**PART III: CONSUMER INFORMATION**

# Pr Tri-Cira 21

# Pr Tri-Cira 28

Norgestimate and Ethinyl Estradiol tablets

Apotex Standard

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about **Tri-Cira 21 and 28.** Contact your doctor or pharmacist if you have any questions about the drug.

## ABOUT THIS MEDICATION

**What the medication is used for:**

- prevention of pregnancy
- to treat moderate acne

**What it does:**

Tri-Cira 21 and 28 are a birth control pill (oral contraceptive) that contains two female sex hormones (norgestimate and ethinyl estradiol). It 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 older than age 35.

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 per cent effective in preventing pregnancy when:

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

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

The chance of becoming pregnant increases with incorrect use.

**Other Ways to Prevent Pregnancy:**

Other methods of birth control are available to you. They are usually less effective than birth control pills. When 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.

**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 should always be supervised by your doctor.

**Do not use Tri-Cira 21 and 28** 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 or thrombophlebitis (inflammation of the veins)
- a stroke, heart attack, or coronary artery disease (chest pain) or a condition that may be a first sign of a stroke (such as a transient ischemic attack or small reversible stroke)
- disease of the heart valves with complications

- persistent high blood pressure
- over age 35 and smoke
- scheduled for major surgery
- prolonged bed rest
- loss of vision due to blood vessel disease of the eye
- known or suspected cancer of the breast or sex organs;
- liver tumour associated with the use of the pill or other estrogen-containing products;
- jaundice (yellowing of skin and eyes) or liver disease if still present
- diabetes with complications of the kidneys, eyes, nerves, or blood vessels
- migraines with visual and/or sensory disturbances
- known abnormalities of blood clotting system that increase your risk for developing blood clots
- pancreatitis (inflammation of the pancreas) associated with high levels of fatty substance (triglycerides) in your blood
- very high blood cholesterol or triglyceride levels
- pregnant or if pregnancy is suspected
- you are taking ombitasvir, paritaprevir, ritonavir, with or without dasabuvir for the treatment of Hepatitis C
- allergic reaction to ethinyl estradiol, norgestimate or to any of the other ingredients in Tri-Cira 21 and 28 (see **What the nonmedicinal ingredients are**).

**What the medicinal ingredients are:**

Norgestimate and ethinyl estradiol

**What the nonmedicinal ingredients are:**
WHITE tablet: Hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium croscarmellose and titanium dioxide.

LIGHT BLUE tablet: FD&C Blue No.1 Aluminum Lake, FD&C Blue No.2 Aluminum Lake, FD&C Yellow No. 5 Aluminum Lake, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium croscarmellose and titanium dioxide.

BLUE tablet: FD&C Blue No.1 Aluminum Lake, FD&C Blue No.2 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium croscarmellose and titanium dioxide.

GREEN tablet: FD&C Blue No. 2 Aluminum Lake, hydroxypropyl methylcellulose, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polysorbate, sodium croscarmellose, titanium dioxide and triacetin.

**What dosage forms it comes in:**
Tri-Cira 21 and 28 (norgestimate and ethinyl estradiol) tablets are available in a 21-day regimen and a 28-day regimen.

21-day Pill Pack contains: 7 WHITE tablets each containing 0.18 mg norgestimate and 0.035 mg ethinyl estradiol, 7 LIGHT BLUE tablets each containing 0.215 mg norgestimate and 0.035 mg ethinyl estradiol and 7 BLUE tablets each containing 0.25 mg norgestimate and 0.035 mg ethinyl estradiol

28-day Pill Pack contains: 7 WHITE tablets each containing 0.18 mg norgestimate and 0.035 mg ethinyl estradiol, 7 LIGHT BLUE tablets each containing 0.215 mg norgestimate and 0.035 mg ethinyl estradiol, 7 BLUE tablets each containing 0.25 mg norgestimate and 0.035 mg ethinyl estradiol and 7 GREEN tablets with inactive ingredients.

