

Brevicon[®]
(Norethindrone and Ethinyl Estradiol) Tablets USP, 0.5 mg/0.035 mg

Norinyl[®] 1+35
(Norethindrone and Ethinyl Estradiol) Tablets USP, 1 mg/0.035 mg

Norinyl[®] 1+50
(Norethindrone and Mestranol) Tablets USP, 1 mg/0.05 mg

Revised: October 2007

Rx only

IN-5386/S

PATIENT LABELING

5386

Watson

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BRIEF SUMMARY

PATIENT PACKAGE INSERT

This product (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

Oral contraceptives, also known as "birth control pills" or "the pill," are taken to prevent pregnancy and, when taken correctly, have a failure rate of about 1% per year when used without missing any pills. The typical failure rate of large numbers of pill users is less than 3% 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 life-threatening or may cause temporary or permanent disability. The risks associated with taking oral contraceptives increase significantly if you:

- Smoke
- Have high blood pressure, diabetes or 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

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

Cigarette smoking increases the risk of serious cardiovascular side effects from oral 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 oral contraceptives are strongly advised not to 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 3 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) or 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), eye or other organs of the body. As mentioned above, smoking increases the risk of heart attacks and strokes and subsequent serious medical consequences.
2. Liver tumors, which may rupture and cause severe bleeding. A possible but not definite association has been found with the pill and liver cancer. However, liver cancers are extremely rare. The chance of developing liver cancer from using the pill is thus even rarer.
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 doctor or health care provider if you notice any unusual physical disturbances while taking the pill. In addition, drugs such as rifampin, as well as some anti-convulsants and some antibiotics, may decrease oral contraceptive effectiveness.

Studies to date of women taking the pill have not shown an increase in the incidence of cancer of the breast or cervix. There is, however, insufficient evidence to rule out the possibility that the pill may cause such cancers. Some studies have reported an increase in the risk of developing breast cancer, particularly at a younger age. This increased risk appears to be related to duration of use.

Taking the pill provides some important non-contraceptive health 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 health care provider. Your health care provider 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 health care provider believes that it is a good medical practice to postpone it. You should be reexamined at least once a year while taking oral contraceptives. The detailed patient information leaflet gives you further information which you should read and discuss with your health care provider.

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 doctor or clinic.
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, for any reason, or IF YOU TAKE SOME MEDICINES, including some antibiotics, your pills may not work as well.
 - Use a back-up method (such as condoms, foam, or sponge) until you check with your doctor or clinic.
6. IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL, talk to your doctor or clinic 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 doctor or clinic.

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4. BE SURE YOU HAVE READY AT ALL TIMES:
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 - AN EXTRA, FULL PILL PACK.

Brevicon, Norinyl 1+35, Norinyl 1+50

Active Pill Colors: White or Yellow-Green or Blue

Reminder Pill Color: Orange

WHO SHOULD NOT TAKE ORAL CONTRACEPTIVES

Cigarette smoking increases the risk of serious cardiovascular side effects from oral 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 oral contraceptives are strongly advised not to smoke.

Some women should not use the pill. For example, you should not take the pill if you are pregnant or think you may be pregnant. You also should not use the pill if you have any of the following conditions:

- A history of heart attack or stroke
- Blood clots in the legs (thrombophlebitis), brain (stroke), 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 a diagnosis is reached by your doctor)
- Yellowing of the whites of the eyes or of the skin (jaundice) during pregnancy or during previous use of the pill
- Liver tumor (benign or cancerous)
- Known or suspected pregnancy

Tell your health care provider if you have ever had any of these conditions. Your health care provider can recommend a safer method of birth control.

OTHER CONSIDERATIONS BEFORE TAKING ORAL CONTRACEPTIVES

Tell your health care provider if you have or have had:

- Breast nodules, fibrocystic disease of the breast, or an abnormal breast x-ray or mammogram
- Diabetes
- Elevated cholesterol or triglycerides
- High blood pressure
- Migraine or other headaches or epilepsy
- Mental depression
- Gallbladder, heart or kidney disease
- History of scanty or irregular menstrual periods

Women with any of these conditions should be checked often by their health care provider if they choose to use oral contraceptives.

