

**PACKAGE INSERT FOR PATIENTS**  
**USING ORAL CONTRACEPTIVES**  
**(BIRTH CONTROL PILLS) AND THOSE**  
**CONSIDERING THE USE OF ORAL CONTRACEPTIVES**

SYNPHASIC is a birth control pill (oral contraceptive) that contains two female sex hormones. SYNPHASIC contains 35 mcg of ethinyl estradiol and 1 mg of norethindrone (white tablets) and 35 mcg of ethinyl estradiol and 0.5 mg of norethindrone (blue tablets). SYNPHASIC has been shown to be highly effective in preventing pregnancy when taken as prescribed by your doctor. Pregnancy is always more risky than taking birth control pills, except in smokers over 35.

The birth control pill is not suitable for every woman. In a small number of women, serious side effects may occur. Your doctor can advise you if you have any conditions that would pose a risk to you. The use of the birth control pill always should be supervised by your doctor.

## **INTRODUCTION**

This pamphlet will give you information to make an informed choice on the use of oral contraceptives. Oral contraceptives are also known as birth control pills or "the pill."

You should read this pamphlet if you are thinking about any method of birth control. If you have decided to take birth control pills, this pamphlet will help you understand both the risks and the benefits. It also will give you information on how to use birth control pills.

When taken as directed, birth control pills are a very effective way to prevent pregnancy. Only sterilization is more effective. The pill is convenient and has many benefits other than birth control. Most women do not develop serious and unpleasant side effects from using birth control pills.

The pill has important advantages over other methods of birth control. It also has certain risks that no other method has and some of these risks may continue after you have stopped using the pill. Your doctor is the best person to explain the consequences of any possible risks. Only you however can decide whether the advantages are worth the risks.

You can help your doctor prescribe birth control pills as safely as possible. Tell your doctor about yourself, and be alert for the earliest signs of possible trouble.

Read this pamphlet carefully and discuss its contents with your doctor.

## **TYPES OF BIRTH CONTROL PILL**

There are two types of birth control pills:

1. the "combination pill" is the most common type. It contains two female sex hormones - an estrogen and a progestin. The amounts and types of estrogen and progestin differ from one preparation to another. The amount of estrogen is more important. The effectiveness and some dangers of birth control pills are related mainly to the amount of estrogen.
2. the "mini-pill" is the second type. It contains only one female sex hormone - a progestin.

## **HOW BIRTH CONTROL PILLS WORK**

Birth control pills work in two ways:

1. They inhibit the monthly release of an egg by the ovaries.
2. They change the mucus produced by the cervix. This slows the movement of the sperm through the mucus and through the uterus (womb).

## **EFFECTIVENESS OF BIRTH CONTROL PILLS**

Combination birth control pills are more than 99 percent effective in preventing pregnancy when:

- the pill is **TAKEN AS DIRECTED**, and
- the amount of estrogen is 20 micrograms or more.

A 99 percent effectiveness rate means that if 100 women used birth control pills for one year, one woman in the group would get pregnant.

The mini-pill (progestin only) is slightly less effective than combination birth control pills.

## **OTHER WAYS TO PREVENT PREGNANCY**

Other methods of birth control are available to you. They are usually less effective than birth control pills. Used properly, however, other methods of birth control are effective enough for many women. The following table gives reported pregnancy rates for various forms of birth control, including no birth control. The reported rates represent the number of women out of 100 who would become pregnant in one year.

### Reported Pregnancies per 100 Women per Year

Combination pill	less than 1 to 2
Intrauterine device (IUD)	less than 1 to 6
Condom with spermicidal foam or gel	1 to 6
Mini-pill	3 to 6
Condom	2 to 12
Diaphragm with spermicidal foam or gel	3 to 18
Spermicide	3 to 21
Sponge with spermicide	3 to 28
Cervical cap with spermicide	5 to 18
Periodic abstinence (rhythm), all types	2 to 20
No birth control	60 to 85

Pregnancy rates vary widely because people differ in how carefully and regularly they use each method. (This does not apply to IUDs since they are implanted in the uterus.) Regular users may achieve pregnancy rates in the lower ranges. Others may expect pregnancy rates more in the middle ranges.

