



WHAT IS THE CONTRACEPTIVE PATCH?

OrthoEvra™ is a transdermal contraceptive. It is a thin beige square patch with one sticky side that is applied directly to the skin. When used correctly it will stay in place and provide a stable dose of medication. Patches are applied weekly for three weeks and removed on the fourth week. During the patch-free week a woman will usually have her period.

WHAT MEDICATIONS ARE IN THE PATCH?

HOW DOES IT DIFFER FROM OTHER METHODS OF BIRTH CONTROL?

The patch contains a combination of the hormones estrogen and progestin. These are the same hormones used in most birth control pills and are similar to the natural hormones produced by the body during the menstrual cycle. The primary difference between the patch and the pill is the manner in which the medication is delivered into the blood stream. The medication in the patch is absorbed through the skin directly into the blood stream.

HOW DOES THE PATCH WORK?

The progestin component in the patch prevents the ovary from releasing an egg (ovulation). If ovulation does not occur, a woman cannot become pregnant. The uterine lining is also thinner than normal. This change in the uterine lining helps inhibit the implantation of a fertilized egg; therefore, providing additional protection in case ovulation occurs. These hormones also cause an alteration in the cervical mucus, making it more difficult for sperm to enter the uterus.

HOW EFFECTIVE IS THE PATCH?

In studies provided to the Food and Drug Administration (FDA) during the FDA approval process, effectiveness ratings are listed as 99% *when used according to recommendations on the label*. This is comparable to the pill and other hormonal contraceptives. The risk of pregnancy increases if the patch is used incorrectly.

ARE THERE RISKS TO USING THE PATCH?

Health risks related to the contraceptive patch are low when compared to the risks of pregnancy. Hormones from patches are absorbed and removed differently from the body than hormones from the birth control pills taken by mouth. You will be exposed to about 60% more estrogen if you use OrthoEvra than if you use a typical birth control pill containing 35 micrograms of estrogen. In general, increased estrogen exposure may increase the risk of side effects. However, it is not known with certainty if there are differences in the risk of serious side effects based on the differences between OrthoEvra and a birth control pill containing 35 micrograms of estrogen. Estrogen affects the way the body forms blood clots. There is some evidence that the patch increases the risk of blood clots compared to low dose oral contraceptives. Blood clots may form in the legs, lungs, brain or other vital organs causing serious health problems. Cigarette smoking increases the risk of cardiovascular complications, which is greater when a woman smokes more than 15 cigarettes daily and increases significantly when she is also over 35 years of age. Other factors increasing the risk of blood clots are high cholesterol, diabetes, high blood pressure, obesity and migraine headaches with aura or neurological symptoms.

If you experience any of the following symptoms, you should seek medical care immediately.

- A** - Abdominal pain (severe)
- C** - Chest pain- shortness of breath, coughing up blood
- H** - Headache (severe), numbness or weakness in arms or legs
- E** - Eye problems (vision loss, blurring, flashing lights)
- S** - Severe leg pain in calf or thigh

WHAT ARE THE BENEFITS OF USING A PATCH FOR CONTRACEPTION?

The benefits of the patch are similar to those of other combined hormonal contraceptives. In addition to the high rates of effectiveness, other benefits include:

- Once-weekly patch applications eliminate the need to think about birth control on a daily basis.
- Provides regular menstrual periods.
- Easily reversible - ovulation usually returns quickly when a woman stops wearing the patch; however, women who have irregular menstrual cycles do occasionally experience a delay in the return of menses.

- Side effects diminish quickly when use of the patch is discontinued.
- Reduces chances of ovarian cysts and tubal pregnancy.
- Changes in the cervical mucus help decrease the risk of pelvic inflammatory infections.

ARE THERE OTHER THINGS I SHOULD CONSIDER?

- OrthoEvra™ Contraceptive Patches are **not recommended** for those weighing 198 pounds or more because contraceptive effectiveness may be decreased.
- The patch may be worn on the buttock, abdomen, back/shoulder area, or the outside of the upper arm. It should **not** be worn on the front shoulder/breast areas. It may be visible to others when bathing or changing clothes.
- The patch offers no protection against sexually transmitted infections such as chlamydia, gonorrhea and HIV. Condoms offer protection against STI's. Condoms can be used in combination with the patch.
- People with allergic reactions to other types of adhesives or tape may develop a rash with the patch.
- Bathing, showering, swimming, exercise, perspiration, hot tubs, etc. should not affect the patch; however, it is a good idea to check the patch daily to make sure it is in place and is sticking well.
- Vomiting and diarrhea should not interfere with the effectiveness of the patch.
- Always inform your health care providers that you are using the patch. It is a medication just like any pills you may take.

