

PART III: CONSUMER INFORMATION

PrEVRA®
norelgestromin and ethinyl estradiol
Transdermal System

This leaflet is Part III of a three-part "Product Monograph" published when EVRA® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about EVRA®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- prevention of pregnancy

What it does:

EVRA® is a hormonal contraceptive patch that contains two female sex hormones (norelgestromin and ethinyl estradiol). The EVRA® patch sticks to the skin and continuously releases the hormones through the skin and into the blood stream. The EVRA® patch produces a hormone exposure pattern that is different from that of the birth control pill. Talk to your health professional about how this relates to your use of EVRA®.

Hormonal contraceptives, including EVRA®, have been shown to be highly effective in preventing pregnancy when taken as prescribed by your doctor. Pregnancy is always more risky than taking hormonal contraceptives, except in smokers older than age 35.

Hormonal contraceptives like EVRA® work in two ways:

1. they inhibit the monthly release of an egg by the ovaries
2. they change the mucus produced by the cervix. This slows the movement of the sperm through the mucus and through the uterus (womb).

Effectiveness of Hormonal Contraceptive Methods:

When EVRA® is used correctly, the chance of becoming pregnant is comparable to that of combination birth control pills, which are more than 99 percent effective in preventing pregnancy (when the pills are **taken as directed**, and the amount of estrogen is 20 µg or more).

A 99 percent effectiveness rate means that if 100 women used the contraceptive patch for one year, one woman in the group would get pregnant.

The chance of becoming pregnant increases with incorrect use.

Other Ways to Prevent Pregnancy:

Other methods of birth control are available to you. They are usually less effective than hormonal contraceptive methods such as the birth control pill or EVRA®. When used properly, however, other methods of birth control are effective enough for many women.

The following table gives reported pregnancy rates for various forms of birth control, including no birth control. The reported rates represent the number of women out of 100 who would become pregnant in one year.

Reported Pregnancies per 100 Women per Year:

Combination pill	less than 1 to 2
Intrauterine device (IUD)	less than 1 to 6
Condom with spermicidal foam or gel	1 to 6
Mini-pill	3 to 6
Condom	2 to 12
Diaphragm with spermicidal foam or gel	3 to 18
Spermicide	3 to 21
Sponge with spermicide	3 to 28
Cervical cap with spermicide	5 to 18
Periodic abstinence (rhythm), all types	2 to 20
No birth control	60 to 85

Pregnancy rates vary widely because people differ in how carefully and regularly they use each method. (This does not apply to IUDs since they are implanted in the uterus.) Regular users may achieve pregnancy rates in the lower ranges. Others may expect pregnancy rates more in the middle ranges.

The effective use of birth control methods other than the contraceptive patch may require more effort than replacing a single patch every week for three out of four weeks. It is an effort that many couples undertake successfully.

When it should not be used:

EVRA® is not suitable for every woman. In a small number of women, serious side effects may occur. Your doctor can advise you if you have any conditions that would pose a risk to you. The use of EVRA® should always be supervised by your doctor.

Do not use EVRA® if you have or have had any of the following conditions:

- blood clots in the legs, lungs, eyes, or elsewhere, or thrombophlebitis (inflammation of the veins)
- stroke, heart attack, or coronary artery disease (e.g., angina pectoris)
- disease of the heart valves with complications
- severe high blood pressure
- diabetes with complications
- known abnormalities of the blood clotting system that increase your risk for developing blood clots
- very high blood cholesterol or triglyceride levels
- over age 35 and smoke
- migraine headache

- you are scheduled for major surgery
- prolonged bed rest
- jaundice (yellowing of the eyes or skin), liver disease or liver tumour
- known or suspected cancer of the breast or uterus (womb) or other estrogen-dependent cancer
- unusual vaginal bleeding without a known reason
- loss of vision due to blood vessel disease of the eye
- you are pregnant or suspect you may be pregnant
- you are taking paritaprevir, ritonavir, ombitasvir with or without dasabuvir for the treatment of Hepatitis C
- allergy (hypersensitivity) to ethinyl estradiol, norelgestromin or to any of the other ingredients in EVRA[®] (see **What the medicinal ingredients are and What the nonmedicinal ingredients are**)

What the medicinal ingredients are:

norelgestromin; ethinyl estradiol

What the nonmedicinal ingredients are:

Backing layer: polyethylene outer layer and a polyester inner layer.