The effective use of birth control methods other than birth control pills and IUDs requires more effort than taking a single pill every day. It is an effort that many couples undertake successfully.

## WHO SHOULD NOT USE BIRTH CONTROL PILLS

You should not use birth control pills if you have or have had any of the following conditions:

- unusual vaginal bleeding that has not yet been diagnosed
- blood clots in the legs, lungs, eyes, or elsewhere
- a stroke, heart attack or chest pain (angina pectoris)
- known or suspected cancer of the breast or sex organs
- liver tumour associated with the use of birth control pills or other estrogen-containing products
- jaundice or liver disease if still present

The pill should not be taken if you are pregnant or if pregnancy is suspected.

There are also conditions that your doctor will want to watch closely or that might cause your doctor to recommend a method of contraception other than birth control pills:

- breast conditions:
  - > a family history of breast cancer
  - > breast disorders including pain, discharge from the nipples, thickenings, or lumps. In some circumstances, benefit may be derived from taking the pill; in other cases, adverse effects may follow.
- diabetes
- high blood pressure
- abnormal levels of fats in the bloodstream (high cholesterol or triglycerides)
- cigarette smoking
- migraine headaches
- heart or kidney disease
- epilepsy
- mental depression
- fibroid tumours of the uterus
- gallbladder or pancreatic disease

- plans for forthcoming surgery
- history of jaundice or other liver disease

You also should inform your doctor about a family history of blood clots, heart attacks or strokes.

## **THE RISK OF BIRTH CONTROL PILLS**

### **1. Circulatory disorders (including blood clots in legs, lungs, heart, eyes or brain)**

Blood clots are the most common serious side effect of birth control pills. Clots can occur in many areas of the body.

- In the brain, a clot can result in a stroke.
- In a blood vessel of the heart, a clot can result in a heart attack.
- In the legs and pelvis, a clot can break off and travel to the lung resulting in a pulmonary embolus.
- In a blood vessel leading to an arm or leg, a clot can result in damage to or loss of a limb.

Any of these conditions can cause death or disability. Clots also occur rarely in the blood vessels of the eye, resulting in blindness or impaired vision.

Women who use birth control pills have a higher incidence of blood clots. While the risk of blood clots increases with age in both pill users and non users, the increased risk from the pill appears to be present at all ages. The risk of clotting seems to increase with higher estrogen doses. **It is important, therefore, to use as low a dosage of estrogen as possible.**

Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels. This risk increases with age and becomes significant in birth control pill users over 35 years of age. Women should not smoke.

## 2. **Breast cancer**

The most significant risk factors for breast cancer are increasing age and a history of breast cancer in the family (mother or sister). Other established risk factors include obesity, never having children, and having your first full-term pregnancy at a late age.

Some women who use birth control pills may be at increased risk of developing breast cancer before menopause which occurs around age 50. These women may be long-term users of birth control pills (more than eight years) or women who start using birth control pills at an early age. In a few women, the use of birth control pills may accelerate the growth of an existing but undiagnosed breast cancer. Early diagnosis, however, can reduce the effect of breast cancer on a woman's life expectancy. The potential risks related to birth control pills seem to be small, however.

Women with the following conditions should be examined yearly by their doctors no matter what method of contraception they use:

- a history of breast cancer in the family
- breast nodules or thickenings
- discharge from the nipple

### 3. **Dangers to developing child if birth control pills are used during pregnancy**

Oral contraceptives should not be taken by pregnant women because they may damage the developing child. An increased risk of heart and limb and other defects has been associated with the use of sex hormones, including oral contraceptives, during pregnancy. In addition, the developing female child whose mother has received DES (diethylstilbestrol), an estrogen, during pregnancy has a risk of developing cancer of the vagina or cervix in her teens or young adulthood.