Also, be sure to inform your doctor or health care provider if you smoke or are on any medications.

RISKS OF TAKING ORAL CONTRACEPTIVES

1. Risk of developing blood clots

Blood clots and blockage of blood vessels are the most serious side effects of taking oral contraceptives. In particular, a clot in the legs can cause thrombophlebitis and a clot that travels to the lungs can cause a 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.

If you take oral contraceptives and need elective surgery, need to stay in bed for a prolonged illness or have recently delivered a baby, you may be at risk of developing blood clots. You should consult your doctor about stopping oral contraceptives three to four weeks before surgery and not taking oral contraceptives for two weeks after surgery or during bed rest. You should also not take oral contraceptives soon after delivery of a baby. It is advisable to wait for at least four weeks

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before you start taking your pills. If you have completed taking a cycle of pills, if you have taken your pills regularly and miss 1 menstrual period, continue taking your pills for the next cycle but be sure to inform your health care provider before doing so. If you have not taken the pills daily as instructed and miss 1 menstrual period, or if you miss 2 consecutive menstrual periods, you may be pregnant. Check with your health care provider immediately to determine whether you are pregnant. Do not continue to take oral contraceptives until you are sure you are not pregnant, but continue to use another method of birth control.

There is no conclusive evidence that oral contraceptive use is associated with an increase in birth defects when taken inadvertently during early pregnancy. Previously, a few studies had reported that oral contraceptives might be associated with birth defects but these studies have not been

repeated. However, you should know that the following medical conditions have been associated with or made worse by the pill:

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Taking the pill provides some important non-contraceptive health 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 health care provider. Your health care provider 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 health care provider believes that it is a good medical practice to postpone it. You should be reexamined at least once a year while taking oral contraceptives. The detailed patient information leaflet gives you further information which you should read and discuss with your health care provider.

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Brevicon, Norinyl 1+35, Norinyl 1+50

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Some women should not use the pill. For example, you should not take the pill if you are pregnant or think you may be pregnant. You also should not use the pill if you have any of the following conditions:

- A history of heart attack or stroke
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- 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 a diagnosis is reached by your doctor)
- Yellowing of the whites of the eyes or of the skin (jaundice) during pregnancy or during previous use of the pill
- Liver tumor (benign or cancerous)
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Tell your health care provider if you have ever had any of these conditions. Your health care provider can recommend a safer method of birth control.

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Tell your health care provider if you have or have had:

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- Elevated cholesterol or triglycerides
- High blood pressure
- Migraine or other headaches or epilepsy
- Mental depression
- Gallbladder, heart or kidney disease
- History of scanty or irregular menstrual periods

Women with any of these conditions should be checked often by their health care provider if they choose to use oral contraceptives.

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1. Risk of developing blood clots

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Some women should not use the pill. For example, you should not take the pill if you are pregnant or think you may be pregnant. You also should not use the pill if you have any of the following conditions:

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- Blood clots in the legs (thrombophlebitis), brain (stroke), lungs (pulmonary embolism) or eyes
- A history of blood clots in the deep veins of your legs
- Chest pain (angina pectoris)
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- Yellowing of the whites of the eyes or of the skin (jaundice) during pregnancy or during previous use of the pill
- Liver tumor (benign or cancerous)
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- Mental depression
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RISKS OF TAKING ORAL CONTRACEPTIVES

1. Risk of developing blood clots

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before you start taking your pills. If you have completed taking a cycle of pills, if you have taken your pills regularly and miss 1 menstrual period, continue taking your pills for the next cycle but be sure to inform your health care provider before doing so. If you have not taken the pills daily as instructed and miss 1 menstrual period, or if you miss 2 consecutive menstrual periods, you may be pregnant. Check with your health care provider immediately to determine whether you are pregnant. Do not continue to take oral contraceptives until you are sure you are not pregnant, but continue to use another method of birth control.

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KEEP TAKING ONE "ACTIVE" PILL EACH DAY until you can talk to your doctor or clinic.

