

DETAILED PATIENT LABELING

ORTHO EVRA[®] (norelgestromin/ethinyl estradiol transdermal system)

Rx only

This product is intended to prevent pregnancy. It does not protect against HIV (AIDS) or other sexually transmitted diseases.

DESCRIPTION

The contraceptive patch ORTHO EVRA[®] is a thin, beige, plastic patch that sticks to the skin. The sticky part of the patch contains the following hormones: norelgestromin (progestin) and ethinyl estradiol (estrogen). These hormones are absorbed continuously through the skin and into the bloodstream. On average, the amount of estrogen delivered through the skin produces estrogen exposure that is higher than the exposure when taking a birth control pill containing 35 micrograms of estrogen. Each patch is sealed in a pouch that protects it until you are ready to wear it.

INTRODUCTION

Any woman who considers using the contraceptive patch ORTHO EVRA[®] should understand the benefits and risks of using this form of birth control. This leaflet will give you much of the information you will need to make this decision and will also help you determine if you are at risk of developing any serious side effects. It will tell you how to use the contraceptive patch properly so that it will be as effective as possible. However, this leaflet is not a replacement for a careful discussion between you and your health care professional. You should discuss the information provided in this leaflet with him or her, both when you first start using the contraceptive patch ORTHO EVRA[®] and during your revisits. You should also follow your health care professional's advice with regard to regular check-ups while you are using the contraceptive patch.

EFFECTIVENESS OF HORMONAL CONTRACEPTIVE METHODS

Hormonal contraceptives, including ORTHO EVRA[®], are used to prevent pregnancy and are more effective than most other non-surgical methods of birth control. When ORTHO EVRA[®] is used correctly, the chance of becoming pregnant is approximately 1% (1 pregnancy per 100 women per year of use when used correctly), which is comparable to that of the pill. The chance of becoming pregnant increases with incorrect use.

Clinical trials suggested that ORTHO EVRA[®] may be less effective in women weighing more than 198 lbs. (90 kg). If you weigh more than 198 lbs. (90 kg) you

should talk to your health care professional about which method of birth control may be best for you.

Typical failure rates for other methods of birth control during the first year of use are as follows:

Implant: <1%
Injection: <1%
IUD: <1-2%
Diaphragm with spermicides: 20%
Spermicides alone: 26%
Female sterilization: <1%
Male sterilization: <1%
Cervical Cap with spermicide: 20 to 40%
Condom alone (male): 14%
Condom alone (female): 21%
Periodic abstinence: 25%
No birth control method: 85%
Withdrawal: 19%

WHO SHOULD NOT USE ORTHO EVRA®

Hormonal contraceptives include birth control pills, injectables, implants, the vaginal ring, and the contraceptive patch. The following information is derived primarily from studies of birth control pills. The contraceptive patch is expected to be associated with similar risks:

Cigarette smoking increases the risk of serious cardiovascular side effects from hormonal contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use hormonal contraceptives, including ORTHO EVRA®, are strongly advised not to smoke.

Some women should not use the ORTHO EVRA® contraceptive patch. For example, you should not use ORTHO EVRA® if you are pregnant or think you may be pregnant. You should also not use ORTHO EVRA® if you have any of the following conditions:

- A history of heart attack or stroke
- Blood clots in the legs (thrombophlebitis), lungs (pulmonary embolism), or eyes
- A history of blood clots in the deep veins of your legs
- Chest pain (angina pectoris)
- Known or suspected breast cancer or cancer of the lining of the uterus, cervix or vagina.

- Unexplained vaginal bleeding (until your doctor reaches a diagnosis)
- Hepatitis or yellowing of the whites of your eyes or of the skin (jaundice) during pregnancy or during previous use of hormonal contraceptives such as ORTHO EVRA[®], NORPLANT, or the birth control pill
- Liver tumor (benign or cancerous)
- Known or suspected pregnancy
- Severe high blood pressure
- Diabetes with complications of the kidneys, eyes, nerves, or blood vessels
- Headaches with neurological symptoms
- Use of oral contraceptives (birth control pills)
- Disease of heart valves with complications
- Need for a prolonged period of bed rest following major surgery
- An allergic reaction to any of the components of ORTHO EVRA[®]

Tell your health care professional if you have ever had any of these conditions. Your health care professional can recommend a non-hormonal method of birth control.

