

BRIEF SUMMARY PATIENT PACKAGE INSERT

Oral contraceptives, also known as "birth control pills" or "the pill," are taken to prevent pregnancy and when taken correctly without missing any pills, have a failure rate of approximately 1% per year. The typical failure rate is approximately 5% per year when women who miss pills are included. For most women oral contraceptives are also free of serious or unpleasant side effects. However, forgetting to take pills considerably increases the chances of pregnancy.

For the majority of women, oral contraceptives can be taken safely. But there are some women who are at high risk of developing certain serious diseases that can be fatal or may cause temporary or permanent disability. The risks associated with taking oral contraceptives increase significantly if you:

- smoke
- have high blood pressure, diabetes, high cholesterol
- have or have had clotting disorders, heart attack, stroke, angina pectoris, cancer of the breast or sex organs, jaundice or malignant or benign liver tumors.

Although cardiovascular disease risks may be increased with oral contraceptive use after age 40 in healthy, non-smoking women (even with the newer low-dose formulations), there are also greater potential health risks associated with pregnancy in older women.

You should not take the pill if you suspect you are pregnant or have unexplained vaginal bleeding.

Do not use ORTHO-NOVUM[®] if you smoke cigarettes and are over 35 years old. Smoking increases your risk of serious cardiovascular side effects (heart and blood vessel problems) from combination oral contraceptives, including death from heart attack, blood clots or stroke. This risk increases with age and the number of cigarettes you smoke.

Most side effects of the pill are not serious. The most common such effects are nausea, vomiting, bleeding between menstrual periods, weight gain, breast tenderness, and difficulty wearing contact lenses. These side effects, especially nausea and vomiting, may subside within the first three months of use.

The serious side effects of the pill occur very infrequently, especially if you are in good health and are young. However, you should know that the following medical conditions have been associated with or made worse by the pill:

1. Blood clots in the legs (thrombophlebitis), lungs (pulmonary embolism), stoppage or rupture of a blood vessel in the brain (stroke), blockage of blood vessels in the heart

(heart attack or angina pectoris) or other organs of the body. As mentioned above, smoking increases the risk of heart attacks and strokes and subsequent serious medical consequences.

2. In rare cases, oral contraceptives can cause benign but dangerous liver tumors. 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.
3. High blood pressure, although blood pressure usually returns to normal when the pill is stopped.

The symptoms associated with these serious side effects are discussed in the detailed leaflet given to you with your supply of pills. Notify your healthcare professional if you notice any unusual physical disturbances while taking the pill. In addition, drugs such as rifampin, bosentan, as well as some seizure medicines and herbal preparations containing St. John's wort (*Hypericum perforatum*) may decrease oral contraceptive effectiveness.

Oral contraceptives may interact with lamotrigine (LAMICTAL[®]), a seizure medicine used for epilepsy. This may increase the risk of seizures so your healthcare professional may need to adjust the dose of lamotrigine.

Various studies give conflicting reports on the relationship between breast cancer and oral contraceptive use. Oral contraceptive use 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 healthcare professional and examine your own breasts monthly. Tell your healthcare 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. However, this finding may be related to factors other than the use of oral contraceptives. There is insufficient evidence to rule out the possibility that the pill may cause such cancers.

Taking the combination pill provides some important non-contraceptive benefits. These include less painful menstruation, less menstrual blood loss and anemia, fewer pelvic infections, and fewer cancers of the ovary and the lining of the uterus.

Be sure to discuss any medical condition you may have with your healthcare professional. Your healthcare professional will take a medical and family history before prescribing oral

contraceptives and will examine you. The physical examination may be delayed to another time if you request it and the healthcare professional believes that it is a good medical practice to postpone it. You should be reexamined at least once a year while taking oral contraceptives. Your pharmacist should have given you the detailed patient information labeling which gives you further information which you should read and discuss with your healthcare professional.

This product (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against transmission of HIV (AIDS) and other sexually transmitted diseases such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.

HOW TO TAKE THE PILL

IMPORTANT POINTS TO REMEMBER

BEFORE YOU START TAKING YOUR PILLS:

1. **BE SURE TO READ THESE DIRECTIONS:**

Before you start taking your pills.

Anytime you are not sure what to do.

