

PACKAGE LEAFLET: INFORMATION FOR THE USER

EVRA transdermal patch Norelgestromin and ethinyl estradiol

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others.
- 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.

In this leaflet:

1. What EVRA is and what it is used for
2. Before you use EVRA
3. Risks of using combined hormonal contraceptives
4. How to use EVRA
5. Possible side effects
6. How to store EVRA
7. Further information

1. What EVRA is and what is it used for

The name of your medicine is EVRA transdermal patch. It is called 'EVRA' in this leaflet. It is used to prevent pregnancy.

EVRA contains two types of hormones:

- norelgestromin
- ethinyl estradiol

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

2. Before you use EVRA

Do not use EVRA if:

- You are allergic (hypersensitive) to norelgestromin, ethinyl estradiol or any of the other ingredients in EVRA (listed in Section 7 below)
- You have ever had a heart attack or a type of chest pain called 'angina'
- You have ever had a stroke or signs which may lead to stroke. This includes a slight, temporary stroke, without any after effects
- You have high blood pressure (160/100 mmHg or above)
- You have diabetes with damaged blood vessels
- You have bad headaches with neurological symptoms such as changes in vision or numbness in any part of your body (migraine with focal aura)
- 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
- 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')
- You have very high fat levels in your blood (cholesterol or triglycerides)
- You have an illness which runs in your family which affects fat levels in your blood (called dyslipoproteinemia)

- You have ever had liver tumours or any problem with your liver
- You have ever been told you might have breast cancer or cancer of the womb, cervix or vagina
- You have unexplained vaginal bleeding.

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

Take special care with EVRA

Medical check-ups

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

Check with your doctor or pharmacist before using EVRA if you have any of the following or they happen or get worse while using EVRA:

- 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 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 hearing loss
- You have epilepsy or any other problem that can cause fits (convulsions)
- You have a problem of the nervous system involving sudden movements of the body called 'Sydenham's chorea'
- You have diabetes
- You have depression
- You have gallstones
- 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 had a skin rash with blisters during pregnancy (called 'herpes gestationis')
- You have 'pregnancy spots'. These are yellowish-brown patches or spots, especially on your face (called 'chloasma')
- You think you might be pregnant.

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

Taking other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

Certain medicines and herbal remedies 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 and griseofulvin)
- Medicines for epilepsy (such as topiramate, barbiturates, phenytoin sodium, carbamazepine, primidone, oxcarbamazepine and felbamate)

- Medicine for high blood pressure in the blood vessels in the lungs (bosentan)
- St. John's Wort - an herbal remedy used for depression.

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.

Blood levels of estrogen from EVRA may be increased if you take certain medicines or drink grapefruit juice.

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

- medicines containing ciclosporin
- the anti-epileptic lamotrigine

(This can increase the risk of fits (seizures)).

Ask your doctor or pharmacist for advice before taking any medicine.

Using EVRA with food and drink

It is not expected that food or drink will affect the way EVRA works.

Pregnancy and breast-feeding

- Do not use EVRA if you are pregnant or think you may be pregnant
- Do not use EVRA if you are breast-feeding or planning to breast-feed.

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy or while breast-feeding.

Driving and using machines

You can drive or operate machinery while using EVRA.

Sexually transmitted disease

EVRA 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

- Tell your doctor or the person taking the sample, if you are having a blood or urine test. This is because EVRA may affect some results of the tests.

3. 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 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
- Very 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.

Tell your doctor immediately if you notice any possible signs of a blood clot, such as:

- Pain or swelling in either leg
- Pain in the chest, which may spread to the arm
- Sudden shortness of breath or sudden coughing
- Unusual, severe or long-lasting headache
- Vision problems
- Difficulty speaking
- Feeling dizzy or fainting spells
- Feeling weak or numb on one side or one part of the body
- Difficulty walking or holding things
- Sudden stomach pain

If you think you might have any of these, talk to your doctor immediately.

Your chance of getting a blood clot increases:

- As you get older
- If blood clots in blood vessels (veins or arteries) runs in the family
- If you smoke, especially if you are over 35 years of age
- If you stay in bed for many days
- If you are very overweight
- If you have just had a baby, miscarriage or abortion
- If you have had a serious injury, particularly of the leg or hip
- If you have had or are going to have a major operation or need to have bed rest for a long time. Normally you should not use EVRA for two weeks before or two weeks after surgery
- If you have ever had blood clots before
- If you have problems with your blood fats (cholesterol or triglycerides)
- If you have high blood pressure
- If you have heart problems (problems with heart valves, abnormal heart rhythm).

Combined hormonal contraceptives and cancer

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.

Cervical cancer

Cervical cancer also has been found more often in women taking combined hormonal contraceptives. However, this may be due to other causes. These include more sexual partners and sexually transmitted disease.

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.**

4. How to use EVRA

Always use EVRA exactly as described in this leaflet.

- 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.

Talk to your doctor about using EVRA after having a baby or after an abortion or miscarriage.

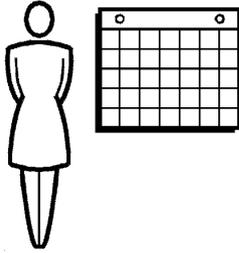
How many patches to use

- 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.