Missed periods, spotting or light bleeding

At times, you may not have a period after you have completed a pack of pills. If you miss 1 period but you have taken the pills exactly as you were supposed to, continue as usual into the next cycle. If you have not taken the pills correctly, and have missed a period, you may be pregnant and you should stop taking the pill until your doctor or clinic determines whether or not you are pregnant. Until you can talk to your doctor or clinic, use an appropriate back-up birth control method. If you miss 2 consecutive periods, you should stop taking the pill until it is determined that you are not pregnant.

Even if spotting or light bleeding should occur, continue taking the pill according to the schedule. Should spotting or light bleeding persist, you should notify your doctor or clinic.

Stopping the pill before surgery or prolonged bed rest

If you are scheduled for surgery or you need to stay in bed for a long period of time you should tell your doctor that you are on the pill. You should stop taking the pill 4 weeks before your operation to avoid an increased risk of blood clots. Talk to your doctor about when you may start taking the pill again.

Starting the pill after pregnancy

After you have a baby it is advisable to wait 4-6 weeks before starting to take the pill. Talk to your doctor about when you may start taking the pill after pregnancy.

Pregnancy due to pill failure

When the pill is taken correctly, the expected pregnancy rate is approximately 1% (i.e., 1 pregnancy per 100 women per year). If pregnancy occurs while taking the pill, there is little risk to the fetus. The typical failure rate of large numbers of pill users is less than 3% when women who have missed pills are included. If you become pregnant, you should discuss your pregnancy with your doctor.

Pregnancy after stopping the pill

There may be some delay in becoming pregnant after you stop taking the pill, especially if you had irregular periods before you started using the pill. Your doctor may recommend that you delay becoming pregnant until you have had one or more regular periods.

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

Overdosage

There are no reports of serious illness or side effects in young children who have swallowed a large number of pills. In adults, overdosage may cause nausea and/or bleeding in females. In case of overdosage, contact your doctor, clinic or pharmacist.

Other information

Your doctor or clinic will take a medical and family history and will examine you before prescribing the pill. The physical examination may be delayed to another time if you request it and the health care provider 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 doctor or clinic if there is a family history of any of the conditions listed previously in this leaflet. Be sure to keep all appointments with your doctor or clinic because this is a time to determine if there are early signs of side effects from using the pill.

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

If you want more information about birth control pills, ask your doctor or clinic. They have a more technical leaflet called **PHYSICIAN LABELING** which you might want to read.

Store at controlled room temperature 15-25°C (59 -77°F).

Keep out of reach of children.

Address medical inquiries to:
Watson Pharma, Inc.
Medical Communications
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IN-5386/S

S1007

BRIEF SUMMARY PATIENT PACKAGE INSERT (continued)

SUNDAY START:

- Take the first "active" white or yellow-green or blue 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 that same day.
- Use another method of birth control as a back-up method if you have sex anytime from the Sunday you start your first pack until the next Sunday (7 days). Condoms, foam, or the sponge are good back-up methods of birth control.

WHAT TO DO DURING THE MONTH

- 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.

- WHEN YOU FINISH A PACK OR SWITCH YOUR BRAND OF PILLS:**

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

WHAT TO DO IF YOU MISS PILLS

If you **MISS 1** white or yellow-green or blue "active" pill:

- 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.

- You do not need to use a back-up birth control method if you have sex.
- If you **MISS 2** white or yellow-green or blue "active" pills in a row in **WEEK 1 OR WEEK 2** of your pack:

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

If you **MISS 2** white or yellow-green or blue "active" pills in a row in **THE 3rd WEEK**:

- If you are a Day 1 Starter:**

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

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.

- 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 doctor or clinic because you might be pregnant.
- You **MAY BECOME PREGNANT** if you have sex in the **7 days** after you miss pills. You **MUST** use another birth control method (such as condoms, foam, or sponge) as a back-up for those 7 days.

If you **MISS 3 OR MORE** white or yellow-green or blue "active" pills in a row (during the first 3 weeks):

- If you are a Day 1 Starter:**

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

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.

- 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 doctor or clinic because you might be pregnant.
- You **MAY BECOME PREGNANT** if you have sex in the **7 days** after you miss pills. You **MUST** use another birth control method (such as condoms, foam, or sponge) as a back-up for those 7 days.