Abnormalities of the urinary tract and sex organs have been reported in male offspring so exposed. It is possible, although this has not been demonstrated, that other estrogens such as those in oral contraceptives could have the same effect in the child if the mother takes them during pregnancy.

There is also no conclusive evidence that the use of birth control pills immediately before a pregnancy will adversely affect a baby's development. When a woman stops taking birth control pills to become pregnant, however, her doctor may recommend a different method of contraception until she has a period on her own. In this way, the pregnancy can be more accurately dated.

### 4. **Gallbladder disease and liver tumours**

Users of birth control pills have a greater risk of developing gallbladder disease requiring surgery within the first year of use. The risk may double after four or five years of use.

The short and long-term use of birth control pills also has been linked with the growth of benign or malignant liver tumours. Such tumours are extremely rare. Benign tumours do not spread but they may rupture and produce internal bleeding which may cause death.

## 5. Other side effects of birth control pills

Some users of birth control pills have unpleasant side effects. These side effects are temporary and are not hazardous to health.

There may be tenderness of the breasts, nausea, and vomiting. Some users will experience weight gain or loss. Many of these side effects occurred with high dose combination birth control pills. These side effects are less common with the low dose pills prescribed today.

Unexpected vaginal bleeding or spotting and changes in the usual menstrual period also may occur. These side effects usually disappear after the first few cycles.

They are **NOT** an indication to stop taking birth control pills. Unless more significant complications occur, a decision to stop using the pill or to change the brand of pill should be made only after three consecutive months of use.

Occasionally, users develop high blood pressure that may require stopping the use of birth control pills. High blood pressure may persist after stopping the pill and may lead to serious disease of the kidney and circulatory system.

Other side effects may include:

- growth of pre-existing fibroid tumours of the uterus
- mental depression
- liver problems with jaundice (yellowing of the skin)
- an increase or decrease in hair growth, sex drive and appetite
- skin pigmentation
- headaches
- rash
- vaginal infections

Infrequently, there is a need to change contact lens prescription or an inability to use contact lenses.

A woman's menstrual period may be delayed after stopping birth control pills. There is no evidence that the use of the pill leads to a decrease in fertility. As mentioned, it is wise to delay starting a pregnancy for one menstrual period after stopping birth control pills.

## **NON-CONTRACEPTIVE BENEFITS OF BIRTH CONTROL PILLS**

Several health advantages have been linked to the use of birth control pills.

### **EFFECTS ON MENSES**

- increased menstrual cycle regularity
- decreased menstrual blood loss
- decreased incidence of iron deficiency anemia secondary to reduced menstrual blood loss
- decreased incidence of dysmenorrhea (painful periods) and premenstrual syndrome (PMS)

### **EFFECTS RELATED TO OVULATION INHIBITION**

- decreased incidence of functional ovarian cysts
- decreased incidence of ectopic pregnancy

### **EFFECTS ON OTHER ORGANS OF THE REPRODUCTIVE TRACT**

- decreased incidence of acute uterine tube inflammation
- decreased incidence of endometrial cancer (50 per cent)
- decreased incidence of ovarian cancer (40 per cent)
- potential beneficial effects on endometriosis

- decreased incidence of acne, excessive hair growth and other male hormone-related disorders

## EFFECTS ON BREASTS

- decreased incidence of benign (non-cancerous) breast disease
- decreased incidence of breast biopsies

The non-contraceptive benefits of oral contraceptives should be considered in addition to the efficacy of these preparations when counselling patients regarding contraceptive method selection.

**Birth control pills DO NOT PROTECT** against sexually transmitted diseases (STDs), including HIV/AIDS. For protection against STDs, it is advisable to use latex condoms **IN COMBINATION WITH** birth control pills.