## WARNINGS AND PRECAUTIONS

**Serious Warnings and Precautions**

**Cigarette smoking increases the risk of serious side effects on the heart and blood vessels. This risk increases with age and becomes significant in hormonal contraceptive users older than 35 years of age, and with the number of cigarettes smoked. For this reason, combination oral contraceptives, including Tri-Cira 21 and 28, should not be used by women who are over 35 years of age and smoke.**

**Birth control pills DO NOT PROTECT against sexually transmitted infections (STIs), including HIV/AIDS.**

**For protection against STIs, it is advisable to use latex or polyurethane condoms IN COMBINATION WITH birth control pills.**

**Do not use Tri-Cira 21 and 28 if you are taking ombitasvir, paritaprevir, ritonavir, with or without dasabuvir for the treatment of Hepatitis C. Using these drugs at the same time as Tri-Cira 21 and 28 has the potential to cause problems with your liver, such as an increase in the ALT liver enzyme. Consult with your doctor or pharmacist about restarting Tri-Cira 21 and 28 after finishing your Hepatitis C treatment (see ABOUT THIS MEDICATION - When it should not be used).**

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.

**BEFORE you use Tri-Cira 21 and 28, talk to your doctor or pharmacist if the following apply to you:**

- have a history of breast disease (e.g., breast lumps) or a family history of breast cancer
- diabetes
- high blood pressure
- abnormal levels of fats in the bloodstream (high cholesterol or triglycerides)
- are very overweight
- cigarette smoking
- migraine headaches
- heart or kidney disease
- epilepsy
- depression
- fibroid tumours of the uterus
- wear contact lenses
- pregnant or breast-feeding
- 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
- hereditary angioedema or have had episodes of swelling in body parts such as hands, feet, face, or airway passages
- gallbladder or pancreatic disease
- history of jaundice (i.e., yellowing of skin and eyes) or other liver disease
- have or have previously had chloasmas (yellow-brownish patches on your skin, pigment spots during pregnancy, especially on your face). If this happens, avoid sunlight and UV radiation

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

Tri-Cira 21 and 28 are **NOT** to be used before menarche (your first menstrual period) or in postmenopausal women.

If you see a different doctor, inform him or her that you are using Tri-Cira 21 and 28.

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

Also tell your doctor if you are scheduled for **MAJOR** surgery. You should consult your doctor about stopping the use of Tri-Cira 21 and 28 four weeks before surgery and not using Tri-Cira 21 and 28 for a time period after surgery or during bed rest.

Tri-Cira 21 and 28 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 Tri-Cira 21 and 28 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. If you and your doctor decide that, for you, the benefits of Tri-Cira 21 and 28 outweigh the risks, you should be aware of the following risks:

## THE RISKS OF USING TRI-CIRA 21 AND 28

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

Women who use hormonal contraceptives like Tri-Cira 21 and 28 have a higher incidence of blood clots compared to non-users. Blood clots are the most common serious side effects of birth control pills. The risk of developing blood clots is especially high during the first year a woman ever uses a hormonal contraceptive or restarts the same or a different hormonal contraceptive after a break of 4 weeks or more. Clots can occur in many areas of the body. 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 and/or swelling in the calf. These symptoms could indicate a possible blood clot in the leg.
- crushing chest pain or heaviness. These symptoms could indicate a possible heart attack.
- sudden severe or worsening headache or vomiting, dizziness or fainting, disturbances 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 blood clot in the eye.

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 or in a blood vessel leading to an arm or leg, resulting in damage to or loss of a limb.

Women who use birth control pills have a higher incidence of blood clots. 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 strong 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.

**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.

Chronic infection with the Human Papilloma Virus (HPV) is believed to be the most important risk factor for cervical cancer. In women who use combination oral contraceptives (COCs) like Tri-Cira 21 and 28 for a long time the chance of getting cervical cancer may be slightly higher. This finding may not be caused by the pill itself but may be related to sexual behaviour and other factors.

**4. Gallbladder disease**

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

**5. Liver tumours**

The short and long-term use of birth control pills also has been linked with the growth of liver tumours. Such tumours are **EXTREMELY** rare.

Contact your doctor immediately if you experience nausea, vomiting, severe pain or a lump in the abdomen.

**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. There is no evidence, however, that the pill can damage a developing child. You should check with your doctor about risks to your unborn child from any medication taken during pregnancy.

**7. Use after pregnancy, miscarriage or an abortion**

Your doctor will advise you of the appropriate time to start the use of Tri-Cira 21 and 28 after childbirth, miscarriage, or therapeutic abortion.

**8. Pregnancy after stopping Tri-Cira 21 and 28**

You will have a menstrual period when you stop taking Tri-Cira 21 and 28. You should delay pregnancy until another menstrual period occurs within four to six weeks.
Contact your doctor for recommendations on alternative methods of contraception during this time.

