallen off after doing these activities.

If you need to place a new patch on a new area of the body on a day other than your regular "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 applied in a different place of the body until the regular "Patch Change Day" arrives.
- Only one patch can be used at a time.

If you have trouble remembering to change your EVRA patch:
Consult the doctor, pharmacist or nurse regarding how to make changing the patches easier or regarding use of another contraceptive method.

If the patch becomes loose, lifts at the edges or falls off:
For less than one day (up to 24 hours):
- Try to put the same patch on again or immediately put on a new patch.
- Back-up contraception is not needed.
- Your "Patch Change Day" should remain the same.
- Do not try to put the same patch back on:
  - if it is no longer sticky.
  - if it has became stuck to itself or another surface.
  - if it has other material stuck to it.
  - if it is the second time it has become loose or if it has fallen off before.
- Do not use any tape or wrappings to keep the patch in place.
- If you cannot put the same patch back on, immediately put on a new patch.

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 during the first week (7 days) of the new cycle.

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

If you forget to change the patch
At the start of any new patch cycle (Week 1 (Day 1)):
If you forget to put on your patch, you are at high risk of becoming pregnant.
- Use non-hormonal contraception as back-up for one week (7 days).
- Put on 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 the patch cycle (Week 2 or 3):
If you forget to change the patch for one or two days (up to 48 hours):
- Put on a new patch as soon as you remember.
- Put on the next patch on your normal "Patch Change Day".

No back-up contraception is needed.

If you forget to change the patch for more than 2 days (48 hours or more)**:**
- If you forget to change the patch for more than two days, you may become pregnant.
- 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 non-hormonal contraception during the first week (7 days) of the new cycle.

At the end of the patch cycle (Week 4):
If you forget to take off the patch:
- Take it off as soon as you remember.
- Start the next cycle on the normal "Patch Change Day", which is the day after Day 28.

No back-up contraception is needed.

If you have no period or have irregular bleeding while using EVRA:
EVRA may cause unexpected vaginal bleeding and spotting during the weeks when you are wearing the patch.
- This effect usually stops after the first few cycles.
- Improper use may also cause spotting or light bleeding.
- Continue using this preparation and if the bleeding lasts beyond the first three cycles, consult the doctor or pharmacist.

If you do not get your period during the patch-free week (Week 4), you should continue applying a new patch on the usual "Patch Change Day".
- If you have been using EVRA according to the instructions 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, consult the doctor or pharmacist as you may be pregnant.

If you used more than one patch at any time:
Take the patches off and refer to a doctor immediately.
Use of more than one patch at any time may cause:
- nausea and vomiting
- vaginal bleeding

If you stopped using EVRA:
You may get irregular, little or no menstruation, especially in the first three months and particularly if the menstruation was irregular before you started using EVRA.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have any further question on the use of EVRA, refer to a doctor, pharmacist or nurse.

4. SIDE EFFECTS

As with any medicine, use of EVRA may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
If you notice any undesirable effects, particularly if they are persistent and severe, inform your doctor.
An increased risk of blood clots in the veins (VTE - venous thromboembolism) or blood clots in the arteries (ATE - arterial thromboembolism) exists in women taking combined hormonal contraceptives. For more information on the different risks in taking combined hormonal contraceptives - see section 2 "Before using the medicine".

Very common side effects (effects occurring in more than 1 in 10 women):
- Headache
- Nausea
- Breast tenderness.

Common side effects (effects occurring in 1-10 in 100 users):
- Vaginal thrush
- Mood disorders such as depression, mood swings or changes in mood, anxiety, crying
- Dizziness
- Migraine
- Stomach ache or bloating
- Vomiting or diarrhoea
- Acne, skin rash, skin itching or 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
- Skin reaction where the patch has been placed (redness, irritation, itching or rash)
- Feeling tired or generally unwell
- Weight gain.