## Periodic examination

A complete medical and family history is necessary before birth control pills are prescribed. A physical examination should include measuring blood pressure and examining the breasts, abdomen, pelvic organs, and limbs.

A second visit to your doctor should take place three months or sooner after starting birth control pills. During this visit, any side effects should be evaluated and your blood pressure checked again. Afterward, an annual examination similar to the first visit is recommended. A Pap smear is usually taken before starting birth control pills and then at intervals recommended by your doctor.

## IF YOU DECIDE TO TAKE BIRTH CONTROL PILLS

If you and your doctor decide that, for you, the benefits of birth control pills outweigh the risks, you should be aware of the following:

1. Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels. This risk increases with age and becomes significant in birth control pill users over 35 years of age. Women should not smoke.

2. Take the pills only on the advice of your doctor and carefully follow all directions given to you. You must take the pills exactly as prescribed. Otherwise, you may become pregnant.
3. Visit your doctor three months or sooner after the initial examination. Afterward, visit your doctor at least once a year.
4. Be alert for the following symptoms and signs of serious adverse effects. Call your doctor immediately if they occur:
  - sharp pain in the chest, coughing blood, or sudden shortness of breath. These symptoms could indicate a possible blood clot in the lung.
  - pain in the calf. This symptom could indicate a possible blood clot in the leg.
  - crushing chest pain or heaviness. This symptom could indicate a possible heart attack.
  - sudden severe or worsening headache or vomiting, dizziness or fainting, disturbance of vision or speech, or weakness or numbness in an arm or leg. These symptoms could indicate a possible stroke.
  - sudden partial or complete loss of vision. This symptom could indicate a possible blood clot in the eye.

- severe pain or lump in the abdomen. These symptoms could indicate a possible tumour of the liver.
  - severe depression
  - yellowing of the skin (jaundice)
  - unusual swelling of the extremities
  - breast lumps. **ASK YOUR DOCTOR FOR ADVICE AND INSTRUCTION ON REGULAR SELF-EXAMINATION OF YOUR BREASTS.**
5. Birth control pills should never be taken if you think you are pregnant. They will not prevent the pregnancy from continuing and may interfere with the normal development of the baby.
  6. You will have a menstrual period when you stop taking birth control pills. You should delay pregnancy until another menstrual period occurs within four to six weeks. Contact your doctor for recommendations on alternate methods of contraception during this time.
  7. Your doctor will advise you of the appropriate time to start the use of birth control pills after childbirth, miscarriage, or therapeutic abortion.
  8. The use of oral contraceptives during the period a mother is breastfeeding her infant may not be advisable. The hormonal components are excreted in breast milk and may reduce its quantity and quality. The long-term effects on the developing child are not known.
  9. Should you require **MAJOR** surgery, inform your surgeon that you are using birth control pills.

10. **If you see a different doctor, inform him or her that you are taking birth control pills. Tell the doctor that your birth control pills are Synphasic.**

11. Inform your doctor if you are taking or if you start to take other medications. This applies to both prescription and non-prescription drugs. These medications may change the effectiveness and/or cycle control of your birth control pills. **You may need to use a back-up method of birth control.**

12. **THERE IS NO NEED TO STOP TAKING BIRTH CONTROL PILLS FOR A REST PERIOD.**

13. Birth control pills **DO NOT PROTECT** against sexually transmitted diseases (STDs), including HIV/AIDS. For protection against STDs, it is advisable to use latex condoms **IN COMBINATION WITH** birth control pills.

