

Package leaflet: Information for the user

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

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

Do not use EVRA:

- 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 had a blood clot (thrombosis) in your legs (deep vein thrombosis or DVT) or lungs (pulmonary embolism) or another part of your body
- if you have ever had a heart attack or a type of chest pain called ‘angina’
- if you have ever had a stroke or signs which may lead to stroke. This includes a slight, temporary stroke, without any after effects
- if you have bad headaches with neurological symptoms such as changes in vision or numbness in any part of your body (migraine with focal aura)
- if you have high blood pressure (160/100 mm Hg or above)
- if you have diabetes with damaged blood vessels
- if you have an illness which runs in your family which affects fat levels in your blood (called dyslipoproteinemia)
- if you have an illness which runs in your family which affects the clotting of your blood (such as ‘protein C deficiency’ or ‘protein S deficiency’)
- 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.

Warnings and precautions

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

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, or any of your family, have high fat levels in the blood (triglycerides or cholesterol)
- You have high blood pressure or your blood pressure gets higher
- You have gallstones
- You have a blood problem called porphyria
- You have an immune system problem called 'SLE' (systemic lupus erythematosus)
- You have a blood problem which causes kidney damage called 'HUS' (haemolytic uremic syndrome)
- 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 an inflammatory illness of your gut (Crohn's disease or ulcerative colitis)
- 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:

- Medicines for HIV infection (such as ritonavir, nevirapine)
- Medicines for infection (such as rifampicin, griseofulvin, penicillins and tetracyclines)
- Medicines for epilepsy (such as topiramate, barbiturates, phenytoin, carbamazepine, primidone, oxcarbamazepine and felbamate)
- 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.

EVRA and venous and arterial blood clots (thrombosis)

Using combined hormonal contraceptives, including EVRA, increases the chances of getting a thrombosis (blood clots). It is possible that the risk of blood clots in the legs and/or lungs with EVRA is more than the risk with combined birth control pills. This risk of developing blood clots is not affected by how long you use the medicine. The risk returns to normal, a few months after you stop using the medicine.

Blood clots can cause a blockage in a vein or artery and this may make you permanently disabled or even cause death.

- Blood clots can form in a vein in your leg (deep vein thrombosis or DVT) and travel to the lungs. This can cause chest pain and make you breathless or collapse. This is called a 'pulmonary embolism' or PE
- Rarely, blood clots can form in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke)

- In extremely rare cases, blood clots can happen in other places such as the liver, gut, kidney or eye. Blood clots in the eye may cause loss of eyesight or double vision.

The risk of venous blood clots in users of combination hormonal contraceptives increases:

- with increasing age
- if one of your close relatives ever had a blood clot in the leg, lung (pulmonary embolism), or other organ. Your doctor may refer you to a specialist for advice about whether you should use EVRA
- if you have had or are going to have a major operation, especially one on a hip or leg, have been in a serious accident or need to have bed rest for a long time. Tell your doctor that you are taking EVRA as it may be necessary to stop using the contraceptive patch. Normally you should not use EVRA for four weeks before surgery and you should not resume until two weeks after you are back on your feet
- if you are overweight
- if your veins feel hard or tender to the touch or you have varicose veins

The risk of an arterial blood clot in users of combination hormonal contraceptives increases:

- with increasing age
- if you smoke. You are strongly advised to stop smoking when you use EVRA, especially if you are older than 35 years.
- if you have high levels of fat in your blood (cholesterol or triglycerides)
- if you are overweight
- if you have high blood pressure
- if you have a problem with your heart (a problem with a heart valve or a disturbance of the heart rhythm called atrial fibrillation)
- if one of your close relatives ever had a heart attack or stroke. Your doctor may refer you to a specialist for advice about whether you should use EVRA

Stop taking EVRA and contact your doctor immediately if you notice any possible signs of a blood clot, such as:

- severe pain and/or swelling in either leg
- sudden severe pain in the chest, which may reach the left arm
- sudden breathlessness
- sudden cough without an obvious cause
- any unusual, severe or long-lasting headache
- partial or complete blindness or double vision
- difficulty in speaking or inability to speak
- feeling dizzy or fainting spells
- weakness, strange feeling, or numbness on one side or in one part of the body
- difficulty walking or holding things
- sudden stomach pain

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

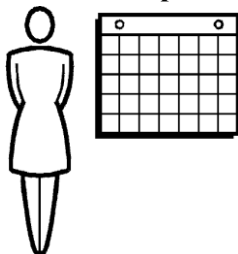
If you are breast-feeding

- 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

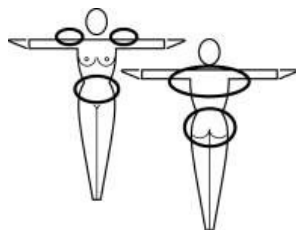
- Change EVRA on the same day of each week. This is because it is designed to work over 7 days
- Never go without wearing a patch for more than 7 days in a row
- Only wear one patch at a time
- Do not put the patch on skin that is red, irritated or cut
- To work properly the patch must stick firmly to 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.



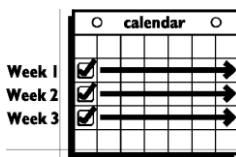
Put the patch on your skin

- 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.

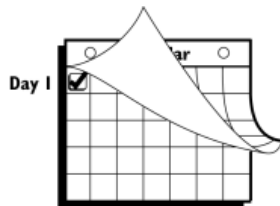
This makes a total of three weeks with the patches.

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, this medicine can cause side effects although not everybody gets them.

Tell your doctor if you notice any unwanted effects. If you think that you have a serious side effect when using EVRA, take off the patch and speak to your doctor or pharmacist immediately. In the meantime, you should use another method of contraception.

Serious side effects associated with combined hormonal contraceptives are described in Section 2 above (“What you need to know before you use EVRA”). Please read this section for additional information.

Very common side effects (affects more than 1 user in 10):

- Headache
- Nausea
- Breast tenderness.

Common side effects (affects 1 to 10 users in 100):

- Vaginal yeast infection, sometimes called thrush
- Mood problems such as depression, change in mood or mood swings, anxiety, crying
- Feeling dizzy
- Migraine
- Stomach pain 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 (affects 1 to 10 users in 1,000):

- 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 (affects 1 to 10 users in 10,000):

- Blood clots in veins, blocked arteries, heart attack or stroke
- Non-cancerous (benign) tumours in your breast or liver
- Breast, cervical or liver cancer
- Fibroids in the womb (uterus)
- Anger or feeling frustrated
- Increased interest in sex
- Blood clot in the lung
- Inflammation of the gall bladder or colon
- Brown spots or patches on the face
- Abnormal blood sugar or insulin levels
- Gallstones or blockage of the bile duct
- Yellowing of the skin and whites of the eyes
- Abnormal taste
- Problems when wearing contact lenses.

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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 cm² 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>.