ORTHO EVRA®
150/20 NORELGESTROMIN/ETHINYL ESTRADIOL TRANSDERMAL SYSTEM

Ortho Evra® is a transdermal contraceptive patch that releases 150ug of norelgestromin and 20ug of ethinyl estradiol to the blood stream every 24 hours. However, the bioavailability via the transdermal route is greater (than via the oral route) and results in a 60% increase in exposure to estrogen than from a birth control pill containing 35 mcg of estrogen. It is unproven, but theoretically possible that this increase in estrogen exposure may increase the risk of blood clots. Taken correctly, Ortho Evra® is 99% effective in preventing pregnancy.

I. Client Selection - Clinical trials suggest Ortho Evra® may be less effective in women weighing more than 198 pounds.

A. Indications - Ortho Evra® may be provided:

1. When contraindications do not exist;

2. Post-pregnancy:

   a. Immediately after abortion;

   b. May initiate 3-4 weeks after second trimester abortion or postpartum and non-lactating;

   c. Should exercise caution in nursing women less than six months postpartum. Document discussion of potential risks/benefits such as decrease in milk supply.

B. Contraindications – do not provide (Based on WHO Medical Eligibility Criteria)

1. History of idiopathic or postpartum deep vein thrombosis or thromboembolism; known thrombogenic mutations such as Protein C or S resistance and Factor V Leiden (WHO Medical Eligibility Criteria, 2004) or EXTENSIVE familial history of deep vein thrombosis. (Thrombosis related to either a known trauma or an IV needle is not necessarily a reason to avoid use of Ortho Evra®.)

2. History of thrombotic cerebrovascular accident (stroke);

3. Vascular, coronary artery, ischemic heart disease, myocardial infarction or current angina pectoris, or history thereof;

4. Age $\geq$35 years old and smoking $\geq$15 cigarettes per day;

5. Hypertension: systolic $\geq$160 or diastolic $\geq$100;

6. Diabetes mellitus with clinically manifested vascular disease (diabetic nephropathy, retinopathy, neuropathy or peripheral vascular disease);

7. Known or suspected carcinoma of the breast or endometrium, or other estrogen-dependent neoplasia. Ortho Evra® use may be considered, in consultation with the physician, for women with a past history of breast cancer but no evidence of estrogen dependence in the cancer and no recurrence for 5 years.

8. Benign hepatic adenoma, liver cancer, or history thereof; active viral hepatitis, severe cirrhosis or markedly impaired liver function currently;

9. Migraine headaches with focal neurological symptoms (visual changes, scotoma, flashing lights, dysphasia, numbness of face/extremities);

10. Unexplained abnormal vaginal or uterine bleeding, NOT including irregular menses;

11. Planned major surgery with prolonged immobilization or any surgery on the legs;

12. Suspected pregnancy;

13. Lactation (<6 weeks postpartum).

14. Hypersensitivity to any of the components of Ortho Evra®;

C. Special Conditions Requiring Further Evaluation: In light of the updated labeling regarding increased estrogen exposure, pay particular attention to any of the following conditions that could increase the risk of blood clots. The theoretical/proven risks generally outweigh the advantages of using the method. The patient must be provided with information regarding the way in which these conditions may add to a health risk for her. This discussion must be documented. (Based on WHO Medical Eligibility Criteria)

1. Adverse cardiovascular risk profile (see V. Management of Women with Special Conditions Requiring Further Evaluation p. 4, this protocol);

2. Active or medically treated gallbladder disease, history of COC-related cholestasis.

3. Migraine headaches without focal neurological symptoms **(visual changes, scotoma, flashing lights, dysphasia, numbness of face/extremities)** [see V. Management of Women with Special Conditions Requiring Further Evaluation p. 6, this protocol];

4. Elevated blood pressure measurements – 140-159/90-99 on three separate visits within a two week period. (See Flow Chart for Management of Clients Using Ortho Evra® Who Develop High Blood Pressure – page 6 of this protocol);