OTHER CONSIDERATIONS BEFORE USING ORTHO EVRA[®]

Hormones from ORTHO EVRA[®] get into the blood stream and are processed by the body differently than hormones from birth control pills. **You will be exposed to about 60% more estrogen if you use ORTHO EVRA[®] than if you use a typical birth control pill containing 35 micrograms of estrogen.** In general, increased estrogen may increase the risk of side effects.

The risk of venous thromboembolic events (blood clots in the legs and/or the lungs) may be increased with ORTHO EVRA[®] use compared with use of birth control pills. Studies examined the risk of these serious blood clots in women who used either ORTHO EVRA[®] or birth control pills containing one of two progestins (levonorgestrel or norgestimate) and 30-35 micrograms of estrogen. Results of these studies ranged from an approximate doubling of risk of serious blood clots to no increase in risk in women using ORTHO EVRA[®] compared to women using birth control pills.

You should discuss this possible increased risk with your healthcare professional before using ORTHO EVRA[®]. **Call your healthcare professional immediately if any of the adverse side effects listed under “WARNING SIGNALS” occur while you are using ORTHO EVRA[®].** (See below.)

Also talk to your health care professional about using ORTHO EVRA[®] if:

- you smoke
- you are recovering from the birth of a baby
- you are recovering from a second trimester miscarriage or abortion
- you are breast-feeding
- you weigh 198 pounds or more
- you are taking any other medications

Also, tell your health care professional if you have or have had:

- Breast nodules, fibrocystic disease of the breast, an abnormal breast x-ray or mammogram
- A family history of breast cancer
- Diabetes
- Elevated cholesterol or triglycerides
- High blood pressure
- Migraine or other headaches or epilepsy
- Depression
- Gallbladder disease
- Liver disease
- Heart disease
- Kidney disease
- Scanty or irregular menstrual periods

If you have any of these conditions you should be checked often by your health care professional if you use the contraceptive patch.

RISKS OF USING HORMONAL CONTRACEPTIVES, INCLUDING ORTHO EVRA[®]

The following information is derived primarily from studies of birth control pills. Since ORTHO EVRA[®] contains hormones similar to those found in birth control pills, it is expected to be associated with similar risks:

1. Risk of Developing Blood Clots

Blood clots and blockage of blood vessels that can cause death or serious disability are some of the most serious side effects of using hormonal contraceptives, including the ORTHO EVRA[®] contraceptive patch. In particular, a clot in the legs can cause thrombophlebitis, and a clot that travels to the lungs can cause sudden blocking of the

vessel carrying blood to the lungs. Rarely, clots occur in the blood vessels of the eye and may cause blindness, double vision, or impaired vision.

The risk of venous thromboembolic disease (blood clots in the legs and/or the lungs) may be increased with ORTHO EVRA[®] compared with that of oral contraceptives containing norgestimate and 35mcg of estrogen (see the earlier Section OTHER CONSIDERATIONS BEFORE USING ORTHO EVRA[®]). You should discuss this possible increased risk with your healthcare professional before using ORTHO EVRA[®]. Call your healthcare professional immediately should any of the adverse effects listed under “WARNING SIGNALS” occur while you are using ORTHO EVRA[®]. (See below.)

If you use ORTHO EVRA[®] and need elective surgery, need to stay in bed for a prolonged illness or injury or have recently delivered a baby, you may be at risk of developing blood clots. You should consult your doctor about stopping ORTHO EVRA[®] four weeks before surgery and not using it for two weeks after surgery or during bed rest. You should also not use ORTHO EVRA[®] soon after delivery of a baby. It is advisable to wait for at least four weeks after delivery if you are not breast-feeding. If you are breast-feeding, you should wait until you have weaned your child before using ORTHO EVRA[®]. (See also the section on Breast-Feeding in General Precautions.)

2. Heart Attacks and Strokes

Hormonal contraceptives, including ORTHO EVRA[®], may increase the risk of developing strokes (blockage or rupture of blood vessels in the brain) and angina pectoris and heart attacks (blockage of blood vessels in the heart). Any of these conditions can cause death or serious disability.

Smoking and the use of hormonal contraceptives including ORTHO EVRA[®] greatly increase the chances of developing and dying of heart disease. Smoking also greatly increases the possibility of suffering heart attacks and strokes.

3. Gallbladder Disease

Women who use hormonal contraceptives, including ORTHO EVRA[®], probably have a greater risk than nonusers of having gallbladder disease.

