

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE  
PATIENT MEDICATION INFORMATION**

**LINESSA<sup>®</sup> 21 and LINESSA<sup>®</sup> 28  
desogestrel and ethinyl estradiol tablets**

Read this carefully before you start taking **LINESSA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LINESSA**.

**Serious Warnings and Precautions**

**Smoking**

Cigarette smoking increases the risk of serious heart and circulation problems. This risk increases with age and with the number of cigarettes smoked. It becomes important in women older than 35 years of age, who use hormonal birth control. For this reason, combination birth control pills, including **LINESSA<sup>®</sup>**, should not be used by women who are over 35 years of age and smoke.

**Sexually Transmitted Infections**

Combination birth control pills, including **LINESSA**, **DO NOT PROTECT** against sexually transmitted infections (STIs), including HIV/AIDS. For protection against STIs, you must use latex or polyurethane condoms **IN COMBINATION WITH** birth control pills.

**What is LINESSA used for?**

**LINESSA** is used to prevent pregnancy.

**LINESSA** is 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 healthcare professional. Pregnancy is always more risky than taking birth control pills, except in smokers over 35.

**How does LINESSA work?**

**LINESSA** is a combination birth control pill. It contains two female sex hormones; desogestrel and ethinyl estradiol. Combination birth control pills work in two ways:

- They stop 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 into 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.

### Non-contraceptive benefits of Combined Birth Control Pills

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

- 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.

### What are the ingredients in LINESSA?

Medicinal ingredients: desogestrel and ethinyl estradiol

Non-medicinal ingredients: hydroxypropyl, lactose monohydrate, methylcellulose, polyethylene glycol, starch, stearic acid, titanium dioxide, talc and vitamin E.

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 non-medicinal ingredients: corn starch, FD&C Blue No.2 aluminum lake, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, polyethylene glycol, talc, titanium dioxide and yellow ferric oxide.

**LINESSA comes in the following dosage forms:**

Tablets available in a 21-day or 28-day packs.

LINESSA 21 (21-Day Pack): Each sachet contains a blister card with 21 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 Pack): Each sachet contains a blister card with 28 tablets for oral administration. The blister pack contains the same three dosing phases as LINESSA 21 with an additional seven (7) green “reminder” tablets that do not contain hormones.

**Do not use LINESSA if you have or have had any of the following conditions:**

- allergy (hypersensitivity) to ethinyl estradiol, desogestrel or to any of the other ingredients in LINESSA (see **What are the ingredients in LINESSA?**)
- blood clot in the legs, lungs, eyes or elsewhere, or inflammation of the veins (thrombophlebitis)
- stroke, heart attack or coronary artery disease (e.g. angina or chest pain) 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
- severe high blood pressure
- diabetes with complications
- problems with blood clotting that increases your risk for developing blood clots
- very high blood cholesterol or triglyceride levels
- you smoke
- migraine headaches
- you are scheduled for major surgery
- prolonged bed rest
- jaundice (yellowing of the eyes or skin), severe liver disease and your liver is not working normally
- hepatitis C and are taking combination medication such as ombitasvir/paritaprevir/ritonavir with or without dasabuvir
- liver tumor(s)
- known or 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

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LINESSA. Talk about any health conditions or problems you may have, including 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 angioedema or if you have had episodes of swelling in body parts such as hands, feet, face or airway passages
  - have recently given birth
  - if you are unable to digest lactose or milk products, are on a lactose-free diet or have any of the following rare hereditary diseases:
    - Galactose intolerance
    - Lapp lactase deficiency
    - Glucose-galactose malabsorption
- Because lactose is a non-medicinal ingredient in LINESSA.
- have a family history of blood clots, heart attacks or strokes

**Other warnings you should know about:**

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

Tell your healthcare professional if you are scheduled for any laboratory tests since certain blood tests may be affected by birth control pills, including LINESSA.