2. **THE RIGHT WAY TO TAKE THE PILL IS TO TAKE ONE PILL EVERY DAY AT THE SAME TIME.**

If you miss pills you could get pregnant. This includes starting the pack late.

The more pills you miss, the more likely you are to get pregnant.

3. **MANY WOMEN HAVE SPOTTING OR LIGHT BLEEDING, OR MAY FEEL SICK TO THEIR STOMACH DURING THE FIRST 1-3 PACKS OF PILLS.** If you feel sick to your stomach, do not stop taking the pill. The problem will usually go away. If it doesn't go away, check with your healthcare professional.

4. **MISSING PILLS CAN ALSO CAUSE SPOTTING OR LIGHT BLEEDING,** even when you make up these missed pills.

On the days you take 2 pills to make up for missed pills, you could also feel a little sick to your stomach.

5. **IF YOU HAVE VOMITING OR DIARRHEA, or IF YOU TAKE SOME MEDICINES,** your pills may not work as well. Use a back-up method (such as a condom or spermicide) until you check with your healthcare professional.

6. **IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL,** talk to your healthcare professional about how to make pill taking easier or about using another method of birth control.

7. IF YOU HAVE ANY QUESTIONS OR ARE UNSURE ABOUT THE INFORMATION IN THIS LEAFLET, call your healthcare professional.

BEFORE YOU START TAKING YOUR PILLS

1. DECIDE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILL.

It is important to take it at about the same time every day.

2. LOOK AT YOUR PILL PACK.

The pill pack has 21 "active" pills (with hormones) to take for 3 weeks. This is followed by 1 week of green "reminder" pills (without hormones).

ORTHO-NOVUM[®] 7/7/7: There are 7 white "active" pills, 7 light peach "active" pills, 7 peach "active" pills and 7 green "reminder" pills.

ORTHO-NOVUM[®] 1/35: There are 21 peach "active" pills and 7 green "reminder" pills.

3. ALSO FIND:

1) where on the pack to start taking pills,

2) in what order to take the pills.

4. BE SURE YOU HAVE READY AT ALL TIMES:

ANOTHER KIND OF BIRTH CONTROL (such as a condom or spermicide) to use as a back-up method in case you miss pills.

AN EXTRA, FULL PILL PACK.

WHEN TO START THE FIRST PACK OF PILLS

You have a choice of which day to start taking your first pack of pills. ORTHO-NOVUM[®] 7/7/7 and ORTHO-NOVUM[®] 1/35 are available with the VERIDATE[®] Tablet Dispenser which is preset for a Sunday Start. Day 1 Start is also provided. Decide with your healthcare professional which is the best day for you. Pick a time of day that will be easy to remember.

SUNDAY START:

ORTHO-NOVUM[®] 7/7/7: Take the first white "active" pill of the first pack on the Sunday after your period starts, even if you are still bleeding. If your period begins on Sunday, start the pack the same day.

ORTHO-NOVUM® 1/35: Take the first peach "active" pill of the first pack on the Sunday after your period starts, even if you are still bleeding. If your period begins on Sunday, start the pack the same day.

Use another method of birth control such as a condom or spermicide as a back-up method if you have sex anytime from the Sunday you start your first pack until the next Sunday (7 days).

DAY 1 START:

ORTHO-NOVUM® 7/7/7: Take the first white "active" pill of the first pack during the first 24 hours of your period.

ORTHO-NOVUM® 1/35: Take the first peach "active" pill of the first pack during the first 24 hours of your period.

You will not need to use a back-up method of birth control, since you are starting the pill at the beginning of your period.

WHAT TO DO DURING THE MONTH

1. TAKE ONE PILL AT THE SAME TIME EVERY DAY UNTIL THE PACK IS EMPTY.

Do not skip pills even if you are spotting or bleeding between monthly periods or feel sick to your stomach (nausea). Do not skip pills even if you do not have sex very often.

2. WHEN YOU FINISH A PACK OR SWITCH YOUR BRAND OF PILLS:

Start the next pack on the day after your last green "reminder" pill. Do not wait any days between packs.

