

PART III: CONSUMER INFORMATION

PrTRIQUILAR® (levonorgestrel and ethinyl estradiol tablets USP)

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

ABOUT THIS MEDICATION

What the medication is used for:

- To prevent pregnancy

What it does:

TRIQUILAR is a birth control pill (oral contraceptive) that contains two female sex hormones (levonorgestrel 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:

- They inhibit the monthly release of an egg by the ovaries.
- 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 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.

You should not use TRIQUILAR if you have or have had any of the following conditions:

- blood clots in the legs, lungs, eyes, or elsewhere, or thrombophlebitis (inflammation of the veins)
- stroke, heart attack, or coronary artery disease (eg, angina pectoris), 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
- known abnormalities of the blood clotting system that increases your risk for developing blood clots
- severe high blood pressure
- diabetes with complications
- very high blood cholesterol or triglyceride levels
- you smoke and are over age 35
- migraine headache
- you are scheduled for major surgery
- prolonged bed rest
- you are taking ombitasvir, paritaprevir, ritonavir, with

or without dasabuvir for the treatment of Hepatitis C (an infectious disease that affects the liver, caused by the hepatitis C virus)

- jaundice (yellowing of the eyes or skin), liver disease or liver tumor
- known or suspected cancer of the breast or uterus (womb) or other estrogen-dependent cancer
- unusual vaginal bleeding without a known reason
- loss of vision due to blood vessel disease of the eye
- you are pregnant or suspect you may be pregnant
- pancreatitis (inflammation of the pancreas) associated with high levels of fatty substances in your blood
- allergy (hypersensitivity) to ethinyl estradiol, levonorgestrel or to any of the other ingredients in TRIQUILAR (see **What the Medicinal Ingredients Are** and **What the Nonmedicinal Ingredients Are**)

What the medicinal ingredients are:

levonorgestrel and ethinyl estradiol

What the nonmedicinal ingredients are:

calcium carbonate, cornstarch, glycerine, lactose, magnesium stearate, montanglycol wax, polyethylene glycol, polyvinylpyrrolidone, red ferric oxide, sucrose, talc, titanium dioxide and yellow ferric oxide

What dosage forms it comes in:

TRIQUILAR is a combined oral contraceptive that contains three different combinations of levonorgestrel and ethinyl estradiol as described in the charts below. TRIQUILAR is available in a 21-day or 28-day treatment cycle. Each phase of pills is a different strength and should be taken successively.

TRIQUILAR 21 (21-day Treatment Cycle)

Day	Pill Description	Amount of Levonorgestrel	Amount of Ethinyl Estradiol
1 – 6	light brown	0.05 mg	0.03 mg
7 – 11	white	0.075 mg	0.04 mg
12 – 21	ochreous	0.125 mg	0.03 mg

TRIQUILAR 28 (28-day Treatment Cycle)

Day	Pill Description	Amount of Levonorgestrel	Amount of Ethinyl Estradiol
1 – 6	light brown	0.05 mg	0.03 mg
7 – 11	white	0.075 mg	0.04 mg
12 – 21	ochreous	0.125 mg	0.03 mg
22 – 28	slightly larger, white	no active ingredients	

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 hormonal contraceptive users older than 35 years of age, and with the number of cigarettes smoked. For this reason, combination oral contraceptives, including TRIQUILAR should not be used by women who are over 35 years of age and smoke. Women should not smoke.

Birth control pills DO NOT PROTECT against sexually transmitted diseases (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 TRIQUILAR 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 TRIQUILAR has the potential to cause liver problems, such as an increase in the ALT liver enzyme. You can usually start TRIQUILAR about 2 weeks after finishing treatment with this combination of drugs used for Hepatitis C, but always consult with your doctor or pharmacist.

BEFORE you use TRIQUILAR, talk to your doctor or pharmacist if you:

- smoke
- are overweight
- have a history of breast disease (eg, breast lumps) or a family history of breast cancer
- have high blood pressure
- have high cholesterol
- have diabetes
- have heart or kidney disease
- have a history of seizures/epilepsy
- have a history of depression

- have a history of liver disease or jaundice
- wear contact lenses
- have uterine fibroids (benign tumors of the uterus)
- may be pregnant or are breastfeeding
- have systemic lupus erythematosus
- have inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- have hemolytic uremic syndrome
- have sickle cell disease
- have any problems with the valves in your heart and/or have an irregular heart rhythm
- have been told that you have a condition called hereditary angioedema or if you have had episodes of swelling in body parts such as hands, feet, face or airway passages

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

If you see a different doctor, inform him or her that you are using TRIQUILAR.

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 TRIQUILAR four weeks before surgery and not using TRIQUILAR for a time period after surgery or during bed rest.