Middle layer: polyisobutylene/polybutene adhesive, crospovidone, non-woven polyester fabric, lauryl lactate.

Release liner: polyethylene terephthalate film with polydimethylsiloxane coating on one side.

The EVRA[®] patch does not contain any metal components.

What dosage forms it comes in:

The EVRA[®] transdermal system is available as a thin, beige plastic patch, that sticks to the skin, containing 6 mg norelgestromin and 0.6 mg ethinyl estradiol. The sticky part of the patch contains the hormones norelgestromin and ethinyl estradiol, which are released continuously through the skin and into the bloodstream.

The EVRA[®] transdermal system releases approximately 35 micrograms of ethinyl estradiol and 200 micrograms of norelgestromin every 24 hours.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

The results of a recent study indicate that women using the ORTHO EVRA[®] contraceptive patch (the formulation of EVRA[®] marketed in the United States) had an increased risk of blood clots in the legs and lungs compared to women using an oral contraceptive. A different study indicated no difference in the risk of blood clots in the legs and lungs in women using ORTHO EVRA[®] compared to women using an oral contraceptive. Women who are obese are at particularly high risk of blood clots.

Cigarette smoking increases the risk of serious cardiovascular side effects (heart and blood vessel problems) from hormonal contraceptives. This risk increases with age and with the number of cigarettes smoked. For this reason, hormonal contraceptives, including EVRA[®], should not be used by women who are over 35 and smoke.

The contraceptive patch DOES NOT PROTECT against sexually transmitted infections (STIs), including HIV/AIDS.

For protection against STIs, it is advisable to use latex or polyurethane condoms IN COMBINATION WITH the contraceptive patch.

Do not use EVRA[®] if you are taking ombitasvir, paritaprevir, ritonavir, with or without dasabuvir for the treatment of Hepatitis C. Using these drugs at the same time as EVRA[®] has the potential to cause problems with your liver, such as an increase in the ALT liver enzyme. Consult with your doctor or pharmacist about restarting EVRA[®] after finishing your Hepatitis C treatment (see ABOUT THIS MEDICATION - When it should not be used).

Updated Information on risk of blood clots:

There have now been several studies conducted that have assessed the risk of blood clots in the legs and lungs in women using ORTHO EVRA[®] compared to women using oral contraceptives. These studies reported results ranging from no increase in risk of blood clots to an approximate doubling of risk of blood clots in women using ORTHO EVRA[®].

BEFORE you use EVRA[®] talk to your doctor or pharmacist if you:

- smoke
- weigh more than 90 kg (198 lbs)
- have a history of breast disease (e.g., breast lumps) or a family history of breast cancer
- have high blood pressure
- have high cholesterol
- have diabetes
- have heart or kidney disease

- have a history of seizures/epilepsy
- have a history of depression
- have a history of liver disease or jaundice
- wear contact lenses
- have uterine fibroids (benign tumours of the uterus)
- may be pregnant or are breast-feeding
- 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 should also inform your doctor about a family history of blood clots, heart attacks or strokes.

While wearing EVRA[®] you should not expose the patch area to **sources of heat** such as heating pads, electric blankets, heated waterbeds, heat lamps, saunas and hot tubs, intensive sunbathing, etc., as this may increase the drug’s ability to go through the skin and therefore result in too much exposure to the estrogen in the patch. This may also occur if you develop a fever. Contact your doctor for advice if you develop a fever.

If you see a different doctor, inform him or her that you are using the EVRA[®] contraceptive patch.

Tell your doctor if you are scheduled for any laboratory tests since certain blood tests may be affected by hormonal contraceptives.

Also tell your doctor if you are scheduled for **MAJOR** surgery. You should consult your doctor about stopping EVRA[®] four weeks before surgery and not using the contraceptive patch for a time period after surgery or during bed rest.

EVRA[®] should be used only under the supervision of a doctor, with regular follow-up to identify side effects associated with its use. Your visits may include a blood pressure check, a breast exam, an abdominal exam and a pelvic exam, including a Pap smear. Visit your doctor three months or sooner after the initial examination. Afterward, visit your doctor at least once a year. Use EVRA[®] only on the advice of your doctor and carefully follow all directions given to you. You must use the contraceptive patch exactly as prescribed. Otherwise, you may become pregnant.