WHAT TO DO IF YOU MISS PILLS

ORTHO-NOVUM® 7/7/7:

If you **MISS 1** white, light peach, or peach "active" pill:

1. Take it as soon as you remember. Take the next pill at your regular time. This means you may take 2 pills in 1 day.

2. You do not need to use a back-up birth control method if you have sex.

If you **MISS 2** white or light peach "active" pills in a row in **WEEK 1 OR WEEK 2** of your pack:

1. Take 2 pills on the day you remember and 2 pills the next day.
2. Then take 1 pill a day until you finish the pack.
3. You **COULD BECOME PREGNANT** if you have sex in the 7 days after you miss pills. You **MUST** use another birth control method (such as a condom or spermicide) as a back-up method for those 7 days.

If you **MISS 2** peach "active" pills in a row in **THE 3RD WEEK**:

1a. If you are a Sunday Starter:

Keep taking 1 pill every day until Sunday. On Sunday, **THROW OUT** the rest of the pack and start a new pack of pills that same day.

1b. If you are a Day 1 Starter:

THROW OUT the rest of the pill pack and start a new pack that same day.

2. You may not have your period this month but this is expected. However, if you miss your period 2 months in a row, call your healthcare professional because you might be pregnant.
3. You **COULD BECOME PREGNANT** if you have sex in the 7 days after you miss pills. You **MUST** use another birth control method (such as a condom or spermicide) as a back-up method for those 7 days.

If you **MISS 3 OR MORE** white, light peach, or peach "active" pills in a row (during the first 3 weeks):

1a. If you are a Sunday Starter:

Keep taking 1 pill every day until Sunday. On Sunday, **THROW OUT** the rest of the pack and start a new pack of pills that same day.

1b. If you are a Day 1 Starter:

THROW OUT the rest of the pill pack and start a new pack that same day.

1. You may not have your period this month but this is expected. However, if you miss your period 2 months in a row, call your healthcare professional because you might be pregnant.
2. You **COULD BECOME PREGNANT** if you have sex in the 7 days after you miss pills. You **MUST** use another birth control method (such as a condom or spermicide) as a back-up method for those 7 days.

ORTHO-NOVUM® 1/35:

If you **MISS 1** peach "active" pill:

1. Take it as soon as you remember. Take the next pill at your regular time. This means you may take 2 pills in 1 day.
2. You do not need to use a back-up birth control method if you have sex.

If you **MISS 2** peach "active" pills in a row in **WEEK 1 OR WEEK 2** of your pack:

1. Take 2 pills on the day you remember and 2 pills the next day.
2. Then take 1 pill a day until you finish the pack.
3. You **COULD BECOME PREGNANT** if you have sex in the 7 days after you miss pills. You **MUST** use another birth control method (such as a condom or spermicide) as a back-up method for those 7 days.

If you **MISS 2** peach "active" pills in a row in **THE 3RD WEEK**:

1a. If you are a Sunday Starter:

Keep taking 1 pill every day until Sunday. On Sunday, **THROW OUT** the rest of the pack and start a new pack of pills that same day.

1b. If you are a Day 1 Starter:

THROW OUT the rest of the pill pack and start a new pack that same day.

2. You may not have your period this month but this is expected. However, if you miss your period 2 months in a row, call your healthcare professional because you might be pregnant.
3. You **COULD BECOME PREGNANT** if you have sex in the 7 days after you miss pills. You **MUST** use another birth control method (such as a condom or spermicide) as a back-up method for those 7 days.

If you **MISS 3 OR MORE** peach "active" pills in a row (during the first 3 weeks):

1a. If you are a Sunday Starter:

Keep taking 1 pill every day until Sunday. On Sunday, **THROW OUT** the rest of the pack and start a new pack of pills that same day.

1b. If you are a Day 1 Starter:

THROW OUT the rest of the pill pack and start a new pack that same day.

2. You may not have your period this month but this is expected. However, if you miss your period 2 months in a row, call your healthcare professional because you might be pregnant.
3. You **COULD BECOME PREGNANT** if you have sex in the 7 days after you miss pills. You **MUST** use another birth control method (such as a condom or spermicide) as a back-up method for those 7 days.

A REMINDER

If you forget any of the 7 green "reminder" pills in Week 4: **THROW AWAY** the pills you missed. Keep taking 1 pill each day until the pack is empty. You do not need a back-up method.