**9. Use while breast-feeding**

The hormones in birth control pills are known to appear in breast milk. These hormones may decrease the flow of breast milk. Adverse effects on the child have been reported, including yellowing of the skin (jaundice) and breast enlargement. You should use another method of contraception and only consider starting the birth control pill once you have weaned your child completely.

## INTERACTIONS WITH THIS MEDICATION

Certain drugs may interact with birth control pills to make them less effective in preventing pregnancy or cause an increase in breakthrough bleeding. You may also need to use a nonhormonal method of contraception during any cycle in which you take drugs that can make oral contraceptives less effective.

**Drugs that may interact with Tri-Cira 21 and 28 include:**

- drugs used for epilepsy (e.g., primidone, phenytoin, phenobarbital, carbamazepine, lamotrigine, oxcarbazepine, topiramate, rufinamide)
- drugs used for tuberculosis (e.g., rifampin and rifabutin)
- antibiotics (e.g., penicillins, tetracyclines) for infectious diseases
- (fos)aprepitant (used for nausea)
- selegiline (used for Parkinson’s disease)

- tizanidine (used for multiple sclerosis [MS])
- drugs used for HIV/AIDS (e.g., atazanavir, indinavir, nelfinavir, ritonavir, ritonavir-boosted protease inhibitors, etravirine, nevirapine), or HIV/AIDS combination medications that contain cobicistat
- boceprevir, telaprevir (used to treat Hepatitis C)
- ombitasvir, paritaprevir, ritonavir, with or without dasabuvir (used to treat Hepatitis C)
- salicylic acid
- bosentan (used for pulmonary hypertension which is high blood pressure in the blood vessels between the heart and the lungs)
- theophylline (used for asthma)
- stimulants (e.g., modafinil)
- lipid-lowering drugs (e.g., atorvastatin, rosuvastatin,)
- colesevelam
- cyclosporine (an immunosuppressive drug to prevent graft rejection after transplantation)
- omeprazole (used for gastric wound and heart burn)
- antifungals (e.g., griseofulvin, voriconazole, itraconazole, fluconazole, ketoconazole)
- the herbal remedy St. John's wort (primarily used for the treatment of depressive moods)
- antihypertensive drugs (for high blood pressure)
- antidiabetic drugs and insulin (for diabetes)
- prednisone, prednisolone
- sedatives and hypnotics (e.g., benzodiazepines, barbiturates, chloral hydrate, glutethimide, meprobamate, temazepam)
- pain medication (meperidine, morphine, acetaminophen)
- antidepressants (e.g., clomipramine)
- some nutritional supplements (e.g., vitamin B12, vitamin C, folic acid)
- antacids (use 2 hours before or after taking Tri-Cira 21 and 28
- grapefruit juice.

Tri-Cira 21 and 28 may also interfere with the working of other drugs.

Please inform your doctor and pharmacist if you are taking or have recently taken any other drugs or herbal products, even those without a prescription. Also tell any other doctor or dentist who prescribes another drug (or the dispensing pharmacist) that you use Tri-Cira 21 and 28. They can tell you if you need to use an additional method of contraception and if so, for how long.

*This is not a complete list of possible drug interactions with Tri-Cira 21 and 28. Talk to your doctor for more information about drug interactions.*

## PROPER USE OF THIS MEDICATION

**HOW TO TAKE TRI-CIRA 21 AND 28:**
**1. READ THESE DIRECTIONS**

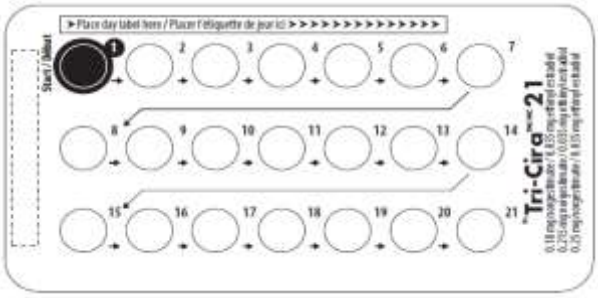
- before you start taking your pills, and
- any time you are not sure what to do.