5. Age ≥35 years old and smoking <15 cigarettes per day;

6. Seizure disorder, currently taking anticonvulsants that affect liver enzymes (see V. Management of Women with Special Conditions Requiring Further Evaluation p. 7, this protocol);

II. Client Education/Informed Consent:

A. All clients choosing to use Ortho Evra® must receive the following information:

1. Fact sheet on all contraceptive options available, if she is a new client or is undecided as to what method she wishes to use

2. A copy of the FDA approved detailed patient labeling pamphlet. The importance of reading the FDA pamphlet must be explained to the patient. Patients must be counseled that Ortho Evra® results in an increased exposure to estrogen when compared to the average oral contraceptive. It is unproven, but theoretically possible that this increased exposure may increase the risk of blood clots. Danger signs indicative of blood clots, and emergency phone numbers must be discussed/given/documented.

3. Instructions on how to apply and remove Ortho Evra®. (For instructions, see Contraceptive Technology, Eighteenth Edition, pp. 447)

4. Information that the effectiveness of Ortho Evra® may be decreased by some medications (See V. Drug Interactions p. 7, this protocol)

5. The importance of scheduled follow-up visits (See VII. Follow Up, page 8 of this protocol)

6. Importance of informing their other providers of their use of Ortho Evra®

7. Information regarding discontinuation of the method, and the recommendation that she complete the cycle she is taking. If she does not wish to become pregnant, she should start using another method before the day she was due to apply a new patch.

8. Information regarding sexually transmitted infections, including counseling that Ortho Evra® provides no protection. Use of either male or female condoms should be recommended for clients in need of protection from STDs.

B. All clients choosing to use Ortho Evra® must sign the following:

1. General family planning program consent

2. Hormonal contraceptive consent for the provision of Ortho Evra® (does not need to be re-initialed every year unless there is a change in health status)

III. Medical Screening and Evaluation

A. History – as per Title X Guidelines (See Nursing Policy Section IV – Health Care Services)

B. Examination – as per Title X Guidelines (See Nursing Policy Section IV – Health Care Services)

C. Laboratory – tests per Title X Guidelines (See Nursing Policy Section IV – Health Care Services)

D. Provision of Ortho Evra® through Delayed Exam – See Delayed Exam protocol

IV. Provision of Ortho Evra®

CURRENT METHOD	APPLY PATCH	BACK UP
No effective contraception in preceding cycle	On or prior to day 5 of cycle, OR apply patch during this office visit if pregnancy can be ruled out (Quick Start), OR apply patch the day after taking emergency contraceptive pills (ECPs), (Jump Start)	Back up method recommended for 7 days
COC's **or NuvaRing®** in preceding cycle	Anytime within 7 days of the last COC tablet taken or NuvaRing® removed (no later than when a new cycle would have been started)	None
Progestin-only pills (POPs) in preceding cycle	Any day of the month. There should be no skipped days between last pill and first day of Ortho Evra® use	Back up method recommended for 7 days

CURRENT METHOD	APPLY PATCH	BACK UP
Implanon® implant in preceding cycle	On the same day the implant is removed	Back up method recommended for 7 days
DMPA in preceding cycle	On or before the day when the next injection is due	Back up method recommended for 7 days
ParaGard® or Mirena® in place	On the same day that the IUD is removed	Back up method recommended for 7 days
Post first trimester abortion	Within 5 days of a completed procedure	None
Post second trimester abortion and postpartum	3-4 weeks post second trimester abortion; 3-4 weeks postpartum in women who elect not to breast feed, if menses has not re-started; >6 months in lactating women.	Back up method should be considered for 7 days
Any other contraceptive method	On first day of cycle On days 2-5 of cycle	No back up method is needed Back up method should be used for 7 days

V. Management of Women with Special Conditions Requiring Further Evaluation

A. Adverse Cardiovascular Risk Profile

If a woman has two or more risk factors, the case must be evaluated by, and use of Ortho Evra® approved by a physician:

1. Age ≥35;
2. Smoking cigarettes;
3. High cholesterol levels;
4. Diabetes;
5. Chronic hypertension.

B. Diabetes mellitus

1. Ortho Evra® use in women with diabetes must be individualized. As risk factors increase in number or severity, it may become less appropriate to prescribe Ortho Evra®.
2. Consider involving the primary care provider managing the patient's diabetes if she is initiated on Ortho Evra®.