Uncommon side effects (effects occurring in 1-10 in 1,000 users):
- Allergic reaction, hives
- Swelling due to fluid retention in the body
- High levels of fats in the blood (cholesterol or triglycerides)
- Problems sleeping (insomnia)
- Less interest in sex
- Eczema or redness of the skin
- Abnormal breast milk production
- Premenstrual syndrome
- Vaginal dryness
- Various reactions on the skin where the patch has been placed
- Swelling
- A rise in blood pressure or high blood pressure
- Increased appetite
- Hair loss
- Sensitivity to sunlight.

Rare side effects (effects occurring in 1-10 in 10,000 users):
- Harmful blood clots in veins or arteries, such as:
  - in the legs or feet
  - in the lungs
  - heart attack
  - stroke
  - mini-stroke or transient ischaemic attack (stroke-like symptoms)
  - blood clots in the liver, stomach/intestines, kidneys or eyes

  The chance of having a blood clot can increase if you suffer from other factors that increase this risk (see section 2 for more information on the factors that increase the risk for blood clots and the symptoms of a blood clot).
- Breast, cervical or liver cancer
- Skin reactions where the patch has been placed, such as a rash with blisters or ulcers
- Non-cancerous (benign) tumours in the breast or liver
- Fibroids in the uterus
- Anger or feeling frustrated
- Increased interest in sex
- Changes in taste
- Problems when wearing contact lenses
- Sudden sharp increase in blood pressure (hypertensive crisis)
- Inflammation of the gallbladder or colon
- Abnormal growth of cells in the cervix
- Brown 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
- A severe allergic reaction that may include swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- Skin rash with red tender nodules on the legs and shins
- Itchy skin
- Red, itchy, flaky or scaly skin
- Suppressed lactation
- Vaginal discharge
- Oedema in the legs
- Oedema
- Swelling in the arms, hands, legs or feet.

If you have digestive system problems
- The amount of hormones absorbed from EVRA is not affected by vomiting or diarrhoea.
- There is no need for extra contraception if you have digestive system problems.

You may have spotting or light bleeding or breast tenderness or nausea during the first 3 cycles. The problem will usually go away, but if not, consult the doctor or pharmacist.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD EVRA BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
Do not use EVRA after the expiry date (EXP DATE) that appears on the package. The expiry date refers to the last day of that month.
Do not store above a temperature of 25°C.
Store the patches in their protective sachet, in the original package to protect them from light and moisture.
Do not store in the refrigerator or freezer.

Used EVRA patch contains a certain amount of active hormones. In order to protect the environment, discard the used EVRA patch according to the following instructions:
- Peel back the sealing label on the outside of the aluminium sachet.
- Place the used patch inside, so that the sticky part of the patch will stick to the hidden part.
- Close the cover of the label with the used patch inside and then the patch can be disposed of. Keep out of the reach of children.

Do not throw away used patches into the toilet or household waste. Ask the pharmacist how to discard medicines that are not in use. These measures will help protect the environment.

6. FURTHER INFORMATION

The active ingredients are norelgestromin and ethinyl estradiol. Each 20 cm^2 transdermal patch contains 6 mg norelgestromin and 600 mcg ethinyl estradiol. The active ingredients are released from the patch over 7 days, at a rate of 203 mcg norelgestromin and 34 mcg ethinyl estradiol per 24 hours.
- In addition to the active ingredients, the medicine also contains Polyisobutylene/polybutene adhesive, Release Liner, Backing film, Crospovidone, Non woven Polyester fabric, Lauryl lactate.
- What the medicine looks like and the contents of the package

EVRA is a thin, beige, plastic, transdermal patch. The sticky part is stuck on the skin after removing the clear plastic that serves as a protective covering.
EVRA packs contain 3 or 9 patches, where each patch is individually packaged and each three patches are packaged in a transparent plastic package.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 130213081800

Importer and Registration Holder: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Revised in October 2020

EVRA PATCH PL SH 101120