

**PART III: CONSUMER INFORMATION**

**Pr SYNPHASIC\*  
(Norethindrone and Ethinyl Estradiol  
Tablets)**

**This leaflet is part III of a three-part "Product Monograph" published when SYNPHASIC was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SYNPHASIC. Contact your doctor or pharmacist if you have any questions about the drug.**

**ABOUT THIS MEDICATION**

**What the medication is used for:**

SYNPHASIC is used for the prevention of pregnancy.

**What it does:**

SYNPHASIC is a birth control pill (oral contraceptive) that contains two female sex hormones (ethinyl estradiol and norethindrone). 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 chance of becoming pregnant increases with incorrect use.

**Birth control pills work by inhibiting the monthly release of an egg(s) by the ovaries. Some studies have demonstrated changes in the endometrium (lining of the womb) and mucus produced by the cervix (opening of the uterus) with the use of birth control pills.**

**Effectiveness of Birth Control Pills**

Combination birth control pills (like SYNPHASIC) 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.

**Birth control pills may become less effective when:**

- You miss taking tablets
- You have vomiting or diarrhea

- You take other medications that may interact with SYNPHASIC

**Other Ways to Prevent Pregnancy**

Other methods of birth control are available to you. They are usually less effective than birth control pills. However, when used properly, they 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 system (IUS)	less than 1 to 6
Condom with spermicidal foam or gel	1 to 6
Mini-pill (progesterone-only 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 IUSs 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 IUSs requires more effort than taking a single pill every day. It is an effort that many couples undertake successfully.

**When it should not be used:**

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.

Do not use SYNPHASIC if you have any of the following:

- History of or actual thrombophlebitis (inflammation of the veins) or thromboembolic disorders, such as blood clots in the legs, lungs, eyes, or elsewhere.
- History of or actual cerebrovascular disorders, such as a stroke or a condition that may be a first sign of stroke (e.g. mini-stroke).
- History of or actual myocardial infarction or coronary arterial disease, heart attack or chest pain (e.g. angina pectoris).
- Jaundice or active liver disease, or history of or actual benign or malignant liver tumours.
- History of or known or suspected carcinoma of the breast or sex organs.
- History of or known or suspected tumours associated with estrogen containing products.
- Undiagnosed abnormal vaginal bleeding.
- Loss of vision due to blood vessel disease of the eye.
- When pregnancy is suspected or diagnosed.
- Disease of the heart valves with complications
- Irregular heart rhythm
- Migraines with visual and/or sensory disturbances. You may be at increased risk of having a stroke.
- Diabetes affecting your circulation
- Severe or uncontrolled high blood pressure
- History of or actual pancreatitis (inflammation of the pancreas) associated with high levels of fatty substances in your blood.
- Allergic reaction to norethindrone, ethinyl estradiol or to any other ingredients in SYNPHASIC (see What the important nonmedicinal ingredients are)
- Known abnormalities of the blood clotting system that increases your risk for developing blood clots
- Very high blood cholesterol or triglyceride levels
- Heavy smoking (>15 cigarettes per day) and over age 35
- You had an injury or trauma, or are scheduled for major surgery
- Severe obesity (body mass index of 30 or more)

- Prolonged bed rest, or immobility (e.g.: long air travel)
- Have varicose veins
- Need a leg cast
- Have not yet started to menstruate
- Are in menopause
- Are using medicines to treat Hepatitis C which contain combination of ombitasvir, paritaprevir, ritonavir and dasabuvir, with or without ribavirin.

**What the medicinal ingredient is:**

The medicinal ingredients are: norethindrone and ethinyl estradiol

**What the important nonmedicinal ingredients are:**

**Active tablets:** corn starch, FD & C Blue No. 2 (0.5 mg/ 0.035mg (35 mcg) tablets only), lactose hydrous, polyvidone, magnesium stearate.

**Inactive tablets:** FD & C Yellow No. 6 Lake, lactose, lactose monohydrate, magnesium stearate, microcrystalline cellulose.

**What dosage forms it comes in:**

21 day dispensers (9 (1.0 mg/ 0.035 mg (35 mcg)) active tablets and 12 (0.5 mg/ 0.035 mg (35 mcg)) active tablets).

28 day dispensers (9 (1.0 mg/0.035 mg (35 mcg)) active tablets and 12 (0.5 mg/0.035 mg (35 mcg)) active tablets and 7 inactive tablets).

Norethindrone 1.0 mg/ethinyl estradiol 0.035 mg (35 mcg) active tablets: White circular tablets, impressed "SEARLE" on one side and "BX" on the other.

Norethindrone 0.5 mg/ethinyl estradiol 0.035 mg (35 mcg) active tablets: Blue circular tablets, impressed "SEARLE" on one side and "BX" on the other.