C. High Blood Pressure

1. If hypertension is controlled with diet or medication, the complete cardiovascular risk profile (A.1 – 5 above) must be considered.

2. Ortho Evra® may induce hypertension in a very small percentage of previously normotensive women. If an Ortho Evra® user is found to have a significant rise in blood pressure to 140 systolic or above/ 90 diastolic or above, the rise could be due to Ortho Evra®.

3. Management - **Please refer to the flow chart on the next page for management of hypertension that occurs in women using Ortho Evra®:**

Flow Chart for the Management of Clients Using Ortho Evra®

Who Develop High Blood Pressure

SYSTOLIC 140 or above
or
DIASTOLIC 90 or above

↓

Have client return two or more times within two weeks in a resting state for reevaluation.

If any two or more readings on at least two different visits are ≥140 systolic or ≥90 diastolic, consider the following options:

+Physician consultation
+Referral for medical evaluation
+Switch to another method (progestin-only is OK)

Diastolic of ≥100 on any one occasion - stop Ortho Evra® immediately. **Initiate interim method of contraception;** client must be referred for a medical evaluation.

Continuation of Ortho Evra® requires documentation of physician approval and a plan for follow-up.

↓

If Ortho Evra® is discontinued, re-check BP within three months.

- If still ≥140 systolic or ≥90 diastolic, refer for evaluation.
- If <140 systolic or <90 diastolic, may then try a very low dose (20 ug estrogen) combination pill or progestin-only method.

If very low dose (20 ug estrogen) combination pill or progestin only method is initiated:

- Monitor BP monthly for three months. If BP rises to ≥140 systolic or ≥90 diastolic at any time, discontinue estrogen containing methods.
- Offer alternative method.
- Recheck BP within three months. See first bullet in this box.

D. Headaches

1. Management of headaches that start or worsen after the initiation of Ortho Evra® is up to the discretion of the practitioner and client and may include any of the following:

   a. Referral for headache evaluation;

   b. Change in birth control method, including very low dose COCs (20 ug) or progestin only methods;

   c. For headaches during the hormone free interval, discuss with the client extended use regimen of combined oral contraceptives or the extended use of NuvaRing® (off-label). **(See extended use regimen, VI. C, page 7 of the Oral Contraceptive protocol or VI.J, page 7 of the NuvaRing® protocol.)** Ortho Evra®: should **not** be used in an extended regimen.

2. Common Migraine Headaches (without focal neurologic symptoms **[visual changes, scotoma, flashing lights, dysphasia, numbness of face/extremities]**)

   a. A trial of Ortho Evra® may be provided for women with a history of migraine headaches without focal neurological symptoms. The client must be advised to report any increase in the frequency and severity of such headaches.

   b. If migraines worsen in frequency or severity, or if focal neurological symptoms or signs occur **(visual changes, scotoma, flashing lights, dysphasia, numbness of face/extremities)**, Ortho Evra® must be discontinued. Women who develop focal neurological symptoms or signs should be referred promptly for neurologic evaluation.

E. Seizure Disorders

1. A large majority of women with seizure disorders will notice no change in the frequency or severity of seizure activity as a result of initiating Ortho Evra®.

2. Concurrent use of anti-seizure drugs that induce hepatic enzymes may reduce effective plasma steroid levels in Ortho Evra® users. It is the responsibility of the provider to review a client's anti-seizure medication(s) for potential drug interaction with Ortho Evra®.