**2**. **LOOK AT YOUR PILL PACK** to see if it has 21 or 28 pills:

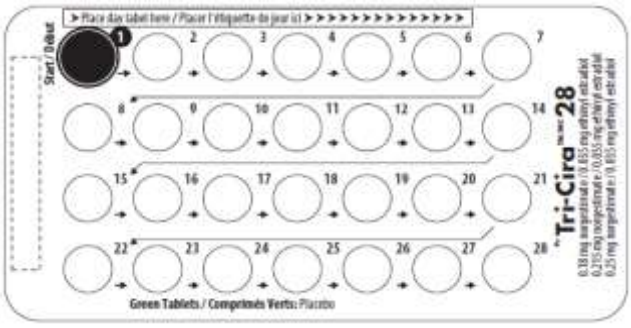
- 21-PILL PACK: 21 active pills (with hormones) taken daily for three weeks, and then no pills taken for one week
  OR
- 28-PILL PACK: 21 active pills (with hormones) taken daily for three weeks, and then seven "reminder" pills (no hormones) taken daily for one week.

**ALSO CHECK:** the pill pack for instructions on 1) where to start and 2) direction to take pills.

**21-Day PILL Package**




**28-Day PILL Package**




**3.** You may wish to use a second method of birth control (e.g. latex or polyurethane 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 or polyurethane 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 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 or polyurethane 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. **THERE IS NO NEED TO STOP TAKING BIRTH CONTROL PILLS FOR A REST PERIOD.**

12. **IF YOUR QUESTIONS ARE NOT ANSWERED HERE, CALL YOUR DOCTOR OR CLINIC.**

**WHEN TO START THE *FIRST* PACK OF 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.

**DIRECTIONS FOR 21-DAY AND 28-DAY PILL PACKS**

1. **THE FIRST DAY OF YOUR MENSTRUAL PERIOD (BLEEDING) IS DAY 1 OF YOUR CYCLE.** The pills may be started up to Day 6 of your cycle. Your starting day will be chosen in discussion with your doctor. You will always begin taking your pill on this day of the week. 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. **IF YOU ARE USING A:**

**21-DAY Pill 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.

Take one pill at approximately the same time every day for 21 days. **THEN DO NOT TAKE A PILL 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.)

**28-DAY Pill Pack:**

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

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.

**INSTRUCTIONS FOR USING YOUR 21-DAY OR 28-DAY PILL PACKS.** FOLLOW THESE INSTRUCTIONS CAREFULLY:

1. **For Day 1 start:** Label the Pill Pack by selecting the day label that starts with Day 1 of your menstrual period (the first day of menstruation is Day 1). For example, if your first day of menstruation is Tuesday, attach the day label that begins with **TUE** in the space provided.

**OR**

**For Day 5 start:** Label the Pill Pack by selecting the day label that starts with the day that is 5 days after your period begins. (Count 5 days including the first day of menstruation.) For example, if your first day of menstruation is Saturday, place the day label that starts with **WED** in the space provided.

**OR**

**For Sunday start:** The first Sunday **after** your period begins, or, if your period starts on Sunday, start that **same day**.

2. Place the day label in the space where you see the words "Place day label here". Having the Pill Pack labelled with the days of the week will help remind you to take your pill every day.
3. To begin taking your pills, start with the pill inside the red circle (where you see the word START). This pill should correspond to the day of the week that you are taking your first pill. To remove the pill, push through the back of the Pill Pack.
4. On the following day, take the next pill in the same row, always proceeding from left to right (→). Each row will always begin on the same day of the week.

**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:**
Symptoms of overdose may include nausea, vomiting or vaginal bleeding. Available information from cases of accidental ingestion of oral contraceptives by children indicates no serious effects.

If you think you have taken too much Tri-Cira 21 and 28, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