If you and your doctor decide that, for you, the benefits of the EVRA[®] contraceptive patch outweigh the risks, you should be aware of the following:

THE RISKS OF USING EVRA[®]

1. Circulatory disorders (including blood clots in legs, lungs, heart, eyes or brain)

There have been cases of heart attack, stroke and blood clots in the legs, lungs and eyes in women using EVRA[®]. Blood clots are the most common serious side effects of hormonal contraceptives, including the contraceptive patch. The risk of developing blood clots is especially high during the first year a woman ever uses a hormonal contraceptive or restarts the same or a different hormonal

contraceptive after a break of 4 weeks or more. Clots can occur in many parts of the body.

Be alert for the following symptoms and signs of serious adverse effects. Call your doctor immediately if they occur:

- sharp pain in the chest, coughing blood, or sudden shortness of breath. These symptoms could indicate a possible blood clot in the lung.
- pain and/or swelling in the calf. These symptoms could indicate a possible blood clot in the leg.
- crushing chest pain or heaviness. These symptoms could indicate a possible heart attack.
- sudden severe or worsening headache or vomiting, dizziness or fainting, disturbances of vision or speech, or weakness or numbness in an arm or leg. These symptoms could indicate a possible stroke.
- sudden partial or complete loss of vision. This symptom could indicate a blood clot in the eye.

Any of these conditions can cause death or disability. Clots also occur rarely in the blood vessels of the eye, resulting in blindness or impaired vision, or in a blood vessel leading to an arm or leg, resulting in damage to or loss of a limb.

Women who use hormonal contraceptives have a higher incidence of blood clots. The risk of clotting seems to increase with higher estrogen doses. **It is important, therefore, to use as low a dosage of estrogen as possible.**

2. Breast cancer

The most significant risk factors for breast cancer are increasing age and a strong history of breast cancer in the family (mother or sister). Other established risk factors include obesity, never having children, and having your first full-term pregnancy at a late age.

Some women who use hormonal contraceptives may be at increased risk of developing breast cancer before menopause, which occurs around age 50. These women may be long-term users of hormonal contraceptives (more than eight years) or women who start using hormonal contraceptives at an early age. In a few women, the use of hormonal contraceptives may accelerate the growth of an existing but undiagnosed breast cancer. Early diagnosis, however, can reduce the effect of breast cancer on a woman’s life expectancy. The potential risks related to hormonal contraceptives seem to be small, however.

A yearly breast examination by a health care professional is recommended for all women.

ASK YOUR DOCTOR FOR ADVICE AND INSTRUCTIONS ON REGULAR SELF-EXAMINATION OF YOUR BREASTS.

3. Cervical cancer

Some studies have found an increase of cancer of the cervix in women who use oral contraceptives, although this finding may be related to factors other than the use of oral contraceptives.

However, there is insufficient evidence to rule out the possibility that oral contraceptives may cause such cancers.

4. Liver tumours

The short- and long-term use of birth control pills also has been linked with the growth of liver tumours. Such tumours are **extremely** rare. Since the contraceptive patch contains hormones similar to those in birth control pills, this association may also exist with the contraceptive patch.

Contact your doctor immediately if you experience severe pain or a lump in the abdomen.

5. Gallbladder disease

Users of hormonal contraceptives, including the contraceptive patch, have a greater risk of developing gallbladder disease including inflammation and gallstones requiring surgery within the first year of use. The risk may double after four or five years of use.

6. Seizures (convulsions)

There have been rare cases of seizures (convulsions) in women using EVRA[®]. It is important to contact your doctor immediately if you experience a new seizure or worsening of a previous seizure disorder (e.g., epilepsy).

7. Body weight >90 kg (198 lbs)

The effectiveness of EVRA[®] may be reduced in women weighing more than 90 kg (198 lbs). If you weigh more than 90 kg (198 lbs) you should talk to your doctor to determine which method of birth control may be right for you.

8. Use in pregnancy

Hormonal contraceptives, including the EVRA[®] contraceptive patch, should not be taken if you think you are pregnant. They will not prevent the pregnancy from continuing. There is no evidence, however, that hormonal contraceptives can damage a developing child. You should check with your doctor about risks to your unborn child from any medication taken during pregnancy.

9. Use after pregnancy, miscarriage or an abortion

Your doctor will advise you of the appropriate time to start the use of EVRA[®] after childbirth, miscarriage, or therapeutic abortion.