Tell your healthcare professional if you are scheduled for MAJOR surgery or if your ability to move around will be limited for a long period of time. In these cases, you should talk to your healthcare professional about stopping the use of LINESSA four weeks before surgery and not using LINESSA for a period of time after surgery or during bed rest.

LINESSA should be used only under the supervision of a healthcare professional, with regular follow-up to check for 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 healthcare professional three months or sooner after the initial examination. Afterward, visit your healthcare professional at least once a year. Use

LINESSA only on the advice of your healthcare professional and carefully follow all directions given to you. You must use LINESSA exactly as prescribed. Otherwise, you may become pregnant.

**If you and your healthcare professional decide that, for you, the benefits of LINESSA outweigh the risks, you should be aware of the following:**

### **The Risks of Using Combination Birth Control Pills**

#### **1. Circulatory problems (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 form of birth control. The risk is also higher if you restart a hormonal birth control (the same product or a different product) after a break of 4 weeks or more. Clots may occur in many areas of the body.

Seek immediate medical help if any of the following symptoms 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, redness, skin feeling “warm to the touch” 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, 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 birth control have a higher risk of developing blood clots, but not as high as the risk during pregnancy. 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 speed up 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 healthcare professional for advice and instructions on how to perform regular breast self exams.**

### **3. Cervical cancer**

Some studies have found an increase in cancer of the cervix in women who use hormonal birth control pills, however, there is not enough evidence to say for sure that hormonal birth control does not cause these 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 birth control pills for a long time the chance of getting cervical cancer may be slightly higher. This may not be caused by the birth control 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 has been linked with the growth of liver tumors or liver injury (e.g., hepatitis and problems with how the liver works). These tumors are **extremely** rare.

Contact your healthcare professional immediately if you experience yellowing of the skin or eyes, dark urine, nausea, vomiting, severe pain or a lump in the abdomen.

### **5. Gallbladder disease**

Users of hormonal birth control 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 healthcare professional about risks to your unborn child from any medication taken during pregnancy.

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

You will be at increased risk for blood clots. Your healthcare professional 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 not get pregnant until another menstrual period occurs within four to six weeks. In this way, the pregnancy can be more accurately dated. Contact your healthcare professional for recommendations on alternate methods of birth control during this time.

### **9. Use while breast feeding**

If you are breast-feeding, consult your healthcare professional before starting **LINESSA**. Side effects in the child have been reported, including yellowing of the skin (jaundice) and breast enlargement. You should use another method of birth control while you are breast-feeding. The use of birth control pills is generally not recommended until the breast-feeding mother has completely weaned her child.

**Certain drugs may interact with combination birth control pills and prevent them from working properly making them less effective in preventing pregnancy or causing unexpected bleeding (spotting or breakthrough bleeding).**

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.** Also tell any healthcare professional who prescribes another medicine that you use LINESSA. They can tell you if you need to use an additional method of birth control and if so, for how long.

**The following may interact with LINESSA:**

- medicines used for the treatment of epilepsy (e.g., primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate);
- medicines used for the treatment of tuberculosis (e.g., rifampicin, rifabutin)
- medicines used for treatment of HIV infections (e.g., ritonavir) and Hepatitis C Virus (e.g. boceprevir, telaprevir, ombitsavir, paritaprevir, dasabuvir)
- antibiotics used to treat bacterial infections (e.g., penicillins, tetracyclines, metronidazole)
- antifungals used to treat fungal infections (e.g. griseofulvin)
- medicines used to lower cholesterol (e.g. clofibrate)
- blood thinners used to prevent blood clots
- the herbal remedy St. John's wort used to treat depression
- medicines used to lower high blood pressure
- insulin and other medicines used to treat diabetes
- prednisone and cyclosporin used to suppress the immune system
- sedatives and hypnotics (e.g. benzodiazepines, barbiturates, chloral hydrate, glutethimide, meprobamate)
- antidepressants (e.g. clomipramine)
- other medicines such as phenylbutazone, antihistamines, pain medications and medicines used to treat migraines
- some nutritional supplements (e.g. Vitamin E and Vitamin B12)
- antacids (use 2 hours before or after taking LINESSA)

LINESSA may also interfere with how other medicines work, causing LINESSA and other drugs to become less effective. You may need to use another method of birth control if you are taking drugs that interfere with LINESSA.