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## HOW TO TAKE BIRTH CONTROL PILLS

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1. **Read These Directions**
- before you start taking your pills, and
  - any time you are not sure what to do.
2. **Look at your pill pack** to see if it has 21 or 28 pills:

- 21-PILL PACK: 21 active pills (with hormones) taken daily for three weeks, and then take no pills for one week.

or

- 28-PILL PACK: 21 active pills (with hormones) taken daily for three weeks, and then seven "reminder" pills (no hormones) taken daily for one week.
3. It is recommended that you use a second method of birth control (e.g. latex condoms and spermicidal foam or gel) for the first seven days of the first cycle of pill use. This will provide a back-up in case pills are forgotten while you are getting used to taking them.
  4. **When receiving any medical treatment, be sure to tell your doctor that you are using birth control pills.**
  5. **Many women have spotting or light bleeding, or may feel sick to their stomach during the first three months on the pill.** If you do feel sick, do not stop taking the pill. The problem will usually go away. If it does not go away, check with your doctor or clinic.
  6. **Missing pills also can cause some spotting or light bleeding,** even if you make up the missed pills. You also could feel a little sick to your stomach on the days you take two pills to make up for missed pills.
  7. **If you miss pills at any time, you could get pregnant. The greatest risks for pregnancy are:**
    - when you start a pack late; or,
    - when you miss pills at the beginning or at the very end of the pack.

8. **Always be sure you have ready:**
  - **Another kind of birth control** (such as latex condoms and spermicidal foam or gel) to use as a back-up in case you miss pills, and
  - **An extra, full pack of pills.**
9. **If you have vomiting or diarrhea, or if you take certain medicines**, such as antibiotics, your pills may not work as well. Use a back-up method, such as latex condoms and spermicidal foam or gel, until you can check with your doctor or clinic.
10. **If you forget more than one pill two months in a row**, talk to your doctor or clinic about how to make pill-taking easier or about using another method of birth control.
11. **If your questions are not answered here, call your doctor or clinic.**

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### WHEN TO START THE FIRST PACK OF SYNPHASIC PILLS

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#### **Be sure to read these instructions**

- before you start taking your pills, and
- any time you are not sure what to do.

Decide with your doctor or clinic what is the best day for you to start taking your first pack of pills. Your pills may be either a 21 day or a 28 day type.

## A. 21-DAY PACK

With this type of birth control pill, you are on pills for 21 days and off pills for seven days. You must not be off the pills for more than seven days in a row.

1. **The first day of your menstrual period (bleeding) is day 1 of your cycle.** Your doctor may advise you to start taking the pills on Day 1, on Day 5, or on the first Sunday after your period begins. If your period starts on Sunday, start that same day.
2. Label your pack correctly before starting. The pack is pre-printed with a Sunday starting day. If you are starting on a day other than a Sunday, use the Flexi-start™ sticker labels provided. Peel off the label with the chosen starting day and apply over the pre-printed days on top of the card.
3. Take one pill at approximately the same time every day for 21 days; **then take no pills for seven days.** Start a new pack on the eighth day. You will probably have a period during the seven days off the pill. (This bleeding may be lighter and shorter than your usual period.)

## B. 28-DAY PACK

With this type of birth control pill, you take 21 pills which contain hormones and seven pills which contain no hormones.

1. **The first day of your menstrual period (bleeding) is day 1 of your cycle.** Your doctor may advise you to start taking your pills on Day 1, on Day 5, or on the first Sunday after your period begins. If your period starts on Sunday, start that same day.
2. Label your pack correctly before starting. The pack is pre-printed with a Sunday starting day. If you are starting on a day other than a Sunday, use the Flexi-start™ sticker labels

provided. Peel off the label with the chosen starting day and apply over the pre-printed days on top of the card.

3. Take one pill at approximately the same time every day for 28 days. Begin a new pack the next day, **not missing any days on the pills**. Your period should occur during the last seven days of using that pill pack.

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## WHAT TO DO DURING THE MONTH

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1. **Take a pill approximately the same time every day until the pack is empty.**
  - Try to associate taking your pill with some regular activity like eating a meal or going to bed.
  - Do not skip pills even if you have 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:**
  - **21 Pills**

**Wait seven days** to start the next pack. You will have your period during that week.

- **28 Pills**

Start the next pack **on the next day**. Take one pill every day. Do not wait any days between packs.