10. Pregnancy after stopping EVRA[®]

You will have a menstrual period when you stop using EVRA[®]. There may be some delay in becoming pregnant after you stop using the contraceptive patch, especially if you had irregular menstrual cycles before you used the contraceptive patch.

There is no evidence that the use of hormonal contraceptives immediately before a pregnancy will adversely affect a baby's development. When a woman stops taking the contraceptive patch to become pregnant, however, her doctor may recommend a

different form of contraception until she has a period on her own. In this way the pregnancy can be more accurately dated.

11. Use while breast-feeding

If you are breast-feeding, consult your doctor before starting EVRA[®]. Hormonal contraceptives are passed on to the child in the milk. A few adverse effects on the child have been reported, including yellowing of the skin (jaundice) and breast enlargement. In addition, combination hormonal contraceptives may decrease the amount and quality of your milk. If hormonal contraceptives are not resumed until nursing is established, however, the quantity and quality of breast milk does not seem to be affected. You should use a barrier method of contraception since breast-feeding only provides partial protection from becoming pregnant and this partial protection decreases significantly as you breast-feed for longer periods of time. It is recommended that you do not use combination hormonal contraceptives while breast-feeding. You should consider starting EVRA[®] only after you have weaned your child completely.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking, or have been taking, any other medicines, even medicines you buy without a prescription, and herbal products. Certain drugs may interact with hormonal contraceptives, including EVRA[®], to make them less effective in preventing pregnancy or cause unexpected bleeding (spotting or breakthrough bleeding). EVRA[®] may also interfere with how other drugs work. Talk to your doctor or pharmacist about when you may need to use an additional back-up, non-hormonal method of birth control (such as condoms, foam or sponge).

Drugs that may interact with EVRA[®] include:

- drugs used for epilepsy (e.g., carbamazepine, oxcarbazepine, ethosuximide, phenobarbital, phenytoin, primidone, rufinamide, topiramate, lamotrigine)
- antibiotics (e.g. penicillins, metronidazole, cotrimoxazole, nitrofurantoin, sulfonamides)
- drugs used for tuberculosis (e.g., rifampin, rifabutin)
- (fos)aprepitant (drug used for nausea)
- selegiline (drug used for Parkinson's disease)
- tizanidine (drug used for multiple sclerosis [MS])
- Tetracycline has been shown not to interact with EVRA[®]
- drugs used for HIV/AIDS (e.g., atazanavir, indinavir, nelfinavir, ritonavir, ritonavir-boosted protease inhibitors, etravirine, nevirapine)
- cyclosporine
- antifungals (e.g., griseofulvin, itraconazole, ketoconazole, voriconazole, fluconazole)
- salicylic acid
- anticoagulants (blood thinners)
- the herbal remedy St. John's wort (pregnancies and breakthrough bleeding have been reported by users of combined oral contraceptives who also used St. John's wort)
- blood pressure medications
- bronchodilators (drugs used for the treatment of asthma,

chronic obstructive pulmonary disease, chronic bronchitis e.g., theophylline)

- diabetic medications
- prednisone, prednisolone
- lipid-lowering drugs (e.g., atorvastatin, rosuvastatin)
- sedatives (e.g., benzodiazepines, barbiturates, chloral hydrate, glutethimide, meprobamate)
- stimulants (e.g., modafinil)
- antacids
- acetaminophen
- bosentan (drug used for pulmonary hypertension which is high blood pressure in the blood vessels between the heart and the lungs)
- ombitasvir, paritaprevir, ritonavir with or without dasabuvir (used to treat Hepatitis C)
- grapefruit juice; and
- some nutritional supplements (e.g., vitamin C, vitamin B₁₂, folic acid).

This is not a complete list of possible drug interactions with EVRA®. Talk to your doctor for more information about drug interactions.

