

PART III: CONSUMER INFORMATION

PrLINESSA® 21 and PrLINESSA® 28
(desogestrel and ethinyl estradiol tablets, USP)

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

ABOUT THIS MEDICATION

What the medication is used for:

LINESSA® is used to prevent pregnancy.

What it does:

LINESSA is a combination hormonal contraceptive because it contains two female sex hormones (desogestrel and ethinyl estradiol). It is in the form of a tablet, therefore it is known as a birth control pill or oral contraceptive. 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 over 35.

Combination hormonal contraceptives 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. 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:

Combination hormonal contraceptives are 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.

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

- blood clot in the legs, lungs, eyes or elsewhere, or thrombophlebitis (inflammation of the veins).
- stroke, heart attack or coronary artery disease (e.g. Angina pectoris) or a condition that may be a first sign of stroke (such as transient ischemic attack or small reversible stroke).
- disease of the heart valves with complications
- sever high blood pressure
- diabetes with complications
- 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

- migraine headaches
- you are scheduled for major surgery
- prolonged bed rest
- jaundice (yellowing of the eyes or skin), liver disease or liver tumor
- known suspected cancer of the breast or uterus (womb) or other estrogen-dependant 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, desogestrel or to any of the other ingredients in LINESSA (see **What the medicinal ingredient are** and **What the non-medicinal ingredients are**).

What the medicinal ingredient are:

desogestrel and ethinyl estradiol

What the important nonmedicinal ingredients are:

Inactive ingredients include vitamin E, starch, stearic acid, lactose monohydrate, hydroxypropyl methylcellulose, polyethylene glycol, titanium dioxide and talc. The yellow and orange tablets also contain yellow ferric oxide, The orange and red tablets also contain red ferric oxide.

LINESSA 28 also contains 7 green tablets containing the following inactive ingredients: lactose monohydrate, corn starch, magnesium stearate, FD&C Blue No.2 aluminum lake, yellow ferric oxide, hydroxypropyl methylcellulose, polyethylene glycol, titanium dioxide and talc.

What dosage forms it comes in:

LINESSA is available in a 21-day or 28-day treatment cycle.

LINESSA 21 (21-Day treatment cycle): Each sachet contains a blister card with 21 round tablets for oral administration. The 21 tablets are divided into three different dosing phases;

- Seven (7) light yellow tablets containing 0.100 mg desogestrel and 0.025 mg ethinyl estradiol
- Seven (7) orange tablets containing 0.125 mg desogestrel and 0.025 mg ethinyl estradiol
- Seven (7) red tablets containing 0.150 mg desogestrel and 0.025 mg ethinyl estradiol.

LINESSA 28 (28-Day treatment cycle): Each sachet contains a blister card with 28 round tablets for oral administration. The blister pack contains the same three dosing phases as LINESSA[®] 21 with an additional seven (7) green tablets that do not contain hormones.

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 birth control pill users over 35 years of age. Women should not smoke.

Combination hormonal contraceptives **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.

BEFORE you use LINESSA talk to your doctor or pharmacist if you:

- smoke
- are overweight
- have a history of breast disease (e.g. breast lumps) or 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 fibroid tumours (benign tumours of the uterus)
- may be pregnant or are breast feeding
- have systemic lupus erythematosus
- have inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- have haemolytic uremic syndrome
- have sickle cell disease
- have problems with the valves in your heart and/or have an irregular heart rhythm
- have been told that you have a condition called hereditary angiodema 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 and strokes.

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

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

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

THE RISKS OF USING COMBINATION HORMONAL CONTRACEPTIVES

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

Blood clots are the most common serious side effects of birth control pills. The risk of developing clots is high during the first year a woman uses a hormonal contraceptive. Clots may 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, disturbance of vision or speech, or weakness or numbness in an arm or leg. These symptoms could indicate a possible stroke.
- Sudden partial or complete loss of vision. This symptom could indicate a possible blood clot in the eye.

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 hormonal contraceptives 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 is recommended for all women.

ASK YOUR DOCTOR FOR ADVICE AND INSTRUCTIONS OF 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) 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 behavior and other factors.