FINALLY, IF YOU ARE STILL NOT SURE WHAT TO DO ABOUT THE PILLS YOU HAVE MISSED:

Use a **BACK-UP METHOD** anytime you have sex.

KEEP TAKING ONE "ACTIVE" PILL EACH DAY until you can reach your healthcare professional.

Instructions for using your VERIDATE Pill Dispenser:

- Each VERIDATE Pill Dispenser has 28 pills. See Figure A.

ORTHO NOVUM 1/35

- 21 peach pills with hormones, for Days 1 to 21
- 7 green pills (without hormones), for Days 22 to 28

ORTHO NOVUM 7/7/7

- 7 white pills with hormone, for Days 1 to 7
- 7 light-peach pills with hormone, for Days 8 to 14
- 7 peach pills with hormones, for Days 15 to 21
- 7 green pills (without hormones), for Days 22 to 28

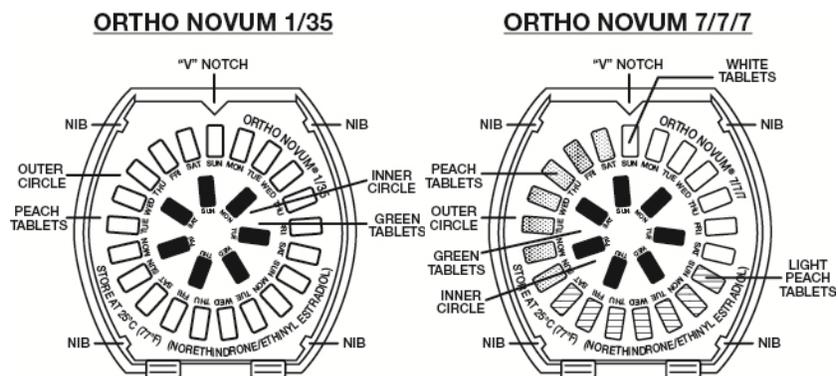


Figure A

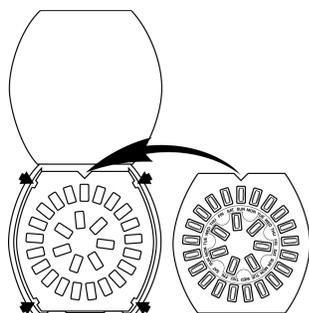


Figure B

Step 1. Place the refill in the VERIDATE Pill Dispenser so that the "V" notch in the refill is at the top of the dispenser. Press the refill down so that it fits firmly under all the nibs. See Figure B.

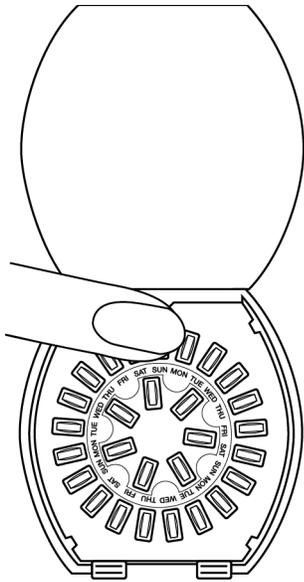


Figure C

Step 2. Starting your pills.

Sunday Start: Remove the first pill at the top of the dispenser (**Sunday**) by pressing the pill through the hole in the bottom of the dispenser. See **Figure C**.

- If your healthcare provider tells you to start taking your pill on Sunday, take your first pill on the first Sunday after your period begins.
- If your period begins on Sunday, take your first pill that day.

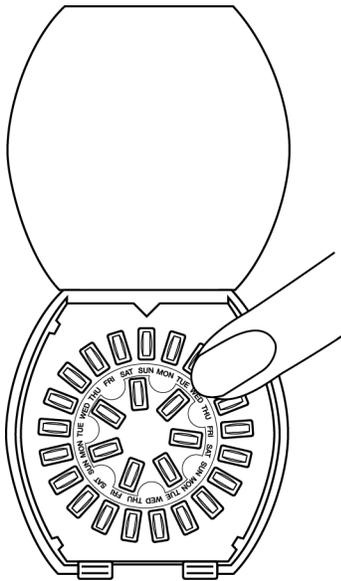


Figure D

Day 1 Start:

If you take ORTHO NOVUM 1/35:

- If your healthcare provider tells you to start taking your pill on “**Day 1**,” choose a peach pill that corresponds with the day of the week on which you are taking the first pill.
- Remove that peach pill by pressing the pill through the hole in the bottom of the dispenser. See **Figure D**.