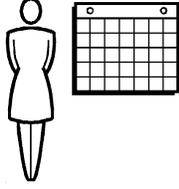
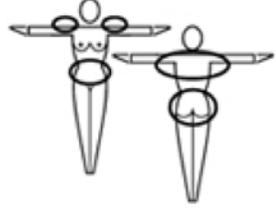
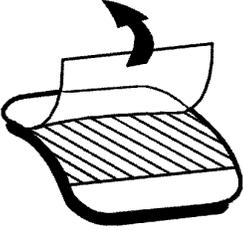
PROPER USE OF THIS MEDICATION

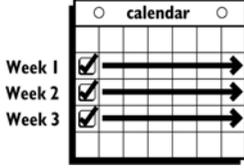
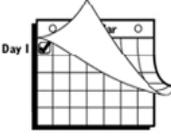
How to Use EVRA®

The transdermal contraceptive system keeps you from becoming pregnant by transferring hormones to your body through your skin. The patch must stick securely to your skin in order for it to work properly. This system uses a 28-day, four-week cycle. You will apply a new patch each week for three weeks - 21 total days. You will not apply a patch during week four. You will have your period this week. This means that every new patch will be applied on the same day of the week. This will be your “Patch Change Day”. *For example, if you apply your first patch on a Monday, all of your patches should be applied on a Monday.* You will wear only one patch at a time.

On the day after week four ends, you will begin a new four-week cycle by applying a new patch.

Save these instructions.

<p>1.</p> 	<p>If this is the first time you are using the birth control patch, wait until the day you get your menstrual period. <i>The day you apply your first patch will be Day 1. Your “Patch Change Day” will be on this day every week.</i></p>
<p>2.</p> <p>CHOOSE ONE OPTION:</p>  <p><input type="checkbox"/> First Day Start or <input type="checkbox"/> Sunday Start</p>	<p>For First Day start: apply your first patch during the first 24 hours of your period. <i>OR</i></p> <ul style="list-style-type: none"> • For Sunday start: apply your first patch on the first Sunday after your period starts. <i>For both a First Day start and a Sunday start, you must use back-up contraception for the first week of your first cycle only.</i>
<p>3.</p> 	<p>Choose a place on your body to apply the patch.</p> <p>Put the patch on your buttock, abdomen, upper outer arm or upper torso, in a place where it won't be rubbed by tight clothing. Never put the patch on your breasts. <i>To avoid irritation, apply each new patch to a different place on your skin.</i></p>
<p>4.</p> 	<p>Using your fingers, open the foil pouch by tearing it along the edge. Firmly grasp a corner of the patch and gently remove it from the foil pouch. <i>Sometimes patches can stick to the inside of the pouch - be careful not to accidentally remove the clear liner as you remove the patch.</i> Then, as indicated above, peel away half of the clear protective liner. Avoid touching the sticky surface.</p>

<p>5.</p> 	<p>Position the patch on your skin and then remove the other half of the liner. Press down firmly on the patch with the palm of your hand for 10 seconds, making sure that the edges stick well. <i>Check your patch every day to make sure it is sticking.</i></p>
<p>6.</p> 	<p>Wear the patch for 7 days (one week). On the “Patch Change Day,” Day 8, remove the used patch. Apply a new patch immediately. <i>The used patch still contains some medicine – throw it away by carefully folding it in half so that it sticks to itself.</i></p>
<p>7.</p> 	<p>You will apply a new patch on week two (Day 8) and again on week three (Day 15), on your “Patch Change Day”. <i>To avoid irritation, do not apply the new patch to the exact same place on your skin.</i></p>
<p>8.</p> 	<p>Do not wear a patch on week four (Day 22 through Day 28). You should have your period during this week.</p>
<p>9.</p> 	<p>Begin your next four-week cycle by applying a new patch on your normal “Patch Change Day”, the day after Day 28 - no matter when your period begins or ends.</p>

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

- **for less than one day**, try to re-apply it or apply a new patch immediately. No back-up contraception is needed. *Your “Patch Change Day” will remain the same.*

- **for more than one day, OR if you are not sure for how long, YOU MAY BECOME PREGNANT. 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 back-up contraception for the first week of your new cycle.*
- do not try to re-apply a patch if it is no longer sticky, if it has become stuck to itself or another surface, if it has other material stuck to it, or if it has become loose or has fallen off before. No tapes or wraps should be used to keep the patch in place. If you cannot re-apply a patch, apply a new patch immediately.

Overdose

In case of suspected overdose, remove all patches and contact your doctor, hospital or regional Poison Control Centre, even if there are no symptoms.

Overdose may cause nausea and vomiting. Vaginal bleeding may occur in women.