3. Use of backup barrier methods, and the benefits and risks of using Ortho Evra® in women with seizure disorders should be discussed with women who use anti-seizure drugs but who need a high degree of protection. Women who are on certain anti-seizure medications and choose to use Ortho Evra® should be advised to use a back up method, such as condoms, for 3 months. Any breakthrough bleeding during this time may indicate a decrease in circulating levels of estrogen and progestin. Such a decrease could result in ovulation. Continued use of a barrier method with the patch (dual method use) or switching to Depo Provera, Implanon, or an IUD may be advised.

F. Drug Interactions

1. Anti-seizure medications: Concurrent use of anti-seizure drugs that induce hepatic enzymes may reduce effective plasma steroid levels in Ortho Evra® users. (See V. E. on previous page)

2. Gabapentin (Neurontin), vigabatrin, ethosuximide and lamotrigine (Lamictal) have no effect on this enzyme system and do not interfere with contraceptive effectiveness. Valproate/ Valproic Acid (Depakote) and felbamate (Felbatol) do not increase breakdown of hormones and may even increase hormone levels.

3. Rifampin increases hepatic clearance of estrogens and progestins; it is recommended that clinicians not prescribe Ortho Evra® for women on this drug (Contraceptive Technology, Eighteenth Edition, p. 419).

4. Antibiotics: Although women on antibiotics do have lower serum progestin and estrogen levels, the levels remain well within the therapeutic range for sex steroids. Back up methods should not be necessary. (Contraceptive Technology, Eighteenth Edition, p. 419)

5. Ortho Evra® can decrease clearance of benzodiazepines such as diazepine (Valium), nitrazepine, chlordiazepine, alprazolam, which suggests the need for lower doses of these medications. Clearance of bronchodilators such as theophylline, aminophylline and caffeine as well as anti-inflammatory corticosteroids may also be reduced.

6. More rapid clearance of acetaminophen and aspirin is also reported.

7. The FDA has alerted providers that the use of St. John's Wort may decrease the therapeutic effect of Ortho Evra®.

VI. Guidelines For Ortho Evra® Use And Management Of Problems/Side Effects

A. The Ortho Evra® product should be stored below 85 degrees F.

B. Ortho Evra® may be applied to the abdomen, buttock, upper outer arm or upper torso (excluding the breast).

C. One Ortho Evra® patch is applied weekly for 3 weeks. It is applied on the same day of the week each week – the "patch change day."

D. It is preferable for the client to place the new patch on a fresh area of skin to avoid skin reactions.

E. There is a one-week patch free period. There should never be more than 7 consecutive patch-free days.

F. Continuous use of Ortho Evra® (without a patch-free week) has not been approved by the FDA. In light of the updated labeling regarding increased estrogen exposure from Ortho Evra® as compared to the average birth control pill, continuous use of Ortho Evra® should *not be recommended.*

G. Following application of the patch the hormones reach reference levels within 48 hours. The patch can maintain serum concentrations in the target range through nine days. Hormone concentrations are not affected by hot tubs, saunas, swimming or sweating.

H. Patch detachment is uncommon, with complete detachment occurring in 2% of clients overall.

1. If a patch is partially or completely detached for less than one day (up to 24 hours) the client should try to reapply it to the same place or replace it with a new patch

immediately. No back-up contraception is needed and her "patch change day" remains the same.

2. If the client's patch has been completely or partially detached for more than one day or an undetermined amount of time, she may not be protected from pregnancy. The client should apply a new patch (which changes her "patch change day") and use back-up contraception for the first week of this new cycle.

I. If the client forgets to apply or change patch in any patch cycle:

1. At the start of any patch cycle (week 1 / day 1): Use back up contraception for one week. The client can apply the first patch of her new cycle as soon as she remembers. This will give the client a new day 1 and a new "patch change day".

2. In the middle of a patch cycle:

a. If the client has forgotten to change her patch for one or two days, she can apply a new patch as soon as she remembers. She should apply her next patch on her normal "patch change day". No back up contraception is needed.

b. If the client has forgotten to change her patch for more than two days, she should start a new four week cycle as soon as she remembers by putting on a new patch. She will have a new day 1 and a new "patch change day". She should use back up contraception for the first week of her new cycle.