Inactive tablets: orange tablets, impressed "SEARLE" on one side and "P" on the other.

**WARNINGS AND PRECAUTIONS**

### Serious Warnings and Precautions

Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels. This risk increases with age and becomes significant in OC- users over 35 years of age. You should not use birth control pills while smoking.

Oral contraceptives **do not protect** against sexually transmitted infections (STIs) including HIV/AIDS. For protection against STIs, it is advisable to use latex condoms **in combination with** oral contraceptives.

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.

**If you see a different doctor, inform him or her that you are taking SYNPHASIC.**

**BEFORE you use SYNPHASIC talk to your doctor or pharmacist if:**

- Pregnant or breastfeeding
- History of jaundice or other liver disease
- High blood pressure
- Migraines and headaches
- Diabetes or family history of diabetes
- Wear contact lenses
- Family history of breast disease (e.g. breast lumps) or a family history of breast cancer
- Fibroid tumours on the uterus
- History of emotional disorders, especially depression
- Metabolic or endocrine diseases and abnormal metabolism of calcium and phosphorus
- Rheumatoid arthritis or synovitis
- Hereditary or history of angioedema (episodes of swelling in body parts such as hands, feet, face, or airway passage)
- Abnormal level of fat in the blood stream (high cholesterol or triglycerides)
- Smoke cigarettes
- Heart or kidney disease
- Epilepsy/seizures
- Gallbladder or pancreatic disease
- Family history of blood clots, heart attacks or strokes.
- Persistent irregular vaginal bleeding

- Overweight
- Systemic lupus erythematosus
- Inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- Hemolytic uremic syndrome
- Sickle cell disease
- Problems with the valves in your heart and/or have an irregular heart rhythm
- Have Hepatitis C

If you detect any new masses on your breasts while taking SYNPHASIC you should advise your doctor.

If you have to undergo a **major** elective surgery, you should advise your surgeon that you are taking SYNPHASIC. You should consult your doctor about stopping the use of SYNPHASIC four weeks before surgery and not use SYNPHASIC for a time period after surgery or during bed rest.

Tell your doctor if you are scheduled for any laboratory tests since certain blood tests may be affected by hormonal contraceptives.

SYNPHASIC should be used only under the supervision of a doctor, with regular follow-up to identify side effects associated with its use. Your visits may include a blood pressure check, a breast exam, an abdominal exam and a pelvic exam, including a Pap smear. Visit your doctor three months or sooner after the initial examination. Afterward, visit your doctor at least once a year. Use SYNPHASIC only on the advice of your doctor and carefully follow all directions given to you. You must use the birth control pill exactly as prescribed. Otherwise, you may become pregnant.

Breakthrough bleeding/spotting may occur while you are taking an oral contraceptive, especially during the first three months of use. If this bleeding persists or recurs, you should advise your doctor. Women with history of amenorrhea (absence of menstrual periods) or oligomenorrhea (irregular or infrequent menstrual periods) may remain anovulatory or become amenorrheic following discontinuation of oral contraceptives.

### The Risks of Using 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.**

## 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 a yearly breast examination by a doctor is recommended for all women.

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

ASK YOUR DOCTOR FOR ADVICE AND INSTRUCTIONS ON REGULAR SELF-EXAMINATION OF YOUR BREASTS.

## 3. Cervical cancer

Some studies have found an increase of cancer of the cervix in women who use hormonal contraceptives, although this finding may be related to factors other than the use of oral contraceptives. However, there is insufficient evidence to rule out the possibility that oral contraceptives may cause such cancers.

## 4. 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, she should be aware that pregnancy may be delayed for some months. 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.

**5. 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.

**6. Use during pregnancy**

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.

**7. Pregnancy after stopping taking birth control pills**

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.

**8. Use after pregnancy, miscarriage or abortion**

Your doctor will advise you of the appropriate time to start the use of birth control pills after childbirth, miscarriage, or therapeutic abortion.

**9. Use while breastfeeding**

If you are breast feeding, consult your doctor before starting the birth control pill. The hormones in birth control pills are known to appear in breast milk. These hormones may decrease the flow of breast milk. The long-term effects on the developing child are not known. However, cases of breast enlargement have been reported in breast-fed infants. You should use another method of contraception and only consider starting the birth control pill once you have weaned your child completely.

**10. Increase in epileptic seizures**

Stop taking SYNPHASIC and notify your doctor if

you are having seizures more often.

**INTERACTIONS WITH THIS MEDICATION**

The concurrent administration of SYNPHASIC with other drugs may result in an altered effectiveness of either drug. It is important to advise your doctor of any drug you are taking, both prescription and non-prescription, before you take SYNPHASIC.