TRIQUILAR 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 TRIQUILAR 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 TRIQUILAR outweigh the risks, you should be aware of the following:

THE RISKS OF USING TRIQUILAR

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

Women who use hormonal contraceptives have a higher incidence of blood clots. 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. Clots can occur in many parts 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 which may increase with deep breathing; coughing blood; sudden shortness of breath or rapid breathing; sense of anxiety; severe light headedness or dizziness; rapid or irregular heartbeat. These symptoms could indicate a possible blood clot in the lung.
- pain and/or swelling in the calf or along a vein in the leg; pain or tenderness in the leg which may be felt only when standing or walking, increased warmth in the affected leg; red or discoloured skin on the leg. These symptoms could indicate a possible blood clot in the leg.
- crushing chest pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the chest, arm, or below the breastbone; discomfort radiating to the back, jaw, throat, arm, stomach; fullness, indigestion or choking feeling; sweating, nausea, vomiting or dizziness; extreme weakness, anxiety, or shortness of breath; rapid or irregular heartbeats. These symptoms could indicate a possible heart attack.
- sudden severe or worsening headache or vomiting; sudden trouble walking, dizziness, loss of balance or coordination; loss of consciousness or fainting with or without seizure; sudden confusion, disturbances of vision, speech or understanding; sudden weakness or numbness of the face, 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.
- other signs of a blood clot can include: sudden pain, swelling, slight blue discoloration of an extremity; acute abdomen

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.

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.**

Cancer of the breast, cervix, or liver may be life-threatening or may result in death.

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 hormonal contraceptives 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 health care professional 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.

4. Liver tumors

The short and long-term use of birth control pills also have been linked with the growth of liver tumors. Such tumors are **extremely** rare.

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

5. Gallbladder disease

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.

6. Use in pregnancy

Birth control pills should not be taken by pregnant women. There is no evidence, however, that the birth control 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 TRIQUILAR after childbirth, miscarriage, or therapeutic abortion.

8. Pregnancy after stopping TRIQUILAR

You will have a menstrual period when you stop using TRIQUILAR. You should delay pregnancy until another menstrual period occurs within four to six weeks. In this way the pregnancy can be more accurately dated. Contact your doctor for recommendations on alternate methods of contraception during this time.

9. Use while breastfeeding

If you are breastfeeding, 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. 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

There are some medicines you must not take with TRIQUILAR (see **When It Should Not Be Used**). Certain drugs may interact with birth-control pills to make them less effective in preventing pregnancy or cause an increase in breakthrough bleeding. Please inform your doctor or 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 TRIQUILAR. They can tell you if you need to use an additional method of contraception and if so, for how long.

Drugs that may interact with TRIQUILAR include:

- drugs used for the treatment of epilepsy (eg, primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate); tuberculosis (eg, rifampin, rifabutin), HIV infections (eg, ritonavir, nevirapine), and Hepatitis C Virus infections (eg, boceprevir, telaprevir)
- ombitasvir, paritaprevir, ritonavir, with or without dasabuvir (used to treat Hepatitis C)
- antibiotics (eg, penicillins, tetracyclines, clarithromycin, erythromycin) for infectious diseases
- cyclosporine
- antifungals (eg, griseofulvin, fluconazole, itraconazole, ketoconazole, voriconazole)
- cholesterol-lowering drugs (eg, clofibrate)
- drugs used for the treatment of certain heart diseases or for high blood pressure (eg, diltiazem, verapamil)
- antidiabetic drugs and insulin (for diabetes)
- prednisone
- sedatives and hypnotics (eg, benzodiazepines, barbiturates, chloral hydrate, glutethimide, meprobamate)

- meperidine (pain medication)
- antidepressants (eg, clomipramine)
- tizanidine (drugs used for multiple sclerosis [MS])
- theophylline (drug used for asthma)
- some nutritional supplements (eg, Vit. B₁₂, folic acid)
- antacids (use 2 hours before or after taking TRIQUILAR)

TRIQUILAR may also interfere with the working of other drugs.

Herbal or food products that may interact with TRIQUILAR include:

the herbal remedy St. John’s wort (primarily used for the treatment of depressive moods)
grapefruit juice

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

PROPER USE OF THIS MEDICATION

Usual dose:

HOW TO TAKE TRIQUILAR

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 hormone-containing (6 light brown, 5 white, and 10 ochreous) pills taken daily for three weeks, and then no pills taken for one week.



OR

- **28-Pill Pack:** 21 hormone-containing (6 light brown, 5 white and 10 ochreous) pills taken daily for three weeks, and then seven hormone-free “reminder” (slightly larger, white) pills taken daily for one week.



ALSO CHECK the pill pack for: 1) where to start, and 2) direction to take pills in (follow the arrows).

3. You should use a second method of birth control (eg, 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. **IF YOU EXPERIENCE VOMITING OR DIARRHEA, OR IF YOU TAKE CERTAIN MEDICINES**, such as antibiotics, your pills may not work as well. Use a backup method, such as latex or polyurethane condoms and spermicidal foam or gel, until you can check with your doctor or clinic.
6. Visit your doctor three months or sooner after the initial examination. Afterwards, visit your doctor at least once a year.
7. 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.
8. Your doctor will advise you of the appropriate time to start the use of birth control pills after childbirth, miscarriage, or therapeutic abortion.
9. **THERE IS NO NEED TO STOP TAKING BIRTH CONTROL PILLS FOR A REST PERIOD.**
10. **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 the best day is for you to start taking your first pack of pills. Your pills may be either a 21-day or a 28-day type.