**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.

| **SUNDAY START** | **OTHER THAN SUNDAY START** |
|---|---|
| **MISS ONE PILL** | **MISS ONE PILL** |
| 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. | 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. |
| **MISS TWO PILLS IN A ROW** | **MISS TWO PILLS IN A ROW** |
| **First Two Weeks**<br>1. Take two pills the day you remember and two pills the next day.<br>2. Then take one pill a day until you finish the pack.<br>3. Use a back-up method of birth control if you have sex in the seven days after you miss the pills.<br>**Third Week**<br>1. Keep taking one pill a day until Sunday.<br>2. On Sunday, safely discard the rest of the pack and start a new pack that day.<br>3. Use a back-up method of birth control if you have sex in the seven days after you miss the pills.<br>4. You may not have a period this month.<br>**If you miss two periods in a row, call your doctor or clinic.** | **First Two Weeks**<br>1. Take two pills the day you remember and two pills the next day.<br>2. Then take one pill a day until you finish the pack.<br>3. Use a back-up method of birth control if you have sex in the seven days after you miss the pills.<br>**Third Week**<br>1. Safely dispose of the rest of the pill pack and start a new pack that same day.<br>2. Use a back-up method of birth control if you have sex in the seven days after you miss the pills.<br>3. You may not have a period this month.<br>**If you miss two periods in a row, call your doctor or clinic.** |
| **MISS THREE OR MORE PILLS IN A ROW** | **MISS THREE OR MORE PILLS IN A ROW** |
| **Any Time in the Cycle**<br>1. Keep taking one pill a day until Sunday.<br>2. On Sunday, safely discard the rest of the pack and start a new pack that day.<br>3. Use a back-up method of birth control if you have sex in the seven days after you miss the pills.<br>4. You may not have a period this month.<br>**If you miss two periods in a row, call your doctor or clinic.** | **Any Time in the Cycle**<br>1. Safely dispose of the rest of the pill pack and start a new pack that same day.<br>2. Use a back-up method of birth control if you have sex in the seven days after you miss the pills.<br>3. You may not have a period this month.<br>**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 or polyurethane 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** 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.

- Combination estrogen and progestin birth control pills reduce the incidence of cancer of the uterus and ovaries.
- Birth control pills reduce the likelihood of developing benign (non-cancerous) breast disease and ovarian cysts.
- Users of birth control pills lose less menstrual blood and have more regular cycles. The risk of developing iron-deficiency anemia is thus reduced.
- There may be a decrease in painful menstruation and premenstrual syndrome (PMS).
- Acne, excessive hair growth and male hormone-related disorders also may be improved.
- Ectopic (tubal) pregnancy may occur less frequently.
- Acute pelvic inflammatory disease may occur less frequently.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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.

The following additional symptoms have been reported in women taking hormonal contraceptives in general:

- difficulty wearing contact lenses
- vaginal irritation or infections
- change in skin pigmentation (can be permanent)
- urinary tract infections or inflammation
- upper respiratory tract infections (colds, bronchitis, runny or stuffy nose, sore throat, etc.)
- severe headaches
- insomnia
- amenorrhea (lack of a period or breakthrough bleeding)
- flu-like symptoms
- allergy, fatigue, fever, rash
- diarrhea, flatulence
- blood clots in a vein – this can lead to blocked blood vessels in the liver, which cause an enlarged liver, pain and swelling from build-up of fluid around the gut (Budd-Chiari syndrome)

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.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

| Symptom/effect | | Talk with your doctor or pharmacist | | Stop taking drug and get immediate medical help |
|---|---|---|---|---|
| | | Only if severe | In all cases | |
| Un-common | Abdominal pain, nausea or vomiting or lump in the abdomen | | ✓ | |
| | Breast lump | | ✓ | |
| | Crushing chest pain or heaviness | | | ✓ |
| | Pain or swelling in the leg | | | ✓ |

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

| Symptom/effect | | Talk with your doctor or pharmacist | | Stop taking drug and get immediate medical help |
|---|---|---|---|---|
| | | Only if severe | In all cases | |
| | Persistent sad mood | | | ✓ |
| | Sharp pain in the chest, coughing blood, or sudden shortness of breath | | | ✓ |
| | Sudden partial or complete loss of vision or double vision | | | ✓ |
| | Sudden severe headache or worsening of headache, vomiting, dizziness, fainting, disturbance of vision or speech, or weakness or numbness in the face, arm or leg | | | ✓ |
| | Unexpected vaginal bleeding | | ✓ | |
| | Unusual swelling of the extremities | | ✓ | |
| | Yellowing of the skin or eyes (jaundice) | | | ✓ |
| Very Rare | A severe allergic reaction which may include swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing. | | | ✓ |

*This is not a complete list of side effects. For any unexpected effects while taking Tri-Cira 21 and 28, contact your doctor or pharmacist.*

## HOW TO STORE IT

Store in original packaging, between 15°C to 30°C. Leave contents in carton until time of use to protect from light. Keep out of the sight and reach of children.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

## MORE INFORMATION

**If you want more information about Tri-Cira 21 and 28:**

- Talk to your healthcare professional

- Find the full Product Monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (https://health-products.canada.ca/dpd-bdpp/index-eng.jsp). Find the Consumer Information on the manufacturer's website (http://www.apotex.ca/products), or by calling 1-800-667-4708.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9

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