**Drugs that may interact with SYNPHASIC include:**

- Anticonvulsants (carbamazepine, ethosuximide, felbamate, oxcarbazepine, phenobarbital, phenytoin, primidone, topiramate, lamotrigine)
- Antibiotics (ampicillin, cotrimoxazole, penicillin, rifampin, chloramphenicol, metronidazole, neomycin, nitrofurantoin, sulfonamides, tetracyclines, troleandomycin, rifabutin)
- Antifungals (griseofulvin, fluconazole)
- Cholesterol Lowering Agents (clofibrate, atorvastatin)
- Sedatives and Hypnotics (benzodiazepines, barbiturates, chloral hydrate, glutethimide, meprobamate, chlordiazepoxide, lorazepam, oxazepam, diazepam)
- Antacids
- Alpha-II Adrenoreceptor Agents (clonidine)
- Antidiabetic Drugs (oral hypoglycemics and insulin)
- Antihypertensive Agents (guanethidine, methyl dopa and beta blockers)
- Antipyretics (acetaminophen, antipyrine, ASA)
- Betamimetic Agents (isoproterenol)
- Corticosteroids (prednisone, dexamethasone)
- Phenothiazine Tranquilizers (all phenothiazines, reserpine and similar drugs)
- HIV infection (ritonavir, indinavir, nevirapine)
- Bronchodilator (theophylline)
- Stimulants (modafinil)
- Tricyclic antidepressants (clomipramine)
- Others: pheylbutazone, antihistamines, analgesics, antimigraine preparations, anticoagulants, aminocaproic acid,

vitamin E, vitamin B12, vitamin C, cyclosporine, folic acid, meperidine, St John's wort, flunarizine

- Medication for Hepatitis C, containing combinations of boceprevir, telaprevir, ombitasvir, paritaprevir, ritonavir and dasabuvir, with or without ribavirin.

Caffeine and alcohol may also affect the efficacy of Oral Contraceptives.

During concomitant use of SYNPHASIC and substances that may affect its effectiveness, it is recommended that you use a non-hormonal back-up method of birth control in addition to the regular intake of SYNPHASIC. In the case of prolonged use of such substances, oral contraceptive should not be considered the primary contraceptive. After discontinuation of substances that interact with SYNPHASIC, use of a non-hormonal back-up method is recommended for at least 7 days.

*This is not a complete list of possible drug interactions with SYNPHASIC. Talk to your doctor for more information about drug interactions.*

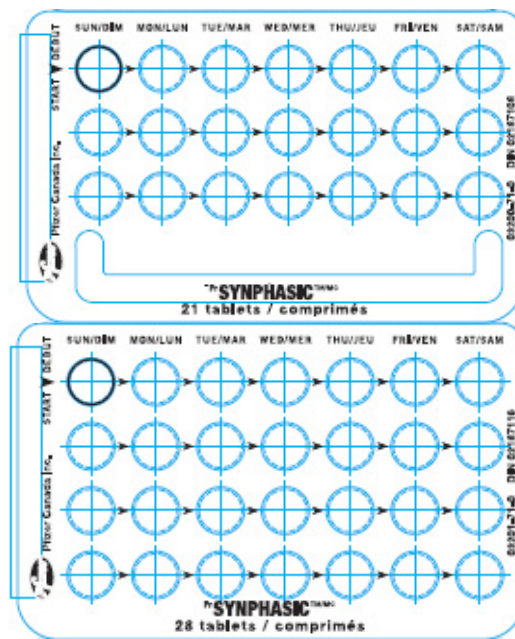
## PROPER USE OF THIS MEDICATION

### Usual dose:

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 no pills for one week

OR

  - 28-PILL PACK: 21 active pills (with hormones) taken daily for three weeks, and then seven inactive “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 back-up in case you miss pills, and

- **An extra, full pack of pills.**

9. **If you experience 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.**

**There is no need to stop taking birth control pills for a rest period.**

**When to start the first pack of SYNPHASIC pills:**

**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 combination:**

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 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 combination**

With this type of birth control pill, you take 21 pills that contain hormones and seven pills that 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 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 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.** Your period should occur during the last seven days of using the pills.

**What to do during the month**

1. **Take a pill at approximately the same time every day until the pack is empty.**
  - Try to associate taking your pill with some regular activity such as 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.

**Overdose:**

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Numerous cases of the ingestion, by children, of estrogen progestogen combinations have been reported. Although mild nausea may occur, there appears to be no other reaction. Treatment should be limited to a laxative such as citrate of magnesia with the aim of removing unabsorbed material as rapidly as possible.

**Missed Dose:**

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.