4. Liver tumors

The short and long-term use of birth control pills also has been linked with the growth of liver tumors or liver injury (e.g., hepatitis, hepatic function abnormal). Such injury or tumors are **extremely** rare.

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

5. Gallbladder disease

Users of hormonal contraceptives 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. They will not prevent the pregnancy from continuing. 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 **LINESSA** after childbirth, miscarriage or therapeutic abortion.

8. Pregnancy after stopping LINESSA

You will have a menstrual period when you stop using **LINESSA**. 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 breast feeding

If you are breast-feeding, consult your doctor before starting the birth control pill. Adverse effects on the child have been reported, including yellowing of the skin (jaundice) and breast enlargement. You should use another method of contraception. The use of oral contraceptives is generally not recommended until the nursing mother has completely weaned her child.

INTERACTIONS WITH THIS MEDICATION

Certain drugs may interact with combination hormonal contraceptives and prevent them from working properly making them less effective in preventing pregnancy or causing unexpected bleeding (spotting or breakthrough bleeding). Please inform your doctor or pharmacist if you are taking or have recently taken any other medications or herbal products, even those without a prescription. Also tell any doctor or dentist (or the dispensing pharmacist) who prescribes another medicine that you use **LINESSA**. 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 LINESSA include:

- drugs used for the treatment of epilepsy (e.g., primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate);
- drugs used for the treatment of tuberculosis (e.g., rifampicin, rifabutin)
- drugs used for treatment of HIV infections (e.g., ritonavir)

- antibiotics (e.g., penicillins, tetracyclines, metronidazole) for infectious diseases
- antifungals (e.g. griseofulvin)
- cholesterol lowering agents (e.g. clofibrate)
- anti-coagulants (blood thinners)
- The herbal remedy St. John’s Wort
- antihypertensive drugs (for high blood pressure)
- antidiabetic drugs and insulin (for diabetes)
- prednisone
- sedatives and hypnotics (e.g. benzodiazepines, barbiturates, chloral hydrate, glutethimide, meprobamate)
- antidepressants (e.g. clomipramine)
- other drugs such as phenylbutazone, antihistamines, analgesics, antimigraine preparations, Vitamin E and Vitamin B12
- cyclosporine
- Antacids (use 2 hours before or after taking **LINESSA**)

LINESSA may also interfere with the working of other drugs.

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

PROPER USE OF THIS MEDICATION

Usual dose:

INFORMATION TO PATIENT ON HOW TO TAKE LINESSA:

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) [7 light yellow, 7 orange and 7 red] taken daily for three weeks, and then no pills for one week;

or

- 28-Pill Pack: 21 active pills (with hormones) [7 light yellow, 7 orange and 7 red] taken daily for three weeks, and then seven (7) [green] “reminder” pills (without hormones) taken daily for one week.

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

3. You may wish to use a second method of birth control (e.g. 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 LINESSA. 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
 - 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 condoms and spermicidal foam or gel) to use as a back-up in case you miss pills, and
 - **AN EXTRA, FULL PACK OF PILLS.**
9. **IF YOU HAVE VOMITING OR DIARRHEA, OR IF YOU TAKE CERTAIN MEDICINES,** such as antibiotics, your pills may not work as well. Use a back-up method, such as 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.**

WHEN TO START THE FIRST PACK OF PILLS
BE SURE TO READ THESE INSTRUCTIONS:

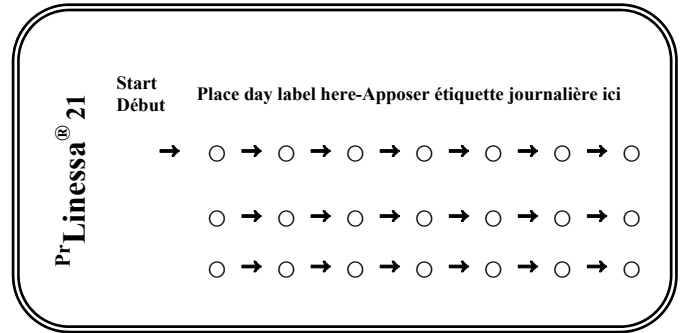
- before you start taking your pills, and
- any time you are not sure what to do.