3. At the end of a patch cycle (week 4) – if the client has forgotten to remove her patch, she can take it off as soon as she remembers. She should start her next cycle on her normal "patch change day" and no back up contraception is needed.

J. Missed period

Rule out pregnancy if:

1. Ortho Evra® patch detached for more than 3 hours.

2. There was a delay of longer than one week in applying new patch.

3. There were two missed periods in a row.

VII. Follow Up

A. The new combined hormonal contraceptive user must be reassessed within 3 months after beginning Ortho Evra® and at least annually thereafter.

B. Please refer to Section IV (Health Care Services) in the Nursing Policy Manual for a complete review of the requirements for revisits for contraceptive patch users.

C. At each Ortho Evra® related medical visit, the patient should be asked about changes in personal history, possible side effects, and her menstrual cycle/bleeding pattern.

SCHEDULE FOR APPLYING THE TRANSDERMAL PATCH

SUNDAY	SUNDAY	SUNDAY	SUNDAY	SUNDAY
Patch #1	**Patch #2**	**Patch #3**	**Patch-free**	**Start next cycle**
28 day cycle				**28-day cycle**

One contraceptive patch will be applied each week on the same day for 3 weeks, followed by a patch-free week.

The following is a sample of a Hormonal Consent Form. This form can be downloaded from the Women's Health Unit website at:
http://www.cdphe.state.co.us/pp/womens/FPNursingConsntsForms.html.

HORMONAL CONSENT

- **ORAL CONTRACEPTIVE (Combined and POP) • ORTHO EVRA • NUVARING**

I have been given information about and have had a chance to ask questions about:

☐ ?Birth control pills: ☐ Combined ☐ Progesterone Only ☐ ?Ortho Evra patch ☐ ?NuvaRing

I know that:

- Birth control pills and Ortho Evra patch do not require a back up method if I start on the first day of my period.
- Progesterone only pills (POP) only have the hormone progesterone. This may make the effectiveness slightly lower than combined birth control pills. I know that I need to take a pill **every day without a break**. There is no hormone-free week like there is with combined pills. My periods might be irregular.
- NuvaRing is left in the vagina for three weeks from the day I insert it, and is then removed and thrown away. A new ring is inserted one week (7 days) after removal of the old one.
- **Ortho Evra (the patch) results in a 60% increase in exposure to estrogen compared to the average birth control pill. It is not known whether this results in a significant increased risk of blood clots.**
- The hormonal methods listed above do not provide me with protection from sexually transmitted diseases. If I need this protection, I have been advised to use condoms PLUS this method.

I have been told that there may be some medical risks when using any of the combined hormonal methods that could include such things as stroke, blood clots, or liver tumors. I have been given a copy of the "Detailed Patient Labeling" which tells how often these problems happen.

I understand that the cardiovascular risks of this method may get worse with age, especially over 35 years of age, and with smoking. I know that the serious health problems that this method can cause are rare. I know to call the clinic or my private doctor, or to go to the emergency room if I have any of these danger signs:

- Severe abdominal pain;
- Chest pain;
- Severe headaches;
- Changes in my vision;
- Severe leg pain.

If I wish to discontinue my method, I have been advised that it is better for me to finish the cycle I am taking before stopping the method. If I do not wish to become pregnant, I must start on another method immediately.

Patient signature **Date**

Staff signature **Date**

Interpreter's Statement

I have translated the information and advice presented orally to the client who has chosen:

☐ Combined birth control pills ☐ Progesterone only birth control pills
☐ Ortho Evra Patch ☐ NuvaRing

I have also read the consent form to her in a language she understands and explained its contents to her. To the best of my knowledge and belief, she understands this explanation and voluntarily consents to the use of the method marked above.

Interpreter's signature **Date**

The following is a sample of a Hormonal Evaluation Form. This form can be downloaded from the Women's Health Unit website at:
http://www.cdphe.state.co.us/pp/womens/FPNursingConsntsForms.html.