### WHAT TO DO IF YOU MISS PILLS

The following chart outlines the actions you should take if you miss one or more of your birth control pills. Match the number of pills missed with the appropriate starting time for your type of pill pack.

<b>SUNDAY START</b>	<b>OTHER THAN SUNDAY START</b>
<p><b>MISS ONE PILL</b> Take it as soon as you remember, and take the next pill at the usual time. This means that you might take two pills in one day.</p>	<p><b>MISS ONE PILL</b> Take it as soon as you remember, and take the next pill at the usual time. This means that you might take two pills in one day.</p>
<p><b>MISS TWO PILLS IN A ROW</b> <b>First Two Weeks:</b></p> <ol style="list-style-type: none"> <li>1. Take two pills the day you remember and two pills the next day.</li> <li>2. Then take one pill a day until you finish the pack.</li> <li>3. Use a back-up method of birth control if you have sex in the seven days after you miss the pills.</li> </ol> <p><b>Third Week:</b></p> <ol style="list-style-type: none"> <li>1. Keep taking one pill a day until Sunday.</li> <li>2. On Sunday, safely discard the rest of the pack and start a new pack that day.</li> <li>3. Use a back-up method of birth control if you have sex in the seven days after you miss the pills.</li> <li>4. You may not have a period this month.</li> </ol> <p><b>IF YOU MISS TWO PERIODS IN A ROW, CALL YOUR DOCTOR OR CLINIC.</b></p>	<p><b>MISS TWO PILLS IN A ROW</b> <b>First Two Weeks:</b></p> <ol style="list-style-type: none"> <li>1. Take two pills the day you remember and two pills the next day.</li> <li>2. Then take one pill a day until you finish the pack.</li> <li>3. Use a back-up method of birth control if you have sex in the seven days after you miss the pills.</li> </ol> <p><b>Third Week:</b></p> <ol style="list-style-type: none"> <li>1. Safely dispose of the rest of the pill pack and start a new pack that same day.</li> <li>2. Use a back-up method of birth control if you have sex in the seven days after you miss the pills.</li> <li>3. You may not have a period this month.</li> </ol> <p><b>IF YOU MISS TWO PERIODS IN A ROW, CALL YOUR DOCTOR OR CLINIC.</b></p>

**MISS THREE OR MORE PILLS IN A ROW**

**Anytime in the Cycle:**

1. Keep taking one pill a day until Sunday.
4. On Sunday, safely discard the rest of the pack and start a new pack that day.
5. Use a back-up method of birth control if you have sex in the seven days after you miss the pills.
4. You may not have a period this month.

**IF YOU MISS TWO PERIODS IN A ROW,  
CALL YOUR DOCTOR OR CLINIC.**

**MISS THREE OR MORE PILLS IN A ROW**

**Anytime in the Cycle:**

1. Safely dispose of the rest of the pill pack and start a new pack that same day.
2. Use a back-up method of birth control if you have sex in the seven days after you miss the pills.
3. You may not have a period this month.

**IF YOU MISS TWO PERIODS IN A ROW, CALL YOUR DOCTOR OR CLINIC.**

**NOTE: 28-DAY PACK:** If you forget any of the seven "reminder" pills (without hormones) in Week 4, just safely dispose of the pills you missed. Then keep taking one pill each day until the pack is empty. You do not need to use a back-up method.

Always be sure you have on hand:

- a back-up method of birth control (such as latex condoms and spermicidal foam or gel) in case you miss pills, and
- an extra, full pack of pills.

**If you forget more than one pill two months in a row, talk to your doctor or clinic.** Talk about ways to make pill-taking easier or about using another method of birth control.

Keep this and all medication out of reach of children.

SYNPHASIC\*

Store between 15 to 25°C.