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

Label the dispenser by selecting the appropriate day label strip: **Day 1** or **Sunday** start (see below for explanation). Place the day label strip in the space where you see the words "Place Day Label Here". Having the dispenser

labelled with the days of the week will help remind you to take your pill every day.

A. LINESSA 21-DAY COMBINATION

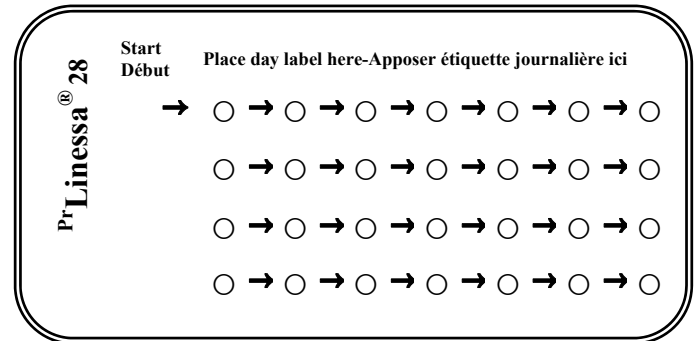


With this type of birth control pill, you are on pills for 21 days and off pills for seven days. You must not be off the pill for more than seven days in a row.

No preceding hormonal contraceptive use (in the past month)

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 or on the first Sunday after your period begins. If your period starts on Sunday, start that same day.
2. Take one pill at approximately the same time every day for 21 days (sequentially following the arrows marked on the dispenser - one light yellow tablet daily for 7 days, one orange tablet daily for 7 days, and one red tablet daily for 7 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. LINESSA 28-DAY COMBINATION



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

No preceding hormonal contraceptive use (in the past month)

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 or on the first Sunday after your period begins. If your period starts on Sunday, start that same day.
2. Take one pill at approximately the same time every day for 28 days (sequentially following the arrows marked on the dispenser - one light yellow tablet daily for 7 days, one orange tablet daily for 7 days, one red tablet daily for 7 days, and one 1 green (inactive) tablet daily for 7 days). Begin a new pack the next day, NOT MISSING ANY DAYS. Your period should occur during the last seven days of using that pill pack.

Changing from a combined hormonal contraceptive (combined oral contraceptive (COC), vaginal ring, or transdermal patch)

The woman should start with LINESSA preferably on the day after the last active tablet (the last tablet containing the active substances) of her previous COC, but at the latest on the day following the usual tablet-free interval or following the last placebo tablet of her previous COC. In case a vaginal ring or transdermal patch has been used, the woman should start using LINESSA preferably on the day of removal, but at the latest when the next application would have been due

Changing from a progestogen-only-method (minipill, injection, implant) or from a progestogen-releasing intrauterine system (IUS)

The woman may switch any day from the minipill (from an implant or the IUS on the day of its removal, from an injectable when the next injection would be due), but should in all of these cases be advised to additionally use a barrier method for the first 7 days of tablet-taking.

Following first-trimester abortion

The woman may start immediately. When doing so, she need not take additional contraceptive measures.

Following delivery or second-trimester abortion

For breastfeeding women see WARNINGS AND PRECAUTIONS - Nursing Women.

Women should be advised to start at day 21 to 28 after delivery or second trimester abortion. When starting later, the woman should be advised to additionally use a barrier method for the first 7 days of tablet-taking. However, if intercourse has already occurred, pregnancy should be excluded before the actual start of COC use or the woman has to wait for her first menstrual period.

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 NEXTDAY.** Take one pill every day. Do not wait any days between packs.

Overdose

Overdosage may cause nausea, vomiting, breast tenderness, dizziness, abdominal pain and fatigue/drowsiness. Withdrawal bleeding may occur in females. In case of overdosage, contact your doctor or pharmacist or call your local poison control centre immediately.