Important information to follow when using the patch

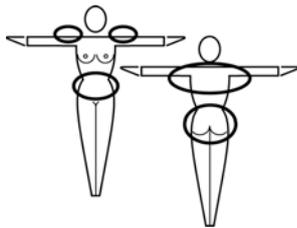
- Change EVRA on the same day of each week. This is because it is designed to work over 7 days
- Never go without wearing a patch for more than 7 days in a row
- Only wear one patch at a time
- Do not put the patch on skin that is red, irritated or cut
- To work properly the patch must stick firmly to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



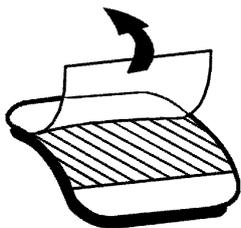
If this is the first time you are using EVRA, wait until the day you get your menstrual period.

- 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.**



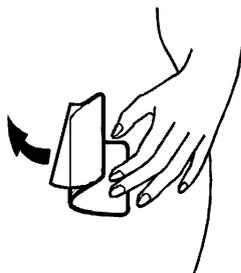
Choose a place on your body to put the patch.

- 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.



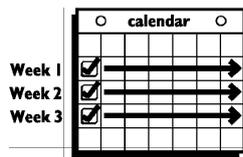
Put the patch on your skin

- 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)

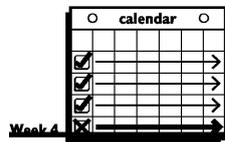
- On the first “Patch Change Day”, Day 8, take off the used patch
- Put on a new patch immediately.



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

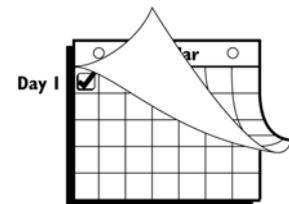
This makes a total of three weeks with the patches.

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.

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 or another healthcare professional at the clinic. 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 switch from the 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, 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 EVRA.

If you switch from the mini-pill to EVRA

- You may start EVRA any day after stopping the mini-pill
- The first day after stopping the mini-pill, put on a patch
- Use a non-hormonal contraceptive until Day 8, when you change your patch.

If you have absent or irregular bleeding with EVRA

EVRA 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 EVRA 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 EVRA 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 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 bleeding. This usually happens in the first 3 months and especially if your periods were not regular before you started using EVRA.

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

5. Possible side effects

Like all medicines, EVRA 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 3 above ("Risks of using combined hormonal contraceptives"). Please read this section for additional information.

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

- Headache
- Feeling sick (nausea)
- Breast tenderness.

Common side effects (affects less than 1 in 10 women):

- Vaginal yeast infection, sometimes called thrush
- Mood problems such as depression, change in mood or mood swings
- Feeling dizzy
- Migraine
- Stomach pain or bloating
- Being sick (vomiting) or diarrhoea
- Acne, skin itching or skin irritation
- Muscle spasms

- Breast pain or enlargement
- Uterine cramps, painful or heavy periods, bleeding between periods or 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 less than 1 in 100):

- Swelling due to water retention in the body
- High levels of fats in the blood (such as cholesterol or triglycerides)
- Uncontrollable emotions
- Anxiety
- Problems sleeping (insomnia)
- Less interest in sex
- Skin rash, redness of the skin
- Swelling of the breasts, lumps in the breast or abnormal breast milk production
- Premenstrual syndrome
- Vaginal bleeding or dryness
- Problems where the patch has been on the skin (such as swelling, discoloured skin, pain, spots, blisters or the skin feeling over-sensitive)
- Swelling
- Rise in blood pressure.

Rare side effects (affects less than 1 in 1000 women):

- Abnormal crying
- Increased interest in sex
- Blood clot in the lung
- Inflammation of the gall bladder
- Yellow-brown pigment spots on the face
- Irregular periods
- A bumpy rash (hives) where the patch has been on the skin
- Rise in cholesterol levels.

Very rare side effects (affects less than 1 in 10,000 women):

- Aggression
- Having more periods than normal.

Other side effects include:

- Other problems where the patch has been on the skin, skin reactions or allergic reactions
- Non-cancerous (benign) tumours in your breast or liver
- Breast, cervical or liver cancer
- Fibroids in the womb (uterus)
- Abnormal blood sugar, cholesterol or insulin levels
- Blood clots, blocked arteries, heart attack or stroke
- Problems when wearing contact lenses
- High blood pressure
- Inflammation of the colon
- Gallstones or blockage of the bile duct
- Abnormal taste
- Yellowing of the skin and whites of the eyes

- Hair loss
- Sensitivity to sunlight
- Less frequent, light or no periods
- Anger, feeling irritable or frustrated.

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.

6. How to store EVRA

Keep out of the reach and sight of children.

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

Do not refrigerate or freeze.

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

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.

Used patches should not be flushed down the toilet or placed in liquid disposal systems. Ask your pharmacist how to dispose of any patches no longer required. These measures will help to protect the environment.

7. Further information

What EVRA contains

The active substances in EVRA are norelgestromin 6mg and ethinyl estradiol 600 micrograms. 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 in the patch are polyisobutylene, polybutene, crospovidone, non-woven polyester fabric and lauryl lactate.

What EVRA looks like and contents of the pack

EVRA is a thin, beige, plastic transdermal patch. 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.

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 medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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