If you forget to change your patch

- **at the start of any patch cycle, Week one (Day 1):** if you forget to apply your patch, **you may become pregnant** - *you must use back-up contraception for one week.* Apply the first patch of your new cycle as soon as you remember. *You now have a new “Patch Change Day” and new Day 1.* If you had sexual intercourse during this time, you may be at risk of pregnancy. Check with your doctor or clinic.
- **in the middle of your patch cycle, Week two or week three:** if you forget to change your patch for one or two days, apply a new patch as soon as you remember. Apply your next patch on your normal “Patch Change Day”. No back-up contraception is needed.

Week two or week three: if you forget to change your 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 contraception for the first week of your new cycle.*

- **at the end of your patch cycle, Week four:** if you forget to remove 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.
- § **at the start of your next patch cycle, Day 1(Week one):** if you forget to apply your patch, **you may become pregnant** - apply the first patch of your new cycle as soon as you remember. *You now have a new “Patch Change Day” and a new Day 1. You must use back-up contraception for the first week of your new cycle.*
- **you should never have the patch off for more than seven days.**

Other Information:

- \$ Always apply your patch to clean, dry, hairless skin. Avoid skin that is red, irritated or cut. Do not use creams, oils, powder or makeup on your skin where you will put a patch or near a patch you are wearing. It may cause the patch to become loose.
- \$ Do not cut, damage or alter the patch in any way.
- \$ If patch use results in uncomfortable irritation, a new patch may be applied to a new location until the next change day. Only one patch should be worn at a time.
- \$ Some medicines may change the way the transdermal contraceptive system works. If you are taking any medication, you must talk to your health professional BEFORE you use the patch. *You may need to use back-up contraception.*

Disposal of EVRA®:

Used patches still contain some active hormones. Throw away the used patch by carefully folding in half so the adhesive side sticks to itself, place the folded patch in a sturdy container, preferably with a child-resistant cap, and dispose of it in the garbage out of the reach of children and pets. Remaining active hormonal ingredients of the patch may have harmful effects if they reach the aquatic environment. Used patches should not be flushed down the toilet or placed in liquid waste disposal systems.

When You Switch From the Pill to EVRA®:

If you are switching from the pill to EVRA®, wait until you get your menstrual period. If you do not get your period within five days of taking the last active pill, check with your doctor or clinic before starting EVRA®.

Important Points to Remember:

1. It is important to use EVRA® exactly as directed in this leaflet. Dosing errors increase your chances of becoming pregnant. This includes starting your contraceptive cycle late or missing your scheduled Change Day.
2. Do not use EVRA® for any condition other than the one for which it was prescribed. EVRA® has been prescribed specifically for you; do not give it to others who may want birth control.
3. You should wear one patch per week for three weeks, followed by one week off. **You should never have the patch off for more than seven days in a row.** If you have the patch off for more than seven days in a row and you have had sexual intercourse during this time, you may be at risk of pregnancy. Check with your doctor or clinic.

4. **If you are not sure what to do about dosing errors:**
 - Use a **back-up method** of birth control any time you have sex.
 - Contact your health professional for instructions.
5. Do not skip patches even if you do not have sex very often.
6. **Many women have spotting or light bleeding, breast tenderness or may feel sick to their stomach during the first three cycles.** If these symptoms occur, do not stop using EVRA®. The problem will usually go away. If it doesn't go away, check with your doctor or clinic.
7. **Mistakes in using your patches can also cause spotting or light bleeding.**
8. Unlike the pill, the amount of drug you get from the EVRA® patch should not be affected by **vomiting or diarrhea.**
9. **If you want to move your “Patch Change Day”** to a different day of the week, contact your doctor.
10. **Be sure to have ready at all times:**
 - **A non-hormonal birth control** (such as condoms, foam, or sponge) to use as a back-up in case of dosing errors.
11. **If you have trouble remembering to change your contraceptive patch,** talk to your doctor or clinic about how to make patch-changing easier or about using another method of birth control.
12. **There is no need to stop taking the EVRA® contraceptive patch for a rest period.**
13. For patch replacement, see **How to Use EVRA®.**

If you have any questions or are unsure about the information in this leaflet, call your doctor or clinic.

Missed Periods:

There may be times when you may not menstruate regularly during your patch-free week. If you have used EVRA® correctly and miss one menstrual period, continue using EVRA® for the next cycle, but be sure to inform your health professional before doing so. If you have not used EVRA® as instructed and missed a menstrual period, or if you missed two consecutive menstrual periods, you may be pregnant. Check with your health professional immediately to determine whether you are pregnant. Stop using EVRA® and use a non-hormonal method of birth control until you are sure you are not pregnant.