Missed Dose:

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

| SUNDAY START | DAY 1 START |
|--|---|
| MISS 1 PILL | MISS 1 PILL |
| Take it as soon as you remember, and take the next pill at the usual time. This means that you might take 2 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 2 pills in one day. |
| MISS 2 PILLS IN A ROW | MISS 2 PILLS IN A ROW |
| First 2 weeks 1. Take 2 pills the day you remember and 2 pills the next day. 2. Then take 1 pill a day until you finish the pack. 3. Use a non-hormonal back-up method of birth control if you have sex in the 7 days after you miss the pills. | First 2 weeks 1. Take 2 pills the day you remember and 2 pills the next day. 2. Then take 1 pill a day until you finish the pack. 3. Use a non-hormonal back-up method of birth control if you have sex in the 7 days after you miss the pills. |
| Third Week: 1. Keep taking 1 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 non-hormonal back-up method of birth control if you have sex in the 7 days after you miss the pills. 4. You may not have a period this month. IF YOU MISS 2 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 non-hormonal back-up method of birth control if you have sex in the 7 days after you miss the pills. 3. You may not have a period this month. IF YOU MISS 2 PERIODS IN A ROW, CALL YOUR DOCTOR OR CLINIC. |

| SUNDAY START | DAY 1 START |
|--|---|
| MISS 3 OR MORE PILLS IN A ROW | MISS 3 OR MORE PILLS IN A ROW |
| Anytime in the Cycle: 1. Keep taking 1 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 non-hormonal back-up method of birth control if you have sex in the 7 days after you miss the pills. 4. You may not have a period this month. IF YOU MISS 2 PERIODS IN A ROW, CALL YOUR DOCTOR OR CLINIC. | Anytime in the Cycle: 1. Safely dispose of the rest of the pill pack and start a new pack that same day. 2. Use a non-hormonal back-up method of birth control if you have sex in the 7 days after you miss the pills. 3. You may not have a period this month. IF YOU MISS 2 PERIODS IN A ROW, CALL YOUR DOCTOR OR CLINIC. |

NOTE: 28-DAY PACK - If you forget any of the 7 green pills (inactive 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 non-hormonal back-up method of birth control (such as 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 Combined Hormonal Contraceptives

Several health advantages have been linked to the use of hormonal contraceptives.

- Reduction in the incidence of cancer of the uterus and ovaries
- Reduction in the likelihood of developing benign (non-cancerous) breast disease and ovarian cysts.
- Less menstrual blood loss and 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

The following side effects have been observed in women taking Combination hormonal contraceptives in general, including LINESSA:

- headache
- dysmenorrhea (painful menstrual cramps)
- abdominal (stomach) pain
- nausea
- upper respiratory tract infections (bronchitis, runny or stuffy nose, sore throat, etc.)
- back pain
- breast tenderness
- pharyngitis (sore throat)
- diarrhea
- vomiting
- asthenia (loss of strength, weakness, fatigue)
- malaise (feeling of physical discomfort or uneasiness)
- cough
- influenza (flu-like symptoms, fever)
- depression
- migraine, severe headaches
- dizziness
- dyspepsia (indigestion)
- vaginal irritation or infections
- cystitis (urinary tract infections or inflammation)
- amenorrhea (lack of a period or breakthrough bleeding, bleeding between menstrual periods)
- weight gain
- difficulty wearing contact lenses
- acne
- insomnia, nervousness
- allergy

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 call your doctor or pharmacist |
|---|-------------------------------------|--------------|---|
| | Only if severe | In all cases | |
| Uncommon | | | |
| sharp pain in the chest, coughing blood, or sudden shortness of breath/blood clot in the lung | | | √ |
| Pain in the calf/blood clot in the leg | | | √ |
| Crushing chest pain or heaviness/heart attack | | | √ |
| Sudden severe or worsening headache or vomiting, dizziness or fainting, disturbance of vision or speech, or weakness or numbness in the arm or leg/stroke | | | √ |
| Sudden partial or complete loss of vision or double vision/blood clot in the eye | | | √ |
| abnormal liver test and/or nausea, vomiting, severe pain or lump in the abdomen/liver tumour | | | √ |
| persistent sad mood | | | √ |
| Yellowing of the skin/jaundice | | | √ |
| Unusual swelling of the extremities | | √ | |
| Breast lumps/breast cancer | | √ | |
| unexpected (abnormal) vaginal bleeding | | √ | |

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

HOW TO STORE IT

Store at room temperature - between 15-30°C. Keep in a safe place out of the reach of children and pets.

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:

- 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 0701C
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

This document plus the full product monograph prepared for health professionals can be found by contacting the sponsor: **Merck Canada Inc.** at 1-800-463-5442.

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