This is not a complete list of possible drug interactions with LINESSA. Talk to your healthcare professional for more information about interactions with other medicines.

**How to take LINESSA:**

**1. Read these Instructions**

- before you start taking LINESSA, 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-Day 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-Day 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.
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 healthcare professional 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 taking birth control pills.** 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 healthcare professional 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. **Do NOT stop taking LINESSA or skip any pills even if you are sick to your stomach, have bleeding between your periods or do not have sex very often.**
  8. **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.
  9. **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.**
  10. **If you have vomiting or diarrhea, or if you take certain medicines,** such as antibiotics, LINESSA may not work as well. Use a back-up method, such as condoms and spermicidal foam or gel, until you can check with your healthcare professional or clinic.
  11. **If you forget more than one pill two months in a row,** talk to your -healthcare professional or clinic about how to make pill-taking easier or about using another method of birth control.
  12. **If your questions are not answered here, call your healthcare professional or clinic.**

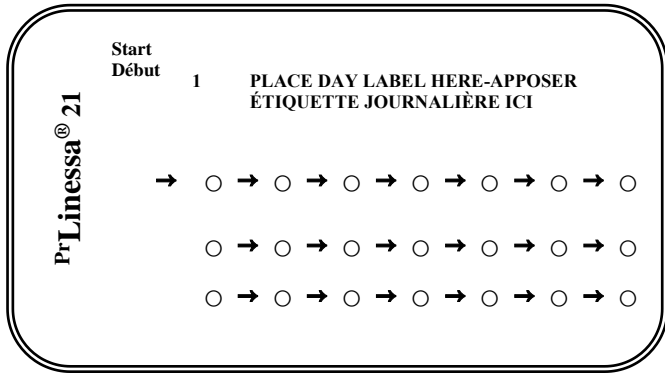
**Usual Adult Dose:**

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

### A. LINESSA 21- Day Pack

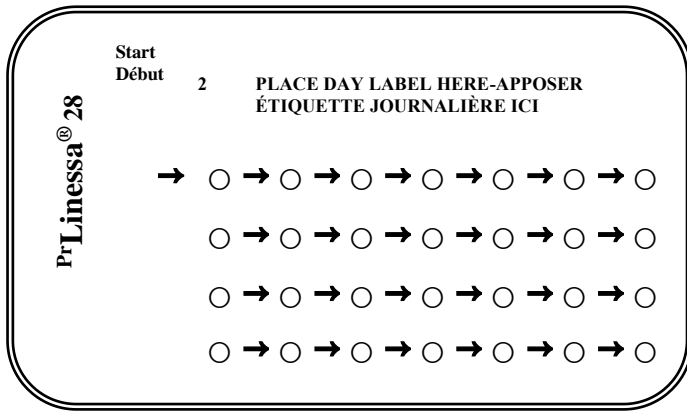


With this type of birth control pill, you are on pills for 21 days and off pills for seven days. You must not be off the pill for more than seven days in a row.

#### **If you have not used hormonal birth control in the past month:**

1. **The first day of your menstrual period (bleeding) is Day 1 of your cycle.** Your healthcare professional may advise you to start taking LINESSA 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. Try to associate taking LINESSA with a regular activity such as eating a meal or going to bed. Follow the arrows marked on the pill pack (one light yellow tablet daily for 7 days, one orange tablet daily for 7 days, and one red tablet daily for 7 days).
3. **Then, do NOT take any pills for seven days.** You will probably have a period during the seven days you do not take LINESSA. This bleeding may be lighter and shorter than your usual period.
4. Start a new pack on the eighth day.