WHAT ABOUT CANCER AND THE PATCH?

There is little information available specifically about the patch and cancer. However, since the patch and birth control pills utilize the same types of hormones, it is expected to have similar effects. That information is included for your review.

- Since 1960, when birth control pills first became available, important information about pills and cancer has been learned.
- Pills reduce the risk of ovarian cancer: three years of use reduces the risk of ovarian cancer by 40%; ten years of use reduces the risk by 80%.
- Pills reduce the risk for endometrial (uterine lining) cancer.
- Most studies suggest that pills neither reduce nor increase the risk for breast cancer. Research continues to evaluate this. Women are encouraged to do monthly self-breast exams and have yearly exams by a health care provider.
- Some studies indicate an increased incidence of cervical cancer. However, this may be more related to factors such as numbers of sexual partners, STI exposure, etc., than to birth control pill use. Annual pap smears provide the best screening for cervical cancer.

Migraine headaches have been associated with an increase risk of stroke. Users of oral contraceptives with a history of migraine headaches are 2-4 times more likely to have a stroke. Other factors that increase the risk of blood clot formation include smoking, high cholesterol, high blood pressure, diabetes, and being overweight.

WHAT ARE THE SIDE EFFECTS?

The most common side effects of the patch are mid-cycle bleeding and spotting and breast tenderness. These side effects will usually resolve within the first 2-3 months of use.

Nausea may occur at the onset of use, but usually will resolve within a few days. Rarely, vomiting will occur. If nausea lasts throughout the month or occurs persistently at the beginning of each patch cycle, you may want to talk with your health care provider. Vitamin B-6 (50 mg. 1-2 tablets daily) may help reduce nausea.

Skin irritation, persistent redness or discoloration, and itching may indicate sensitivity to the patch or adhesive and should be reported to your health care provider.

If you experience the onset of headaches that are more frequent, more persistent or more severe than usual, please contact your health care provider.

Mood swings may occur initially, but will usually diminish with continued use. Vitamin B6 (50 mg. 1-2 tablets daily) may help minimize these symptoms. Contact your health care provider if the symptoms persist or more severe depression symptoms develop.

There are other reactions to hormonal contraceptives that may be either beneficial or detrimental, depending on the individual response to the hormones.

For instance for one person acne may improve; for another it may increase. Menstrual cramps will usually improve, but occasionally a woman will experience an increase in severity of cramps.

Usually the menses will be lighter and shorter, but occasionally a woman will experience heavier or longer menses.

Occasionally a woman may experience a very light or absent period during the patch-free week. If the patches have been used exactly as prescribed, you may re-apply a patch as scheduled. If this occurs two months in a row, please contact your health care provider. If the instructions have not been followed carefully, there may be a risk of pregnancy. For eligible students, home pregnancy test kits are available at McKinley's Health Resource Centers located at McKinley in the main lobby (walk-up window on the left) and at the Illini Union/OASIS, Room 40 (lower level by the Food Court).

WHAT ABOUT DRUG INTERACTIONS?

Contraceptive effectiveness may be reduced when hormonal contraceptives are administered at the same time other drugs are being taken. Breakthrough bleeding or unintended pregnancy can result. Examples of drugs that potentially interfere with contraceptive hormones include antifungals, seizure medications and possibly antibiotics. For additional information please refer to the handout "*Pill Interactions with Other Drugs.*"

HOW DO I GET A PATCH PRESCRIPTION?

A prescription for the patch can be obtained from a McKinley Women's Health provider or an outside provider. For a prescription from a McKinley provider, an annual exam needs to be documented within the past 12 months. First time hormonal contraception users need to take the on-line birth control education session at: <http://www.mckinley.uiuc.edu/bcclass/classoptions1>

HOW DO I USE THE PATCH?

- The patch may be applied to healthy skin on the buttocks, abdomen, back/shoulder area or the upper outer arm. It should not be worn on the front shoulder or breast area.
- Avoid areas that are rubbed by tight clothing.
- Each new patch should be placed in a different location (example: if current patch is on the right buttock, place the next patch on the left buttock).
- Apply a patch once a week, *on the same day each week* (your Patch Change Day) for three weeks. Remove the old patch each week.
- Remove the patch at the beginning of week four and do not re-apply. Your period will come this week.
- Apply a new patch seven days after removing the last patch even if you are still having your period. Repeat the same application schedule monthly.