4. Liver Tumors

In rare cases, combination oral contraceptives can cause benign but dangerous liver tumors. Since ORTHO EVRA[®] contains hormones similar to those in birth control pills, this association may also exist with ORTHO EVRA[®]. These benign liver

tumors can rupture and cause fatal internal bleeding. In addition, some studies report an increased risk of developing liver cancer. However, liver cancers are rare.

5. Cancer of the Reproductive Organs and Breasts

Various studies give conflicting reports on the relationship between breast cancer and hormonal contraceptive use. Combination hormonal contraceptives, including ORTHO EVRA[®], may slightly increase your chance of having breast cancer diagnosed, particularly after using hormonal contraceptives at a younger age. After you stop using hormonal contraceptives, the chances of having breast cancer diagnosed begin to go back down. You should have regular breast examinations by a health care professional and examine your own breasts monthly. Tell your health care professional if you have a family history of breast cancer or if you have had breast nodules or an abnormal mammogram.

Women who currently have or have had breast cancer should not use oral contraceptives because breast cancer is usually a hormone-sensitive tumor.

Some studies have found an increase in the incidence 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.

ESTIMATED RISK OF DEATH FROM A BIRTH CONTROL METHOD OR PREGNANCY

All methods of birth control and pregnancy are associated with a risk of developing certain diseases that may lead to disability or death. An estimate of the number of deaths associated with different methods of birth control and pregnancy has been calculated and is shown in the following table.

ORTHO EVRA[®] is expected to be associated with similar risks as oral contraceptives:

Annual Number of Birth-Related or Method-Related Deaths Associated With Control of Fertility Per 100,000 Nonsterile Women by Fertility Control Method According to Age

Method of control and outcome	15-19	20-24	25-29	30-34	35-39	40-44
No fertility control methods*	7.0	7.4	9.1	14.8	25.7	28.2
Oral contraceptives non-smoker**	0.3	0.5	0.9	1.9	13.8	31.6
Oral contraceptives smoker**	2.2	3.4	6.6	13.5	51.1	117.2
IUD**	0.8	0.8	1.0	1.0	1.4	1.4
Condom*	1.1	1.6	0.7	0.2	0.3	0.4
Diaphragm / spermicide*	1.9	1.2	1.2	1.3	2.2	2.8
Periodic abstinence*	2.5	1.6	1.6	1.7	2.9	3.6

*Deaths are birth-related

**Deaths are method-related

Adapted from H.W. Ory, ref. #35.

In the above table, the risk of death from any birth control method is less than the risk of childbirth, except for oral contraceptive users over the age of 35 who smoke and pill users over the age of 40 even if they do not smoke. It can be seen in the table that for women aged 15 to 39, the risk of death was highest with pregnancy (7-26 deaths per 100,000 women, depending on age). Among pill users who do not smoke, the risk of death is always lower than that associated with pregnancy for any age group, although over the age of 40, the risk increases to 32 deaths per 100,000 women, compared to 28 associated with pregnancy at that age. However, for pill users who smoke and are over the age of 35, the estimated number of deaths exceeds those for other methods of birth control. If a woman is over the age of 40 and smokes, her estimated risk of death is four times higher (117/100,000 women) than the estimated risk associated with pregnancy (28/100,000 women) in that age group.

In 1989 an Advisory Committee of the FDA concluded that the benefits of low-dose hormonal contraceptive use by healthy, non-smoking women over 40 years of age may outweigh the possible risks.

WARNING SIGNALS

If any of these adverse effects occur while you are using ORTHO EVRA[®], call your doctor immediately:

- Sharp chest pain, coughing of blood, or sudden shortness of breath (indicating a possible clot in the lung)

- Pain in the calf (indicating a possible clot in the leg)
- Crushing chest pain or tightness in the chest (indicating a possible heart attack)
- Sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness, or numbness in an arm or leg (indicating a possible stroke)
- Sudden partial or complete loss of vision (indicating a possible clot in the eye)
- Breast lumps (indicating possible breast cancer or fibrocystic disease of the breast; ask your doctor or health care professional to show you how to examine your breasts)
- Severe pain or tenderness in the stomach area (indicating a possibly ruptured liver tumor)
- Severe problems with sleeping, weakness, lack of energy, fatigue, or change in mood (possibly indicating severe depression)
- Jaundice or a yellowing of the skin or eyeballs accompanied frequently by fever, fatigue, loss of appetite, dark colored urine, or light colored bowel movements (indicating possible liver problems)

SIDE EFFECTS OF ORTHO EVRA®

1. Skin Irritation

Skin irritation, redness or rash may occur at the site of application. If this occurs, the patch may be removed and a new patch may be applied to a new location until the next Change Day. Single replacement patches are available from pharmacies.