**B. LINESSA 28- Day Pack**



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

**If you have not used hormonal birth control in the past month:**

1. **The first day of your menstrual period (bleeding) is Day 1 of your cycle.** Your healthcare professional may advise you to start taking LINESSA 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. Try to associate taking LINESSA with a regular activity such as eating a meal or going to bed. (Follow the arrows marked on the pill pack (one light yellow tablet daily for 7 days, one orange tablet daily for 7 days, one red tablet daily for 7 days, and one green “reminder” tablet daily for 7 days). Your period should occur during the last seven days of using the pill pack (i.e. while you are taking the green “reminder” pills).
3. Begin a new pack the next day. **DO NOT miss any days.**

**If you are switching from another combined birth control (combined birth control pill, vaginal ring or transdermal patch):**

Start LINESSA preferably on the day after the last active tablet (the last tablet containing hormones) of your previous combined birth control pill. If you cannot start immediately after the last active tablet of your previous birth control pill, the latest you should start is on the day following your usual tablet-free interval or following the last “reminder” tablet of your previous combined birth control pill. If a vaginal ring or transdermal patch has been used, start using LINESSA preferably on the day of removal, but at the latest when the next application would have been due.

**If you are switching from a progestogen-only-method (mini-pill, injection, implant) or from a progestogen-releasing intrauterine system (IUS):**

You may switch any day from the mini-pill. From an implant or an IUS start on the day of its removal. From an injectable start when the next injection would be due. In all of these cases you should use a back-up (barrier) method for the first 7 days take LINESSA.

**If you are starting following a first-trimester abortion:**

You may start immediately. When doing so, you do not need to use any back-up birth control.

**If you are starting following delivery of a baby or a second-trimester abortion:**

You should start between days 21 and 28 after delivery or second trimester abortion. When starting later, you should use a back-up method for the first 7 days you take LINESSA. If intercourse has already occurred, you must make sure you are not pregnant or wait for your first menstrual period before starting LINESSA. If you are breastfeeding, or planning to breastfeed, talk to your healthcare professional about whether taking LINESSA is right for you.

**Overdose:**

Overdose may cause nausea, vomiting, breast tenderness, dizziness, abdominal pain and fatigue/drowsiness. Withdrawal bleeding may occur.

If you think you have taken too much LINESSA, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

The following chart explains what you should do if you miss one or more birth control pills. Match the number of pills missed with the appropriate starting time for your pill pack.

Sunday Start	Day 1 Start
<b>Miss 1 Pill</b>	<b>Miss 1 Pill</b>
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.
<b>Miss 2 Pills in a Row</b>	<b>Miss 2 Pills in a Row</b>
<p><b>First 2 weeks</b></p> <ol style="list-style-type: none"> <li>1. Take 2 pills the day you remember and 2 pills the next day.</li> <li>2. Then take 1 pill a day until you finish the pack.</li> <li>3. Use a non-hormonal back-up method of birth control if you have sex in the 7 days after you miss the pills.</li> </ol>	<p><b>First 2 weeks</b></p> <ol style="list-style-type: none"> <li>1. Take 2 pills the day you remember and 2 pills the next day.</li> <li>1. Then take 1 pill a day until you finish the pack.</li> <li>2. Use a non-hormonal back-up method of birth control if you have sex in the 7 days after you miss the pills.</li> </ol>
<p><b>Third Week:</b></p> <ol style="list-style-type: none"> <li>1. Keep taking 1 pill a day until Sunday.</li> <li>2. On Sunday, safely discard the rest of the pack and start a new pack that day.</li> <li>3. Use a non-hormonal back-up method of birth control if you have sex in the 7 days after you miss the pills.</li> <li>4. You may not have a period this month.</li> </ol> <p><b>If you miss 2 periods in a row call your healthcare professional.</b></p>	<p><b>Third Week:</b></p> <ol style="list-style-type: none"> <li>1. Safely dispose of the rest of the pill pack and start a new pack that same day.</li> <li>2. Use a non-hormonal back-up method of birth control if you have sex in the 7 days after you miss the pills.</li> <li>3. You may not have a period this month.</li> </ol> <p><b>If you miss 2 periods in a row call your healthcare professional.</b></p>
<b>Miss 3 or More Pills in a Row</b>	<b>Miss 3 or More Pills in a Row</b>