Pregnancy Due to Contraceptive Patch Failure:

The incidence of pregnancy from hormonal contraceptive failure is approximately one percent (i.e. one pregnancy per 100 women per year) if used correctly. The chance of becoming pregnant increases with incorrect use. If contraceptive patch failure occurs, the risk to the fetus is minimal.

Non-contraceptive Benefits of Hormonal Contraceptives:

Several health advantages have been linked to the use of hormonal contraceptives:

- Reduction in the incidence of cancer of the uterus and ovaries.
- Reduction in the likelihood of developing benign (non-

cancerous) breast disease and ovarian cysts.

- Less menstrual blood loss and more regular cycles. The risk of developing iron-deficiency anemia is thus reduced.
- There may be a decrease in painful menstruation and premenstrual syndrome (PMS).
- Acne, excessive hair growth and male hormone-related disorders may also be improved.
- Ectopic (tubal) pregnancy may occur less frequently.
- Acute pelvic inflammatory disease may occur less frequently.

Weight change (increase or decrease)

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The following side effects have been observed in studies of women taking EVRA®:

Skin irritation

Skin irritation, redness or rash may occur at the site of application. If this occurs, a new patch may be applied to a new location until the next Change Day.

Vaginal bleeding

Unexpected vaginal bleeding or spotting usually disappears after the first few cycles of contraceptive patch use and is not usually a reason to stop using EVRA®. If the bleeding persists for more than one cycle or lasts for more than a few days, talk to your doctor.

Other

Very Common: breast discomfort, nausea, headache, painful menstrual periods

Common (frequent): abdominal pain/discomfort, acne, allergy, back pain, bleeding between periods, breast enlargement, breast pain, bronchitis, coughing, diarrhea, dizziness, fatigue, fever, flatulence, flu-like symptoms, genital itching, heavier menstrual flow, inflammation, migraine, muscle pain, rash, runny or stuffy nose, sore throat, urinary tract infection, vaginal discharge, vaginal discomfort/infection, vomiting, weight gain

Uncommon: blood clots in the lung

The following additional symptoms have been reported in women taking hormonal contraceptives in general:

- Abdominal cramps/bloating
- Breast changes (tenderness, enlargement)
- Change in appetite
- Change in menstrual flow, spotting, amenorrhea (lack of menstrual period)
- Change in skin pigmentation (can be permanent)
- Depression
- Difficulty wearing contact lenses
- Excessive hair growth or loss of scalp hair
- Fluid retention/swelling of the extremities
- Increase in size of uterine fibroids (benign growths in the uterus/womb)
- Jaundice (yellowing of the skin or eyes)
- Nervousness

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Un-common	Abdominal pain, nausea or vomiting or lump in the abdomen		✓	
	Breast lump		✓	
	Convulsions or seizure			✓
	Crushing chest pain or heaviness			✓
	Pain or swelling in the leg			✓
	Persistent sad mood			✓
	Sharp pain in the chest, coughing blood, or sudden shortness of breath			✓
	Sudden partial or complete loss of vision or double vision			✓
	Sudden severe headache or worsening of headache, vomiting, dizziness, fainting, disturbance of vision or speech, or weakness or numbness in the face, arm or leg			✓
	Unexpected vaginal bleeding		✓	
	Unusual swelling of the extremities		✓	
	Yellowing of the skin or eyes (jaundice)			✓

This is not a complete list of side effects. For any unexpected effects while taking EVRA®, contact your doctor or pharmacist.

HOW TO STORE IT

Store between 15°C - 25°C. Do not refrigerate or freeze. Store patches in their protective pouches inside the original box. Apply patch immediately upon removal from its packaging.

Keep new and used transdermal systems out of the sight and reach of children and pets.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online at MedEffect® (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada)

Call toll-free at 1-866-234-2345

Complete a Canada Vigilance Reporting Form and:

- Fax toll-free to 1-866-678-6789, or
- Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on MedEffect® Canada Web site at www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals, can be found by going to: Health Canada's website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>), the manufacturer's website (www.janssen.com/canada) or by contacting the sponsor, Janssen Inc., at: 1-800-567-3331 or 1-800-387-8781.

This leaflet was prepared by Janssen Inc.
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