

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### **LINESSA 21 and LINESSA 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**

- Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels. This risk increases with age particularly in women older than 35 years of age, who use hormonal birth control. The risk also increases with the number of cigarettes smoked. For this reason, women who smoke and are over 35 years of age should not use LINESSA.
- Birth control pills DO NOT PROTECT against sexually transmitted infections (STIs), including HIV/AIDS. For protection against STIs, you must use latex or polyurethane condoms AND take your birth control pills.

#### **What is LINESSA used for?**

LINESSA is used to prevent pregnancy in women 18 to 65 years old.

#### **How does LINESSA work?**

LINESSA is a birth control pill. It is considered to be a combination oral contraceptive. This is because 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.

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.

#### **What are the ingredients in LINESSA?**

Medicinal ingredients: desogestrel and ethinyl estradiol

Non-medicinal ingredients:

LINESSA 21 and LINESSA 28:

- Light yellow tablets: hydroxypropyl, lactose monohydrate, methylcellulose, polyethylene glycol, starch, stearic acid, titanium dioxide, talc, vitamin E and yellow ferric oxide.
- Orange tablets: hydroxypropyl, lactose monohydrate, methylcellulose, polyethylene glycol, red ferric oxide, starch, stearic acid, titanium dioxide, talc, vitamin E and yellow ferric oxide.
- Red tablets: hydroxypropyl, lactose monohydrate, methylcellulose, polyethylene glycol, red ferric oxide, starch, stearic acid, titanium dioxide, talc and vitamin E.

LINESSA 28:

- Green tablets: 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:**

LINESSA 21 (21-Day Pack) and LINESSA 28 (28-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: 0.100 mg desogestrel and 0.025 mg ethinyl estradiol
- Seven (7) orange tablets: 0.125 mg desogestrel and 0.025 mg ethinyl estradiol
- Seven (7) red tablets: 0.150 mg desogestrel and 0.025 mg ethinyl estradiol.

LINESSA 28 (28-Day Pack): 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 are allergic to any ingredients in LINESSA or component of the packaging;
- You have or have had a blood clot in the legs (deep vein thrombosis), lung (pulmonary embolism), or somewhere else in your body;
- You have blood vessel disease of the eye that has caused loss of vision;
- You have the following risk factors for blood clots:
  - Severe high blood pressure or high blood pressure that is not under control (hypertension);
  - Blood clot disorders such as:
    - Abnormal Factor V Leiden mutation
    - Activated protein C (APC) resistance
    - Antithrombin-III-deficiency
    - Protein C deficiency
    - Protein S deficiency
    - hyperhomocysteinemia
    - Prothrombin mutation G20210A
    - Antiphospholipid-antibodies
  - You have an unusual amount of lipoproteins in your blood;
  - You have diabetes with complications;
  - Increasing age such as a woman older than 50 years old;
  - You have too much body fat (you are obese);
  - A family history of blood clot disorders;
  - You had or will have a major surgery (including to the legs, pelvis or nervous system);
  - You cannot stand or move for long periods of time, including prolonged bed rest;
  - You are a woman over age 35 and smoke;
- You have or had stroke or heart attack;
- You have or had coronary artery disease (including angina) or a condition that may be a first sign of stroke (such as mini stroke, small reversible stroke, chest pains);
- You have disease of the heart valves with complications;
- You have or had liver disease;
- You have or had jaundice (yellowing of the eyes or skin). This may have been related to other medicines you were taking or may have happened during pregnancy;
- You have or have a history of liver tumors (cancerous or non-cancerous);
- You have or might have breast cancer;

- You have a cancer of the uterus or a cancer that is sensitive to hormones;
- You have unusual vaginal bleeding without a known reason;
- You have or have had migraine headaches with or without focal aura (flashes of light, blind spots and other vision changes);
- You have or have had inflammation of the pancreas (pancreatitis) and high levels of fat in your blood (triglycerides);
- You are pregnant or think you might be pregnant;
- You have hepatitis C and are taking combination medication such as ombitasvir/paritaprevir/ritonavir with or without dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir

**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:**

- have a history of depression;
- have or have a history of kidney problems;
- have a history of liver problems;
- are obese;
- have heart disease;
- have had or will have a major surgery;
- have high blood pressure;
- have or have a family history of diabetes;
- have a history of breast disease or family history of breast cancer;
- have migraine headaches;
- have a family history of blood clots;
- have uterine fibroid tumours (benign tumours of the uterus);
- have cholestasis. This is a condition where the bile flow from the liver is decreased;
- have porphyria;
- are in menopause;
- have inflammatory bowel disease such as Crohn's disease or ulcerative colitis;
- have sickle cell disease. This is a disease that affects hemoglobin, a molecule in red blood cells that delivers oxygen throughout the body;
- have haemolytic uremic syndrome. This is when there is an abnormal breakdown of blood cells, which clogs the kidney;
- have systemic lupus erythematosus. This is a disease of the immune system that affects many organs of the body;
- have a history of seizures/epilepsy;
- have been told that you have a condition called hereditary or acquired angioedema or if you have had episodes of swelling in body parts such as hands, feet, face or airway passages;
- have problems with the valves in your heart and/or have an irregular heart rhythm, or other heart problems;
- have high cholesterol levels;

- wear contact lenses;
- have a history of a skin condition called chloasma (hyperpigmentation);
- are unable to digest lactose or milk products, are on a lactose-free diet or have any of the following diseases:
  - Galactose intolerance
  - Lapp lactase deficiency
  - Glucose-galactose malabsorption

**Other warnings you should know about:**

**LINESSA may not work as well as it should to prevent pregnancy if you:**

- miss pills,
- don't take your pills as directed by your healthcare professional,
- have gastrointestinal problems, or
- are taking certain medicines.

If this happens, you should use another method of birth control, like condoms (barrier method). Talk to your healthcare professional on when you can start LINESSA again.

**Blood clot in legs, lungs, heart, eyes or brain:**

Women who use birth control that contains hormones are more likely to develop blood clots. Blood clots are the most common serious side effects of birth control pills. The risk for blood clots is highest during the first year a woman uses a hormonal birth control. The risk is also high 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 can lead to blindness or impaired vision as well as damage to or loss of a limb and death.

While you are taking LINESSA, if you have any of the following symptoms, contact your healthcare professional right away. These are signs of blood clots:

- Sharp pain in the chest, coughing blood, or sudden shortness of breath. These symptoms could indicate a possible blood clot in the lung.
- Crushing chest pain or heaviness, discomfort radiating to your back, jaw, throat or stomach, feeling full. These symptoms could indicate a possible heart attack.
- Sudden severe or worsening headache, vomiting, dizziness, fainting or seizures, trouble walking, changes in vision or speech, weakness or numbness in your face, arm or leg. These symptoms could indicate a possible stroke.
- Pain and/or swelling, redness or slight blue discoloration, skin feeling “warm to the touch” in the calf, irregular heartbeat, confusion. These symptoms could indicate a possible blood clot in the leg.
- Sudden partial or complete loss of vision. This symptom could indicate a possible blood clot in the eye.

## **Cancer:**

Using birth control pills may increase the risk of certain cancers including cancer of the breast, cervix and liver.

### **Breast cancer**

The risk of breast cancer in women increases as you get older. It also increases if there is a family history of breast cancer (mother or sister). Other factors include obesity, never having children or having your first full-term pregnancy at a late age.

Some women who use birth control pills may be at a higher risk of developing breast cancer before menopause. These women may have used birth control pills for a long time (more than eight years) or may have started using birth control pills at an early age.

In a few women, the use of birth control pills may speed up the growth of a breast cancer that has not been found. Finding breast cancer early can reduce the effect of breast cancer on a woman's life expectancy. The risks for breast cancer related to birth control pills seem to be small. You should, however, have a healthcare professional check your breasts examination at least once per year.

While you are taking LINESSA, check your breasts often. See your healthcare professional if you notice any changes, such as:

- Dimpling or sinking of the skin,
- Changes in the nipple, or
- Any lumps you can see or feel.

### **Cervical cancer**

Women who use birth control pills may have a higher chance of getting cervical cancer. However, this may be due to other reasons including infection with the Human Papilloma Virus (HPV). HPV is an important risk factor for cervical cancer. However, it is possible that oral birth control pills may also cause such cancers.

### **Liver cancer**

Liver cancer (hepatocellular carcinoma) and liver tumours may be linked to oral birth control pills. The risk for liver cancer increases the longer these pills are used. However liver tumours are extremely rare.

If you have yellowing of the skin or eyes, dark urine, nausea, vomiting, severe pain or a lump in the abdomen, contact your healthcare professional right away.

### **Gallbladder disease**

The risk for gallbladder disease that needs surgery is higher in women using birth control pills. The risk is highest in the first year of use and increases the longer these pills are used. The risk may double after four or five years of use.

### **Vaginal bleeding**

Breakthrough bleeding or spotting sometimes happens in women using birth control pills including LINESSA. This is blood coming from the vagina between periods. It is most likely to happen in the first months of starting a birth control pill. If the bleeding is heavy or does not stop, contact your healthcare professional.