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. On the back of the pill pack, there is an area shaded in red which reads “I took my first pill on” followed by the days of the week directly below. Under each day of the week, there is a black circle which may be punctured in order to remember the day you first took your pill.
3. Take your first pill starting at the circle shaded in red marked “1.”
4. Take one pill each day, following the direction of the arrows.
5. When you have taken all 21 pills in this pack, wait seven days and then start a new pack of TRIQUILAR 21. During the seven days when you are not taking any pills, you should have your period.
6. The first pill in every subsequent pack will always be taken on the same day of the week that you first began taking TRIQUILAR 21 pills.

28-DAY COMBINATION

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 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. Select the calendar sticker that is blue coded with the day you take your first pill and discard the rest.
3. Place the selected calendar sticker on the designated area, aligning the blue section with the blue box marked “START.”
4. Take your first pill starting at the blue box marked “START.”
5. Take one pill each day, following the direction of the arrows. Your period should usually occur during the last week of pills.
6. When you have finished this pack, start a new pack of TRIQUILAR 28 on the next day.

7. The first pill in every subsequent pack will always be taken on the same day of the week that you first began taking TRIQUILAR 28 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:

Symptoms of overdose may include nausea, vomiting, or vaginal bleeding. Even girls who have not yet had their first menstrual period but have accidentally taken this medicine may experience such bleeding. Available information from cases of accidental ingestion of oral contraceptives by children indicates no serious effects.

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

Missed dose:

MISSING PILLS 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.

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.

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 Light Brown, White or Ochreous Pill At Any Time	Miss One Light Brown, White or Ochreous Pill At Any Time
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 Light Brown, White or Ochreous Pills in a Row	Miss Two Light Brown, White or Ochreous Pills in a Row
First Two Weeks: 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 (barrier) method of birth control if you have sex in the seven days after you miss the pills.	First Two Weeks: 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 (barrier) method of birth control if you have sex in the seven days after you miss the pills.
Third Week 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 (barrier) 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.	Third Week 1. Safely dispose of the rest of the pill pack and start a new pack that same day. 2. Use a back-up (barrier) 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.
Miss Three or More Light Brown, White or Ochreous Pills in a Row	Miss Three or More Light Brown, White or Ochreous Pills in a Row
Anytime in the cycle 1. Keep taking one pill a day until Sunday. 2. On Sunday, safely discard the	Anytime in the cycle 1. Safely dispose of the rest of the pill pack and start a new pack that same day.

Sunday Start	Other than Sunday Start
rest of the pack and start a new pack that day. 3. Use a back-up (barrier) 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.	2. Use a back-up (barrier) 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 slightly larger, hormone-free white “reminder” pills 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 phone your clinic about how to make pill-taking easier or about using another method of birth control.

Noncontraceptive 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 in 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

The following side effects have been observed in studies of women taking TRIQUILAR:

Common:

painful menstrual periods, spotting, breast pain, increased and decreased libido, breakthrough bleeding, change in skin pigmentation, nausea and/or vomiting, headache, migraine, depression, varicose veins, acne

Uncommon:

increased appetite, swelling, thrombophlebitis (inflammation of veins), weight gain

If you experience new onset of high blood pressure or worsening of high blood pressure, contact your doctor or pharmacist.

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

- difficulty wearing contact lenses
- vaginal irritation or infections
- urinary tract infections or inflammation
- upper respiratory tract infections (colds, bronchitis, runny or stuffy nose, sore throat, etc)
- severe headaches
- depression, insomnia, nervousness
- amenorrhea (lack of a period or breakthrough bleeding)
- back pain
- abdominal pain
- flu-like symptoms
- allergy, fatigue, fever
- diarrhea, flatulence
- rash

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.

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

Symptom / Possible Side Effect	Talk With Your Doctor or Pharmacist		Stop Taking Drug and Call Your Doctor or Pharmacist
	Only if severe	In all cases	
Common Persistent sad mood			✓
Uncommon Abdominal pain, nausea or vomiting or lump in the abdomen		✓	
Breast lump		✓	
Crushing chest pain or heaviness			✓
Pain or swelling in the leg			✓
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)			✓

This is not a complete list of side effects. If you have any unexpected effects while taking TRIQUILAR, contact your doctor or pharmacist.

HOW TO STORE IT

Store in original packaging between 15°C and 30°C. Keep out of reach of children and pets.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

REPORTING SUSPECTED SIDE EFFECTS**Canada Vigilance Program**

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:

- Report online at www.healthcanada.gc.ca/medeffect
- 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, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

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

For more information, please contact your health professional or pharmacist first, or Bayer Medical Information at 1-800-265-7382 or canada.medinfo@bayer.com.

This document plus the full Product Monograph, prepared for health professionals can be found at: <http://www.bayer.ca> or by contacting the manufacturer at the above-mentioned phone number and email address.

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Last revised: May 26, 2017

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