TO APPLY THE PATCH:

- Do not use any creams, oils or lotion on the skin prior to applying a new patch. The skin must be clean, dry and without redness or irritation.
- The patch comes in a sealed foil pouch. There is a clear plastic film covering the adhesive surface. Tear open the foil pouch and carefully peel the patch and plastic covering off the foil liner.
- When applying the patch, remove half of the clear plastic covering the adhesive surface. *Avoid touching the sticky surface with your fingers.* Press the patch onto the skin, and then peel the remainder of the plastic away, smoothing the patch onto the skin. Pressing firmly, move the finger over the entire surface of the patch for 10-15 seconds to be sure it is well adhered.

WHEN DO I START USING THE PATCH?

There are two start options when you have not been using any other hormonal method of birth control:

- **First day start:** Apply a patch on the *first day of your menstrual period.* No backup birth control method is needed.
- **Sunday start:** Apply a patch on the *first Sunday after your period starts.* You must continue to use a condom for the first seven days of the first patch cycle. Thereafter, assuming that the patch application instructions are followed, the contraceptive protection is continuous.
- **Quick Start:** Apply a patch the day of your appointment with your provider, regardless of where you are in your menstrual cycle. This allows you to start the patch immediately, without waiting until you get your period. If you use the Quick Start method, it is necessary to use condoms or another back-up method of birth control for seven days. Women concerned about a possible pregnancy before starting the patch should wait until they get their period and choose either the first day start or Sunday start method. If using the Quick Start method, your period will be delayed until your patch-free week. If you do not get a period during the placebo week, take a urine pregnancy test. You may experience break-through bleeding; continue using the patch as directed, even if unscheduled bleeding occurs.

If switching from the birth control pill or vaginal ring

Apply the patch on the *first day of bleeding*. By doing this, it will not be necessary to use any backup birth control. If starting the patch later than the first day of bleeding, a (back-up contraception) should be used for seven days.

If you later wish to switch your Patch Change Day you may do so by waiting until the patch-free week. Choose the day you want to use as your Patch Change Day and re-apply the patch on the chosen day, instead of waiting for the original Patch Change Day. It is safe to shorten the patch-free week, but you should **never leave the patch off for more than seven days**. If you shorten the patch-free week, you may still be bleeding when you re-apply the patch.

WHAT IF THE PATCH COMES OFF OR THE EDGES LIFT UP?

- Replacement patches may be available. If you need a replacement patch, check with the pharmacy or your provider. Come to Women's Health Walk-in 2:45 - 4:15 p.m., Monday through Friday.
- If the patch edges are lifting up press firmly for 10 to 15 seconds. If it will not stick well you may need to replace the patch. Your Patch Change Day will remain the same. Do not apply tape over the top of the patch.

If the patch comes off

- **For less than 24 hours:** Apply a new patch. No contraceptive back-up is needed. The Patch Change Day remains the same. You may experience some breakthrough bleeding.
- **More than 24 hours:** You may not be protected from pregnancy. Start a new cycle and apply a new patch. *Use a back-up method of contraception for ONE WEEK.* This is now your new Patch Change Day. You may experience bleeding.

WHAT IF I FORGET TO CHANGE THE PATCH?

- **At the start of any patch cycle:** Apply the patch as soon as you remember. **You need to use an additional form of birth control for ONE WEEK.** This is your new Patch Change Day.
- **In week two or three: 24-48 hours late:** Apply a new patch as soon as you remember. No back-up birth control method is needed. The Patch Change Day remains the same.
- **In week two or three: more than 48 hours late:** Apply a new patch as soon as you remember. This will be your new four-week cycle start. *Use a backup form of birth control for ONE WEEK.*
- **In week four of the cycle:** Remove the patch as soon as you remember. Re-apply a patch on your regular Patch Change Day. No additional method of birth control is needed.

OrthoEvra information may be found on the web site at: <http://www.orthoevra.com>.

If you have any questions or concerns, or need an appointment, please call Dial-A-Nurse at 333-2700 and select Women's Health.

References

"What You Should Know About OrthoEvra™" patient instruction booklet. Ortho-McNeil Pharmaceutical, Inc. Raritan, New Jersey, 2001

OrthoEvra™ Package Insert, Ortho-McNeil Pharmaceutical, Inc., included with each OrthoEvra™ Patch Cycle

Speroff, L (April 2000) *International Journal of Fertility*, Oral Contraceptives and Breast Cancer Risk: Summary and Application of Data.

Shulman, Lee (Dec. 2002) *The Female Patient*, supplement An Evolving State.

If you are a registered University of Illinois student and you have questions or concerns, or need to make an appointment, please call: **Dial-A-Nurse at 333-2700**

If you are concerned about any difference in your treatment plan and the information in this handout, you are advised to contact your health care provider.

Visit the McKinley Health Center Web site at: <http://www.mckinley.uiuc.edu>