While you are taking LINESSA you may not get your period each month. If you were not taking LINESSA as directed by your healthcare professional, you should have a pregnancy test. This will rule out if the missed period is because you are pregnant.

If you go more than 6 months without a period contact your healthcare professional. This will be especially important if you also notice secretions from your breasts.

### **Pregnancy, Breastfeeding, Miscarriage and Abortions:**

#### **Use in pregnancy**

Birth control pills should not be taken by pregnant women. Stop taking LINESSA if you get pregnant. You should check with your healthcare professional about risks to your unborn child from any medication taken during pregnancy.

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

Your healthcare professional will tell you when to start using LINESSA after childbirth, miscarriage or an abortion.

#### **Pregnancy after stopping LINESSA**

You will have a menstrual period when you stop using LINESSA. Wait until after your next period before getting pregnant. 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. Speak to your healthcare professional about other forms of birth control you can use during this time.

#### **Breast feeding**

If you are breast-feeding, talk to your healthcare professional before starting LINESSA. Side effects in the child have been reported, including yellowing of the skin (jaundice) and breast growth. You should use another type of birth control while you are breast-feeding. The use of birth control pills should not be used until breast-feeding has stopped.

### **Skin Conditions**

Chloasma may develop while you are using LINESSA. This appears as yellowish-brown patches on the skin, particularly of the face. It is more likely to happen if you have previously had chloasma gravidarum. This is when these patches appear on the skin of the face during pregnancy. This is commonly known as “the mask of pregnancy”. If you have or had chloasma, avoid too much exposure to the sun while using LINESSA.

## **Surgery**

Tell your healthcare professional if you are scheduled for surgery. You may need to stop using LINESSA one month before surgery and during prolonged bedrest. You may need to wait until after your first period, after hospital discharge, before restarting LINESSA. Talk to your healthcare professional about stopping the use of LINESSA one month before surgery and not using LINESSA for a period of time after surgery or during bed rest.

**Driving and Using Machines:** Drive or use machines with caution when taking LINESSA.

## **Check-ups and tests**

Before starting LINESSA, you will need to have examinations and tests. Your healthcare professional will conduct a physical exam. They will examine your breasts, liver, arms and legs. They will conduct a pelvic exam which includes a PAP smear. Your healthcare professional will also ask you some questions about your personal health history and that of your close relatives. They will also measure your blood pressure and do blood tests.

While you are taking LINESSA, you will need to have regular check-ups with your healthcare professional. Your first check up should be about three months after starting LINESSA. Afterward, you will see your healthcare professional about once per year. At these visits, your healthcare professional will conduct physical and internal exams. He or she will also measure your blood pressure and do blood tests.

If you are scheduled for any laboratory tests, be sure to tell your healthcare professional that you are taking LINESSA. This is because birth control pills can affect some blood tests.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

## **The following may interact with LINESSA:**

- Medicines used for the treatment of epilepsy, such as primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate, ethosuximide, phenobarbital, lamotrigine;
- Medicines used to treat tuberculosis, such as rifampicin, rifabutin;
- Medicines used to treat HIV infections, such as ritonavir
- Medicines used to treat hepatitis C Virus such as boceprevir, telaprevir, ombitsavir/paritaprevir/ritonavir, dasabuvir with or without ribavirin, glecaprevir/pibrentasvir, sofosbuvir/velpatasvir/voxilaprevir;
- Alpha-II adrenoreceptor agents including clonidine;
- Medicines used to treat bacterial infections, such as penicillins, tetracyclines, metronidazole, erythromycin, ampicillin, cotrimoxazole, chloramphenicol, neomycin, nitrofurantoin, sulfonamides, troleandomycin;
- Medicines used to treat fungal infections, such as griseofulvin, fluconazole, itraconazole, ketoconazole, voriconazole, clarithromycin;



- Medicines used to lower cholesterol, such as clofibrate;
- Medicines used to prevent blood clots;
- St. John’s wort, an herbal product used to treat depression;
- Medicines used to treat diabetes including insulin and others that lower blood sugar;
- Medicines used to help you relax or sleep, such as benzodiazepines, barbiturates, chloral hydrate, glutethimide, meprobamate, chlordiazepoxide, lorazepam, oxazepam, diazepam, phenothiazines;
- Medicines used to treat depressants, such as clomipramine;
- Medicines used to treat fever, pain or inflammation, such as phenylbutazone, acetaminophen, ASA, antipyrine, meperidine, prednisone;
- Medicines used to help prevent organ rejection, such as cyclosporine;
- Medicines used to treat migraine headaches;
- Medicines used to treat allergies;
- Nutritional supplements, such as vitamin E, vitamin B12, folic acid;
- A medicine used to help treat bleeding called aminocaproic acid;
- Medicines used to treat lung diseases such as asthma and COPD (bronchitis, emphysema) including theophylline;
- Medicines used to slow the heart rate including isoproterenol;
- Medicines used to treat high blood pressure including guanethidine, methyldopa, beta blockers, reserpine, diltiazem and verapamil;

Antacids may affect how LINESSA is absorbed in your body. If you need to use antacids, like TUMS, take them 2 hours before or 2 hours after taking LINESSA.