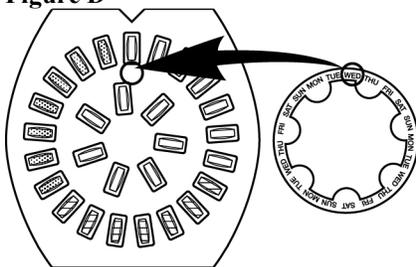


Figure E

If you take ORTHO NOVUM 7/7/7:

- If your healthcare provider tells you to start taking your pill on a day other than Sunday, you will need the calendar label found in your pill package and place it over the calendar in the center of the VERIDATE. See **Figure E**.
- To correctly place the calendar label on the VERIDATE:
 - find your correct starting day
 - find that day printed in blue on the label
 - line your blue starting day up with the first white pill which is directly under the V notch at the top of the dispenser.
- Remove the label from the backing. Press the center of the label down onto the center of the printed calendar.
- Remove that white pill by pressing the pill through the hole in the

bottom of the dispenser. See **Figure F**.

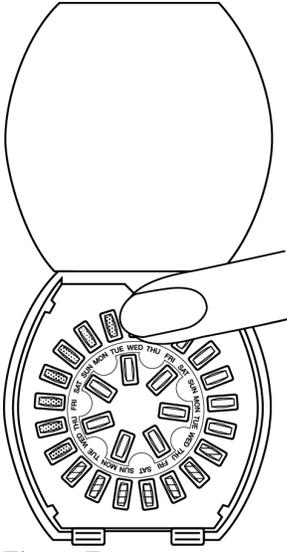


Figure F

Step 3. Continue taking 1 pill every day from the VERIDATE in a clockwise direction until no pills remain in the outer ring. See **Figure G.**

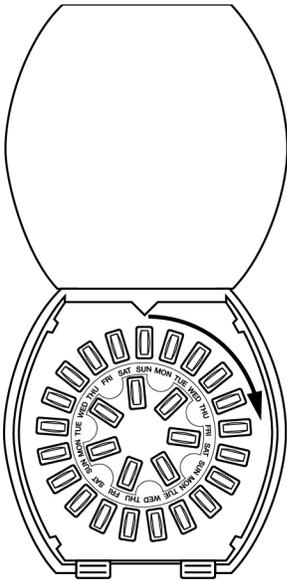


Figure G

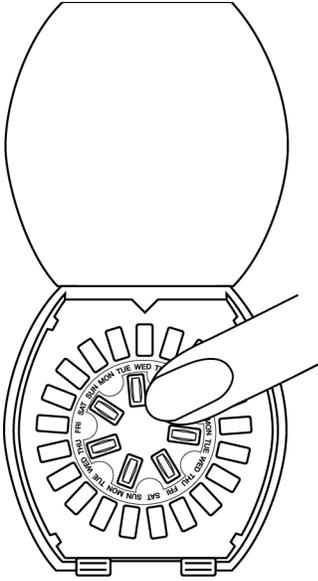


Figure H

Step 4. The next day take a green pill from the inner ring. See Figure H.

- Continue to take a green pill each day until all 7 pills are taken.
- During this time your period should begin.

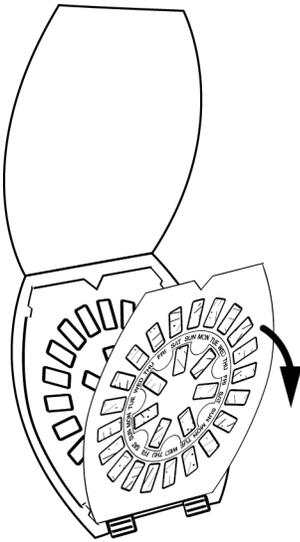


Figure I

Step 5. Insert a new refill:

- After you have taken all the green pills, insert a new refill into the VERIDATE Pill Dispenser and take the first pill on the next day, even if your period is not yet over.
- Lift the empty refill out of the VERIDATE Pill Dispenser. See **Figure I**.
- Follow the instructions in **Step 1** to replace the new refill.