HORMONAL METHOD EVALUATION
ORAL CONTRACEPTIVES (Combined and POP),
EVRA PATCH, NUVARING, IMPLANON (rod implant)

Name _____ **Today's date** _____

Date of birth _____ **Age** _____

First day of last period _____

1. **Please check your current method:**

   ☐ Birth control pill (Combined)
   ☐ Evra
   ☐ Implanon
   ☐ Birth control pill (Progesterone only)
   ☐ Nuvaring

2. **Are you having any problems with your method?** ☐ **No** ☐ **Yes**
   Explain: _____

3. **Do you have any questions?** ☐ **No** ☐ **Yes**
   Explain: _____

4. **Have you had any health problems or seen a physician since your last visit?**
   ☐ **No** ☐ **Yes** **Explain:** _____

5. **Are you taking any other medications?** ☐ **No** ☐ **Yes**
   List: _____

6. **Check if you have had any of the following since you started your method:**

   ☐ Severe headaches
   ☐ Dizziness
   ☐ Vision changes
   ☐ Chest pain
   ☐ Severe leg pain
   ☐ Severe abdominal pain
   ☐ Depression
   ☐ Nausea or vomiting
   ☐ Heavy bleeding
   ☐ Weight gain

_____
Client Signature **Date**

TO BE COMPLETED BY STAFF

S:

O: B/P____ WT____

A:

P:

_____
Staff signature **Date**

The following is a sample of a Headache Evaluation Form. This form can be downloaded from the Women's Health Unit website at:
http://www.cdphe.state.co.us/pp/womens/FPNursingConsntsForms.html.

Headache Evaluation Form

Client #_____ Name _____ Age_____

When you have headaches, how often do you…… (Circle one answer per question)

1. Feel them coming on before they become headaches?	Never	Rarely	Usually	Always
2. Have moderate to severe pain?	Never	Rarely	Usually	Always
3. Have pulsating, pounding, or throbbing pain?	Never	Rarely	Usually	Always
4. Have worse pain on one side of your head?	Never	Rarely	Usually	Always
5. Have worse pain when you move, bend over or walk stairs?	Never	Rarely	Usually	Always
6. Have nausea?	Never	Rarely	Usually	Always
7. Have vomiting?	Never	Rarely	Usually	Always
8. Feel bothered by light?	Never	Rarely	Usually	Always
9. Feel bothered by sound?	Never	Rarely	Usually	Always
10. Need to limit or avoid daily activities?	Never	Rarely	Usually	Always
11. Want to lie down in a quiet, dark room?	Never	Rarely	Usually	Always
12. See zigzag lines, spots, or light flashes?	Never	Rarely	Usually	Always

To give your healthcare provider more complete information, please answer these additional questions:

1. Do any immediate family members also suffer from headaches? Yes No
2. In your lifetime, have you had at least 5 headaches with the symptoms noted above? Yes No
3. At what age did you first experience these headaches?_____
4. On average, how often do you get these headaches? _____
5. Which medicine(s) do you take for your headaches? _____

Check all of the statements that are true:

1. My headache medicine does not make me pain free. ____
2. My headache medicine does not treat other symptoms (e.g., nausea, sensitivity to light). ____
3. I take my headache medicine more than 2 or 3 times per week. ____
4. My headache medicine makes me drowsy. ____
5. I take more than one kind of medicine for my headaches. ____
6. My headache may last 4 to 72 hours (untreated or unsuccessfully treated). ____

Check any of the following that ever bring on one of these headaches:

___Intense lights, smells, or sounds
___Weather changes
___Allergies or sinus pain/pressure
___Stress or tension
___Monthly menstrual cycle/hormonal changes
____Too little sleep or too much sleep
____Missed meals
____Lack of caffeine or too much caffeine
____Changes in mood/excitement
____Foods or alcoholic beverages

Client's Signature:_____Date:_____

TO BE COMPLETED BY STAFF
Assessment:

_____
Clinician Signature Date Agency Name