SUNDAY START	OTHER THAN SUNDAY START
<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> 1. Take two pills the day you remember and two pills the next day. 2. Then take one pill a day until you finish the pack. 3. Use a back-up method of birth control if you have sex in the seven days after you miss the pills. <b>Third Week:</b> 1. Keep taking one pill a day until Sunday. 2. On Sunday, safely discard the rest of the pack and start a new pack that day.  3. 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</p>	<p><b>MISS TWO PILLS IN A ROW</b> <b>First two Weeks:</b> 1. Take two pills the day you remember and two pills the next day. 2. Then take one pill a day until you finish the pack. 3. Use a back-up method of birth control if you have sex in the seven days after you miss the pills. <b>Third Week:</b> 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. <b>IF YOU MISS TWO PERIODS IN A ROW,</b></p>

<p>period this month. <b>IF YOU MISS TWO PERIODS IN A ROW, CALL YOUR DOCTOR OR CLINIC.</b></p>	<p><b>CALL YOUR DOCTOR OR CLINIC.</b></p>
<p><b>MISS THREE OR MORE PILLS IN A ROW</b> <b>Anytime in the Cycle:</b> 1. Keep taking one pill a day until Sunday.  2. On Sunday, safely discard the rest of the pack and start a new pack that day. 3. 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. <b>IF YOU MISS TWO PERIODS IN A ROW, CALL YOUR DOCTOR OR CLINIC.</b></p>	<p><b>MISS THREE OR MORE PILLS IN A ROW</b> <b>Anytime in the Cycle:</b> 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. <b>IF YOU MISS TWO PERIODS IN A ROW, CALL YOUR DOCTOR OR CLINIC.</b></p>

**NOTE: 28-DAY PACK:** If you forget any of the seven inactive "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.

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

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

- Effects of 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; decreased incidence of ovarian cancer; 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
- an increase or decrease in hair growth (hirsutism, loss of scalp hair), sex drive and appetite
- skin pigmentation (brown spots that may not go away). Avoid exposure to the sun, especially if you have a history of brown spots.
- headaches, dizziness
- migraines
- changes or loss of hearing
- cloudy vision, sore eyes
- rash
- vaginal infections
- difficult or painful urination, blood in the urine

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Some users of birth control pills have unpleasant side effects. Most of these side effects are temporary and not hazardous to health. There may be tenderness of the breasts or liquid leaking from your breasts. You can have nausea, and vomiting and tremors. Some users will experience weight gain or loss, change in appetite. 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, nervousness
- increased blood sugar levels, tell your doctor if you are drinking or urinating more frequently.
- liver problems with jaundice (yellowing of the skin)

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. It is recommended to delay starting a pregnancy for one menstrual period after stopping birth control pills.

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>			
<b>Symptom / effect</b>	<b>Talk with your doctor or pharmacist</b>		<b>Stop taking drug and call your doctor or pharmacist</b>
	<b>Only if severe</b>	<b>In all cases</b>	
Allergic Reaction: rash, hives, swelling of the face, lip, tongue or throat, difficulty swallowing or breathing			√
Abdominal pain, nausea or vomiting or lump in the abdomen		√	
Sharp pain in the chest, coughing blood, or sudden shortness of breath (These symptoms could indicate a possible blood clot in the lung)			√

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>			
Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Pain or swelling in the leg (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, or numbness in the face (these symptoms could indicate a possible stroke)			√
Sudden partial or complete loss of vision, double 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 tumor of the liver)		√	
Persistent sad mood		√	
Yellowing of the skin (jaundice)			√
Unexpected vaginal bleeding		√	
Unusual swelling of the extremities		√	
Breast lumps		√	
Crohn's Disease or Ulcerative Colitis: Cramps and bloating, diarrhea		√	

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>			
Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Inflammation of the Pancreas: Abdominal pain that lasts and gets worse when you lie down, nausea, vomiting		√	
Lupus: A combination of fever, muscle or joint pain, and general fatigue and feeling unwell and memory changes.		√	
Raynaud's phenomenon: Pain, numbness change in colour, and feeling cold in the hands and feet.		√	

*This is not a complete list of side effects. For any unexpected effects while taking SYNPHASIC, contact your doctor or pharmacist.*

#### HOW TO STORE IT

Store SYNPHASIC between 15°C and 25°C. Keep SYNPHASIC and all medication out of reach of children.

### **REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

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 Report online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>

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- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
 Health Canada  
 Postal Locator 1908C  
 Ottawa, Ontario  
 K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

### **MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.pfizer.ca>

or by contacting the sponsor, Pfizer Canada ULC, at:  
 1-800-463-6001

This leaflet was prepared by Pfizer Canada ULC

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