Sunday Start	Day 1 Start
<p><b>Anytime in the Cycle:</b></p> <ol style="list-style-type: none"> <li>1. Keep taking 1 pill a day until Sunday.</li> <li>2. On Sunday, safely discard the rest of the pack and start a new pack that day.</li> <li>3. Use a non-hormonal back-up method of birth control if you have sex in the 7 days after you miss the pills.</li> <li>4. You may not have a period this month.</li> </ol> <p><b>If you miss 2 periods in a row call your healthcare professional.</b></p>	<p><b>Anytime in the Cycle:</b></p> <ol style="list-style-type: none"> <li>1. Safely dispose of the rest of the pill pack and start a new pack that same day.</li> <li>2. Use a non-hormonal back-up method of birth control if you have sex in the 7 days after you miss the pills.</li> <li>3. You may not have a period this month.</li> </ol> <p><b>If you miss 2 periods in a row call your healthcare professional.</b></p>

**28- Day Pack** - If you forget any of the 7 green “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.

**What are possible side effects from using LINESSA?**

These are not all the possible side effects you may feel when taking LINESSA. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

**Side effects may include:**

- headache
- painful menstrual cramps
- stomach pain
- nausea
- bronchitis, runny or stuffy nose, sore throat, common cold
- back pain
- breast tenderness
- diarrhea
- vomiting
- loss of strength, weakness, fatigue
- feeling of physical discomfort or uneasiness
- cough
- flu-like symptoms, fever
- migraine, severe headaches
- dizziness
- indigestion
- vaginal irritation or infections
- urinary tract infections or inflammation
- lack of a period or breakthrough bleeding, bleeding between menstrual periods
- weight gain
- difficulty wearing contact lenses
- acne
- insomnia, nervousness

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNCOMMON</b> <b>Blood clot in the lung:</b> sharp pain in the chest, coughing blood, sudden shortness of breath			√
<b>Blood clot in the leg:</b> pain in the calf, swelling, redness, skin feeling “warm to the touch”			√
<b>Heart attack:</b> crushing chest pain or heaviness, heartburn, shortness of breath, nausea, cold sweat, dizziness			√
<b>Stroke:</b> sudden severe or worsening headache, vomiting, dizziness, fainting, vision or speech problems, weakness or numbness in the arm or leg			√
<b>Blood clot on the eye:</b> sudden partial or complete loss of vision or double vision			√
<b>Liver problems including liver tumour:</b> abnormal liver test, yellowing of the skin or eyes, dark urine, nausea, vomiting, severe pain or lump in the abdomen, loss of appetite			√
<b>Depression:</b> persistent sad mood			√
<b>Edema:</b> swelling of the arms or legs		√	
<b>Breast changes (breast lumps/breast cancer):</b> pain and tenderness, lumps, nipple discharge		√	
Unexpected (abnormal) vaginal bleeding		√	
<b>Allergic reaction:</b> rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

**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.*

**Storage:**

Store at room temperature – between 15°C - 30°C.

Keep in a safe place out of reach and sight of children and pets.

**If you want more information about LINESSA:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](https://www.canada.ca/en/health-canada.html) (<https://www.canada.ca/en/health-canada.html>); or by contacting Aspen Pharmacare Canada Inc. at [www.aspenpharma.ca](http://www.aspenpharma.ca) or at 1-844-330-1213.

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