2. Vaginal Bleeding

Irregular vaginal bleeding or spotting may occur while you are using ORTHO EVRA®. Irregular bleeding may vary from slight staining between menstrual periods to breakthrough bleeding which is a flow much like a regular period. Irregular bleeding may occur during the first few months of contraceptive patch use but may also occur after you have been using the contraceptive patch for some time. Such bleeding may be temporary and usually does not indicate any serious problems. It is important to continue using your contraceptive patches on schedule. If the bleeding occurs in more than a few cycles or lasts for more than a few days, talk to your health care professional.

3. Problems Wearing Contact Lenses

If you wear contact lenses and notice a change in vision or an inability to wear your lenses, contact your health care professional.

4. Fluid Retention or Raised Blood Pressure

Hormonal contraceptives, including the contraceptive patch, may cause edema (fluid retention) with swelling of the fingers or ankles and may raise your blood pressure. If you experience fluid retention, contact your health care professional.

5. Melasma

A spotty darkening of the skin is possible, particularly of the face. This may persist after use of hormonal contraceptives is discontinued.

6. Other Side Effects

The most common side effects of ORTHO EVRA[®] include nausea and vomiting, breast symptoms, headache, menstrual cramps, and abdominal pain. In addition, change in appetite, nervousness, depression, dizziness, loss of scalp hair, rash, and vaginal infections may occur.

GENERAL PRECAUTIONS

1. Weight \geq 198 lbs. (90 kg)

Clinical trials suggest that ORTHO EVRA[®] may be less effective in women weighing 198 lbs. (90 kg) or more compared with its effectiveness in women with lower body weights. If you weigh 198 lbs. (90 kg) or more you should talk to your health care professional about which method of birth control may be best for you.

2. Missed Periods and Use of ORTHO EVRA[®] Before or During Early Pregnancy

There may be times when you may not menstruate regularly during your patch-free week. If you have used ORTHO EVRA[®] correctly and miss one menstrual period, continue using your contraceptive patches for the next cycle but be sure to inform your health care professional before doing so. If you have not used ORTHO EVRA[®] as instructed and missed a menstrual period, or if you missed two menstrual periods in a row, you could be pregnant. Check with your health care professional immediately to determine whether you are pregnant. Stop using ORTHO EVRA[®] if you are pregnant.

There is no conclusive evidence that hormonal contraceptive use causes birth defects when taken accidentally during early pregnancy. Previously, a few studies had reported that oral contraceptives might be associated with birth defects, but these findings have not been seen in more recent studies. Nevertheless, hormonal contraceptives, including ORTHO EVRA[®], should not be used during pregnancy. You should check with your health care professional about risks to your unborn child from any medication taken during pregnancy.

3. While Breast-Feeding

If you are breast-feeding, consult your health care professional before starting ORTHO 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 possible, do not use combination hormonal contraceptives such as ORTHO EVRA[®] while breast-feeding. You should use a barrier method of contraception since breast-feeding provides only partial protection from becoming pregnant and this partial protection decreases significantly as you breast-feed for longer periods of time. You should consider starting ORTHO EVRA[®] only after you have weaned your child completely.

4. Laboratory Tests

If you are scheduled for any laboratory tests, tell your doctor you are using ORTHO EVRA[®] since certain blood tests may be affected by hormonal contraceptives.

5. Drug Interactions

Certain drugs may interact with hormonal contraceptives, including ORTHO EVRA[®], to make them less effective in preventing pregnancy or cause an increase in breakthrough bleeding. Such drugs include rifampin, drugs used for epilepsy such as barbiturates (for example, phenobarbital), anticonvulsants such as topiramate (TOPAMAX), carbamazepine (Tegretol is one brand of this drug), phenytoin (Dilantin is one brand of this drug), phenylbutazone (Butazolidin is one brand), certain drugs used in the treatment of HIV or AIDS, and possibly certain antibiotics. Tetracycline has been shown not to interact with ORTHO EVRA[®]. Pregnancies and breakthrough bleeding have been reported by users of combined hormonal contraceptives who also used some form of St. John's Wort.

