

EVRA TRANSDERMAL PATCH

Ethinylestradiol/Norelgestromin

Patient Information Leaflet

This leaflet answers some common questions about EVRA® Transdermal Patch. It does not contain all the available information. It also does not take the place of talking to your doctor or pharmacist.

What is EVRA® patch used for?

EVRA® contains two types of sex hormones, a progestogen called norelgestromin and an estrogen called ethinylestradiol. It is used to prevent pregnancy.

When should I use the medication?

EVRA® patch should be applied once a week for 3 weeks and stop for 1 week. Your menses should begin during the 7-day patch free period. Even if your menses is still ongoing, subsequent pack is to be started after the 7-day patch free period has elapsed.

A barrier method of contraception e.g. condoms, is recommended for the first 7 days the first time you begin using EVRA® patch.

How should it be used?

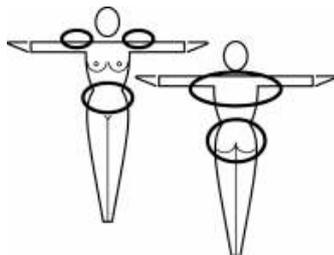
For the first pack of EVRA® patch, apply the first patch on the ____ day of your menses. Wear the patch for 7 days.

The day you apply your first patch will be Day 1.

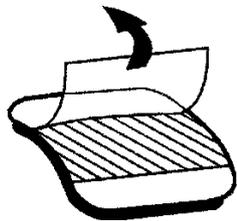
Your "Patch Change Day" will be on this day of the week every week.

Only wear one patch at a time. Do not cut or tamper the patch.

How to use EVRA® patch?



- Always put your patch on **clean, dry and hairless skin**.
- Put it on the **buttock, abdomen, upper outer arm or upper back**.
- Put it on places where it won't be rubbed by tight clothing.
- **Do not put on the breast or waistline, and on any open wounds, cuts or irritated skin.**
- Do not use adhesive or wraps to hold the patch in place
- Do not use creams, oils, lotions, powder or other skin care products on the application site. The patch may not stick well.
- To reduce skin irritation, change the site of application for each new patch.



- Do not use scissors. Use your fingers, open the foil sachet by tearing it along the edge
- There is a clear protective covering on the patch.
- Peel away half of the clear protective covering (refer to picture). Try not to touch the sticky surface.
(Some patches might stick to the inside of the sachet. Be careful not to remove the clear coverings as you remove the patch.)



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

Normal activities e.g. bathing or showering, using a sauna or exercising should not affect how well the patch works. The patch is designed to stay in place during these activities. However, you should check that the patch has not fallen off after doing these activities.

How should I discard used patches?

Used patches may still contain some active ingredients. To discard the used patch, you should close the label sealing the used patch within and discard, keeping out of reach of children.

What should I do if the patch becomes loose, lifts at the edges or falls off?

(a) For less than one day (up to 24 hours)

- Try to put it on again or put on a new patch immediately
- A barrier method of contraception is not needed.
- Your "Patch Change Day" remains the same.
- Do not use tapes or wrapping to keep the patch in place.

- Put on a new patch immediately, 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 looser or has fallen off

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

- Start a new cycle immediately by putting on a new patch.
- Use a barrier method for the first week of your new cycle.

What should I do if I forget to change my patch?

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

- Put on a new patch as soon as you remember
- Put on your next patch on your usual "Patch Change Day"
- A barrier method of contraception is not needed.

If you forget to change your patch for **more than two days (48 hours or more)**:

- Start a new four week cycle as soon as possible.
- You must use a barrier method for the first week of your new cycle.

If you forget to take off your patch (**at Week 4**):

- Take it off as soon as you remember.
- Start your next cycle on your normal "Patch Change Day", the day after Day 28.
- A barrier method of contraception is not needed.

If you forget to take off your patch (**after Week 4**):

- Take it off as soon as you remember.
- Put on the first patch of your new cycle as soon as you remember.
- You must use a barrier method for the first week of your new cycle.
- You now have a new "Patch Change Day" and new Day 1.

What side effects can this medicine cause? What can I do about them?

Spotting or bleeding may occur between your periods during the first 3 months of using EVRA® patch. However, if this continues after the third month, consult your doctor. Other common side effects include:

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| • nausea and vomiting | • intolerance to contact lenses |
| • bloating and abdominal cramps | • weight changes |
| • breast tenderness | • mood swings |
| • headache or migraine | • skin itching or skin irritation |

Consult your doctor about any symptom that becomes bothersome.

Using a combined hormonal contraceptive increases a woman's risk of developing blood clots compared with a woman not taking any combined hormonal contraceptive. The risk of developing blood clot in a vein is highest during the first year. Other risk factors of developing blood clots include smoking and obesity. However, blood clot formation is rare and the doctor would have evaluated and weighed its benefits over risks before making the recommendation.

Report to your doctor if you are experiencing any of the following symptoms:

- Any unusual sudden cough
- Severe pain in the chest which may reach the left arm
- Change in your speech, including slurring of words
- Change in your senses of hearing, smell or taste
- Breathlessness or difficulty in breathing
- Unusual, severe or long lasting headache or worsening of migraine
- Dizziness or fainting
- Severe pain in your abdomen
- Severe pain in legs or swelling in either of your legs.
- Weakness or numbness in any part of your body

Special instructions:

Other medications such as antibiotics or herbal remedies may reduce the effectiveness of EVRA® patch.

Be sure to inform other doctors/dentists about the hormonal contraceptives you are on if you are seeing them for other medical conditions.

If you miss your period, consult your doctor to determine if you are pregnant before continuing to take the next cycle of hormonal contraceptives.

Storage:

Store in its original container, protect from light and moisture. Do not refrigerate or freeze.



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