A REMINDER:

If you forget any of the 7 orange "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 OF BIRTH CONTROL anytime you have sex.

DETAILED PATIENT LABELING (continued)

confirmed. Nevertheless, oral contraceptives or other drugs should not be used during pregnancy unless clearly necessary and prescribed by your doctor. You should check with your doctor about risks to your unborn child from any medication taken during pregnancy.

2. While breast feeding:
If you are breast feeding, consult your doctor before starting oral contraceptives. Some of the drug will be 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, oral contraceptives may decrease the amount and quality of your milk. If possible, do not use oral contraceptives and use another method of contraception while breast feeding. You should consider starting oral contraceptives only after you have weaned your child completely.

3. Laboratory tests

If you are scheduled for any laboratory tests, tell your doctor you are taking birth control pills. Certain blood tests may be affected by birth control pills.

4. Drug interactions

Certain drugs may interact with birth control pills 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) and phenytoin (Dilantin is one brand of this drug); phenylbutazone (Butazolidin is one brand of this drug) and possibly certain antibiotics. You may need to use additional contraception when you take drugs which can make oral contraceptives less effective.

5. This product (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against transmission of HIV infection (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:

- BE SURE TO READ THESE DIRECTIONS:**
Before you start taking your pills.
Anything you are not sure what to do.
- 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 doctor or clinic.

4. MISSING PILLS CAN 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, for any reason, or **IF YOU TAKE SOME MEDICINES**, including some antibiotics, your pills may not work as well.

Use a back-up method (such as condoms, foam, or sponge) until you check with your doctor or clinic.

6. IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL, talk to your doctor or clinic 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 doctor or clinic.

BEFORE YOU START TAKING YOUR PILLS

- DECIDE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILL.**
It is important to take it at about the same time every day.
- LOOK AT YOUR PILL PACK:**

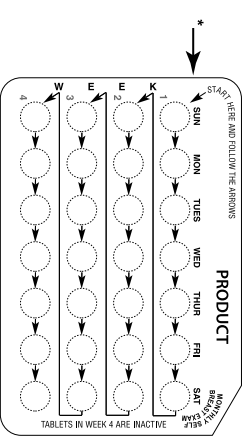
The 28-pill pack has 21 "active" white or yellow-green or blue pills (with hormones) to take for

3 weeks, followed by 1 week of reminder orange pills (without hormones).

ALSO FIND:

- Where on the pack to start taking pills,
- In what order to take the pills (follow the arrows) and
- The week numbers as shown in the picture below.

Brevicon, Norinyl 1+53, Norinyl 1+50
Active Pill Colors: White or Yellow-Green or Blue
Reminder Pill Color: Orange



*For use of day labels, see **WHEN TO START THE FIRST PACK OF PILLS** below.

4. BE SURE YOU HAVE READY AT ALL TIMES: ANOTHER KIND OF BIRTH CONTROL (such as condoms, foam, or sponge) to use as a back-up 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. Decide with your doctor or clinic which is the best day for you. Pick a time of day which will be easy to remember.

DAY 1 START:

- Pick the day label strip that starts with the first day of your period. Place this day label strip over the area that has the days of the week (starting with Sunday) pre-printed on the tablet dispenser. Note: if the first day of your period is a Sunday, you can skip step #1.
- Take the first "active" white or yellow-green or blue 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.

SUNDAY START:

- Take the first "active" white or yellow-green or blue 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 that same day.
- Use another method of birth control as a back-up method if you have sex anytime from the Sunday you start your first pack until the next Sunday (7 days). Condoms, foam, or the sponge are good back-up methods of birth control.

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 "reminder" pill. Do not wait any days between packs.

WHAT TO DO IF YOU MISS PILLS

If you **MISS 1** white or yellow-green or blue "active" pill:

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

If you **MISS 2** white or yellow-green or blue "active" pills in a row in **WEEK 1 OR WEEK 2** of your pack:

- Take 2 pills on the day you remember and 2 pills the next day.
- Then take 1 pill a day until you finish the pack.

3. YOU MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills. You **MUST** use another birth control method (such as condoms, foam, or sponge) as a back-up for those 7 days. If you **MISS 2** white or yellow-green or blue "active" pills in a row in **THE 3rd WEEK**:

- If you are a Day 1 Starter:**

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

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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.