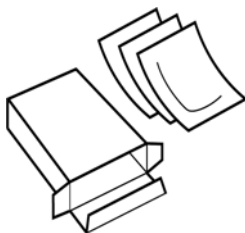
As with all prescription products, you should notify your health care professional of any other medications you are taking. You may need to use a barrier contraceptive when you take drugs that can make ORTHO EVRA[®] less effective.

6. Sexually Transmitted Diseases

ORTHO EVRA[®] is intended to prevent pregnancy. It does not protect against HIV (AIDS) or other sexually transmitted diseases such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.

HOW TO USE ORTHO EVRA®

Instructions for Use



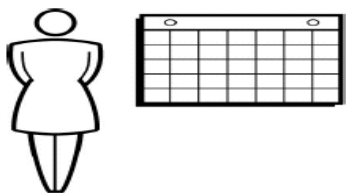
ORTHO EVRA® keeps you from becoming pregnant by transferring hormones to your body through your skin. The patch must stick securely to your skin in order for it to work properly.

This method uses a 28 day (four week) cycle. You should apply a new patch each week for three weeks (21 total days). You should not apply a patch during the fourth week. Your menstrual period should start during this patch-free week.

Every new patch should be applied on the same day of the week. This day 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 should wear only one patch at a time.

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

Save these instructions.



1

If this is the **first time** you are using ORTHO EVRA®, **wait until the day you get your menstrual period.** *The day you apply your first patch will be Day 1. Your ‘Patch Change Day’ will be on this day every week.*

2

You may choose a first day start or Sunday start

CHOOSE ONE OPTION:



First Day Start

or

Sunday Start

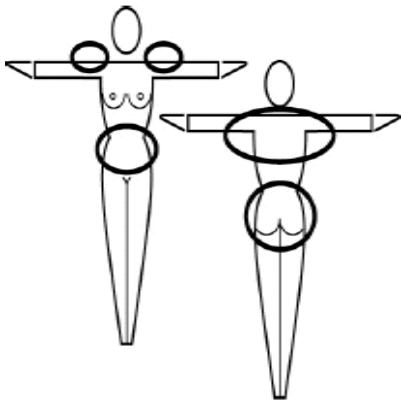
OR

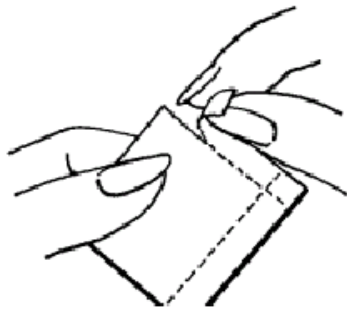
- for **First Day start**: apply your first patch during the first 24 hours of your menstrual period
- for **Sunday start**: apply your first patch on the first Sunday after your menstrual period starts. *You must use back-up contraception, such as a condom, spermicide, or diaphragm for the first week of your first cycle*
- *The day you apply your first patch will be Day 1. Your 'Patch Change Day' will be on this day every week.*

3

Choose a place on your body to put the patch.

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. To avoid irritation, apply each new patch to a different place on your skin.*





4

Open the foil pouch by tearing it along the top edge **and** one side edge.

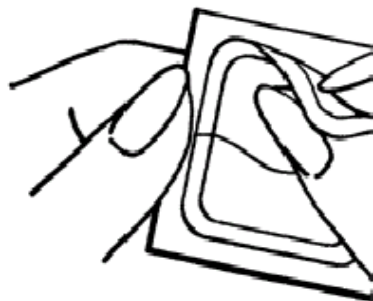
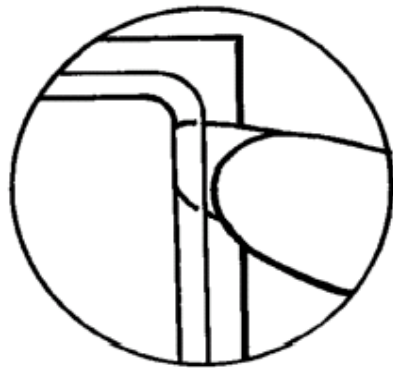
Peel the foil pouch apart and open it flat.



5

You will see that the patch is covered by a layer of clear plastic. It is important to remove the patch **and** the plastic together from the foil pouch.

Using your fingernail, lift one corner of the patch and peel the patch and the plastic off the foil liner.



Sometimes patches can stick to the inside of the pouch – be careful not to accidentally remove the clear liner as you remove the patch.



6

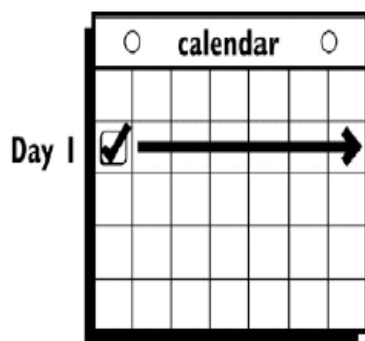
Peel away half of the clear plastic and be careful not to touch the exposed sticky surface of the patch with your fingers.



7

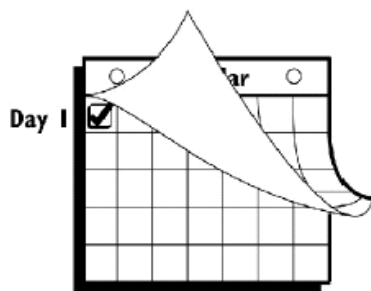
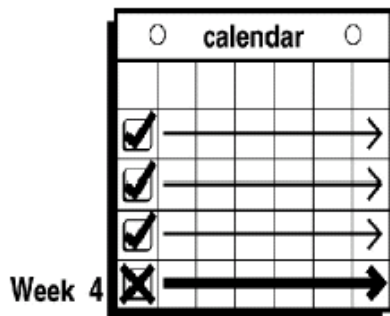
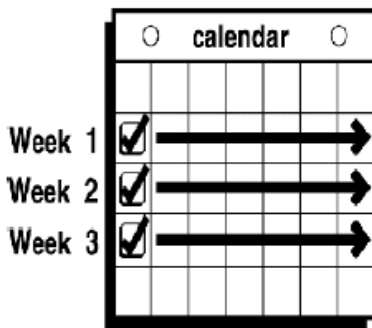
Apply the sticky side of the patch to the skin you've cleaned and dried, then remove the other half of the clear plastic.

Press firmly on the patch with the palm of your hand for 10 seconds, making sure the edges stick well. Run your finger around the edge of the patch to make sure it is sticking properly. Check your patch every day to make sure all the edges are sticking.



8

Wear the patch for seven days (one week). On your 'Patch Change Day,' Day 8, remove the used patch. Apply a new patch immediately. *The used patch still contains some medicine – carefully fold it in half so that it sticks to itself before safely disposing of it in the trash. Used patches should not be flushed down the toilet.*



9

Apply a new patch for week two (on Day 8) and for week three (on Day 15), on your 'Patch Change Day.' *To avoid irritation, do not apply the new patch to the same exact place on your skin.*

10

Do not wear a patch on week four (Day 22 through Day 28). *Your period should start during this week.*

11

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.*

If your patch has become loose or has fallen 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, such as a condom, spermicide, or diaphragm for the first week of your new cycle.

- do not try to re-apply a patch if it's 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 previously become loose or fallen off. 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.

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 COULD 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.*

- **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 COULD 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 COULD BECOME PREGNANT** – 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. 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 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 ORTHO EVRA[®] patch in any way.
- If patch use results in uncomfortable irritation, the patch may be removed and 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 ORTHO EVRA[®] works. If you are taking any medication, you must talk to your health care professional BEFORE you use the patch. *You may need to use back-up contraception.*
- Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F).
- Single replacement patches are available through your pharmacist.
- For further information log on to **www.orthoevra.com** or call toll free **1 877 EVRA 888**

WHEN YOU SWITCH FROM THE PILL TO ORTHO EVRA[®]:

If you are switching from the pill to ORTHO 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 health care professional to be sure that you are not pregnant.

IMPORTANT POINTS TO REMEMBER

1. IT IS IMPORTANT TO USE ORTHO EVRA[®] exactly as directed in this leaflet. Incorrect use increases your chances of becoming pregnant. This includes starting your contraceptive cycle late or missing your scheduled CHANGE DAYS.
2. 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 sex during this time, YOU COULD BECOME PREGNANT.
3. **IF YOU ARE NOT SURE WHAT TO DO ABOUT MISTAKES WITH PATCH USE:**
 - Use a BACK-UP METHOD, *such as a condom, spermicide, or diaphragm* anytime you have sex.
 - Contact your health care professional for instructions.
4. Do not skip patches even if you do not have sex very often.