- 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 doctor or clinic because you might be pregnant.
- You **MAY BECOME PREGNANT** if you have sex in the **7 days** after you miss pills. You **MUST** use another birth control method (such as condoms, foam, or sponge) as a back-up for those 7 days.

If you **MISS 3 OR MORE** white or yellow-green or blue "active" pills in a row (during the first 3 weeks):
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- 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 doctor or clinic because you might be pregnant.
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REMINDER:

If you forget any of the 7 orange "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 OF BIRTH CONTROL anytime you have sex.
KEEP TAKING ONE "ACTIVE" PILL EACH DAY until you can talk to your doctor or clinic.

6. Missed periods, spotting or light bleeding

At times, you may not have a period after you have completed a pack of pills. If you miss 1 period but you have taken the pills exactly as you were supposed to, continue as usual into the next cycle. If you have not taken the pills correctly, and have missed a period, you may be pregnant and you should stop taking the pill until your doctor or clinic determines whether or not you are pregnant. Until you can talk to your doctor or clinic, use an appropriate back-up birth control method. If you miss 2 consecutive periods, you should stop taking the pill until it is determined that you are not pregnant.

Even if spotting or light bleeding should occur, continue taking the pill according to the schedule. Should spotting or light bleeding persist, you should notify your doctor or clinic.

7. Stopping the pill before surgery or prolonged bed rest

If you are scheduled for surgery or you need to stay in bed for a long period of time you should tell your doctor that you are on the pill. You should stop taking the pill 4 weeks before your operation to avoid an increased risk of blood clots. Talk to your doctor about when you may start taking the pill again.

8. Starting the pill after pregnancy

After you have a baby it is advisable to wait 4-6 weeks before starting to take the pill. Talk to your doctor about when you may start taking the pill after pregnancy.

9. Pregnancy due to pill failure

When the pill is taken correctly, the expected pregnancy rate is approximately 1% (i.e., 1 pregnancy per 100 women per year). If pregnancy occurs while taking the pill, there is little risk to the fetus. The typical failure rate of large numbers of pill users is less than 3% when women who have missed pills are included. If you become pregnant, you should discuss your pregnancy with your doctor.

10. Pregnancy after stopping the pill

There may be some delay in becoming pregnant after you stop taking the pill, especially if you had irregular periods before you started using the pill. Your doctor may recommend that you delay becoming pregnant until you have had one or more regular periods.

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

11. Overdosage

There are no reports of serious illness or side effects in young children who have swallowed a large number of pills. In adults, overdosage may cause nausea and/or bleeding in females. In case of overdosage, contact your doctor, clinic or pharmacist.

12. Other information

Your doctor or clinic will take a medical and family history and will examine you before prescribing the pill. The physical examination may be delayed to another time if you request it and the health care provider 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 doctor or clinic if there is a family history of any of the conditions listed previously in this leaflet. Be sure to keep all appointments with your doctor or clinic because this is a time to determine if there are early signs of side effects from using the pill. Do not use the pill for any condition other than the one for which it was prescribed. The pill has been prescribed specifically for you, do not give it to others who may want birth control pills.

If you want more information about birth control pills, ask your doctor or clinic. They have a more technical leaflet called **PHYSICIAN LABELING** which you might want to read.

NON-CONTRACEPTIVE HEALTH BENEFITS

In addition to preventing pregnancy, use of oral contraceptives may provide certain non-contraceptive health benefits:

- Menstrual cycles may become more regular
- Blood flow during menstruation may be lighter and less iron may be lost. Therefore, anemia due to iron deficiency is less likely to occur
- Pain or other symptoms during menstruation may be encountered less frequently
- Ectopic (tubal) pregnancy may occur less frequently
- Non-cancerous cysts or lumps in the breast may occur less frequently
- Acute pelvic inflammatory disease may occur less frequently
- Oral contraceptive use may provide some protection against developing two forms of cancer: cancer of the ovaries and cancer of the lining of the uterus

Store at controlled room temperature 15-25°C (59-77°F).

Keep out of reach of children.

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