5. SOME WOMEN HAVE SPOTTING OR LIGHT BLEEDING, BREAST TENDERNESS OR MAY FEEL SICK TO THEIR STOMACH DURING ORTHO EVRA[®] USE. If these symptoms occur, do not stop using the contraceptive patch. The problem will usually go away. If it doesn't go away, check with your health care professional.
 6. MISTAKES IN USING YOUR PATCHES CAN ALSO CAUSE SPOTTING OR LIGHT BLEEDING.
 7. If you miss TWO PERIODS IN A ROW contact your health care professional because you might be pregnant.
 8. The amount of drug you get from the ORTHO EVRA[®] patch should not be affected by VOMITING OR DIARRHEA.
 9. IF YOU TAKE CERTAIN MEDICINES, ORTHO EVRA[®] may not work as well. Use a non-hormonal back-up method (such as condoms, spermicide, or diaphragm) until you check with your health care professional.
 10. IF YOU WANT TO MOVE YOUR PATCH CHANGE DAY to a different day of the week, finish your current cycle, removing your third ORTHO EVRA[®] patch on the correct day. **During week four**, the “patch-free week” (Day 22 through Day 28), you may choose an earlier Patch Change Day by applying a new patch on the day you prefer. You now have a new Day 1 and a new Patch Change Day. **You should never have the patch off for more than seven days in a row.**
 11. BE SURE YOU HAVE READY AT ALL TIMES:
 - A NON-HORMONAL BIRTH CONTROL method (such as condoms, spermicide, or diaphragm) to use as a back-up in case of dosing errors.
 12. IF YOU HAVE TROUBLE REMEMBERING TO CHANGE YOUR CONTRACEPTIVE PATCH, talk to your health care professional about how to make patch-changing easier or about using another method of birth control.
 13. Single replacement patches are available through your pharmacist.
 14. For Patch replacement, see “How to use ORTHO EVRA[®]” section.
- IF YOU HAVE ANY QUESTIONS OR ARE UNSURE ABOUT THE INFORMATION IN THIS LEAFLET, call your health care professional.

PREGNANCY DUE TO ORTHO EVRA[®] 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 does occur, the risk to the fetus is minimal.

PREGNANCY AFTER STOPPING ORTHO EVRA[®]

There may be some delay in becoming pregnant after you stop using ORTHO EVRA[®], especially if you had irregular menstrual cycles before you used hormonal contraceptives. It may be best to postpone conception until you begin menstruation regularly once you have stopped using ORTHO EVRA[®] and want to become pregnant.

There does not appear to be any increase in birth defects in newborn babies when pregnancy occurs soon after stopping hormonal contraceptives.

OVERDOSAGE

ORTHO EVRA[®] is unlikely to cause an overdose because the patch releases a steady amount of the hormones. Do not use more than one patch at a time. Serious ill effects have not been reported when large doses of oral contraceptives were accidentally taken by young children. Overdosage may cause nausea and vomiting. Vaginal bleeding may occur in females. In case of overdosage, contact your health care professional or pharmacist.

OTHER INFORMATION

Your health care professional will take a medical and family history before prescribing ORTHO EVRA[®] and will examine you. The physical examination may be delayed to another time if you request it and the health care professional believes that it is a good medical practice to postpone it. You should be reexamined at least once a year. Be sure to inform your health care professional if there is a family history of any of the conditions listed previously in this leaflet. Be sure to keep all appointments with your health care professional, because this is a time to determine if there are early signs of side effects of hormonal contraceptive use.

Do not use the drug for any condition other than the one for which it was prescribed. This drug has been prescribed specifically for you; do not give it to others who may want birth control.

If you want more information about ORTHO EVRA[®], ask your health care professional or pharmacist. They have a more technical leaflet called the Prescribing Information that you may wish to read.

Special Precautions for Storage and Disposal

Store at room temperature.

Store patches in their protective pouches. Apply to the skin immediately upon removal from the protective pouch.

Do not store in the refrigerator or freezer.

Used patches still contain some active hormones. Fold each patch in half so that it sticks to itself before safely disposing of it in the trash. Used patches should not be flushed down the toilet.

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