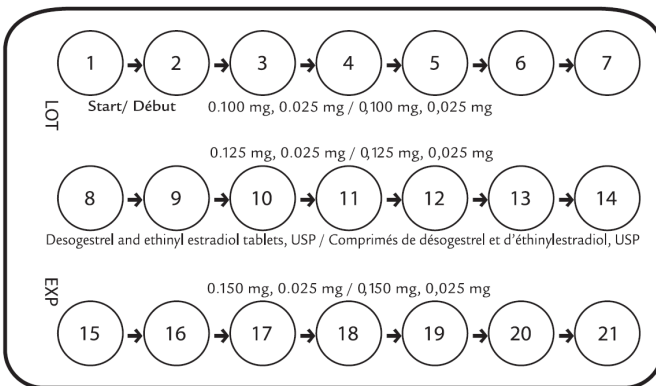
The effects of caffeine and alcohol may also be increased. This is because birth control pills affect how these are metabolized.

**How to take LINESSA:**

- **Read these directions:**
  - before you start taking LINESSA, and
  - any time you are not sure what to do.
- **Look at your pill pack** to see if it has 21 or 28 pills:
  - LINESSA 21 (21-Day Pack):
    - 21 active pills (with hormones): 7 light yellow, 7 orange and 7 red. These are taken daily for three weeks, and then no pills for one week;
  - or
  - LINESSA 28 (28-Day Pack):
    - 21 active pills (with hormones): 7 light yellow, 7 orange and 7 red. These are taken daily for three weeks, then
    - 7 green “reminder” pills (without hormones): taken daily for one week.

- Decide with your healthcare professional what is the best day for you to start taking your first pill. Pick a time of day that will be easy to remember (like when eating a meal or going to bed).
- 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 "Start/ Début". Having the pill pack labelled with the days of the week will help remind you to take your pill every day.
- **Taking LINESSA:**

### A. LINESSA 21 - Day Pack

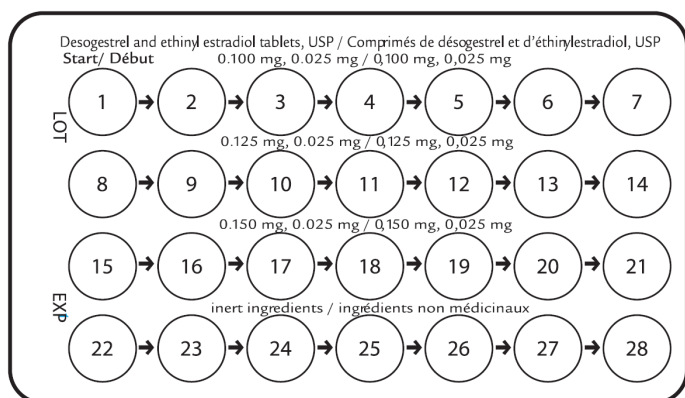


- With this type of birth control pill, you are on pills for 21 days and off pills for 7 days. You must not be off the pill for more than 7 days in a row.

#### 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 tell 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 about the same time every day for 21 days. 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 7 days.** You will probably have a period during the 7 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 about the same time every day for 28 days. 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).
3. Your period should occur during the last 7 days of using the pill pack (i.e. while you are taking the green “reminder” pills).
4. Begin a new pack the next day. **DO NOT miss any days.**

### Other instructions for LINESSA 21 and LINESSA 28:

- 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.
- When receiving any medical treatment, be sure to tell your healthcare professional that you are using birth control pills.

- 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.
- 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.
- If you have vomiting or diarrhea within 3-4 hours of taking a LINESSA pill, LINESSA may not work as well. Use a back-up method of birth control until you can check with your healthcare professional or clinic. See "Missed Dose" below for more instructions.

If your questions are not answered here, ask your healthcare professional or clinic.

### **Switching to LINESSA 21 or LINESSA 28:**

- Talk to your healthcare professional about when to start taking LINESSA.

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

- Switching from another combined birth control pill: Start LINESSA on the day after the last active pill (the last pill containing hormones). If this is not possible, you should start LINESSA on the day after your usual pill-free interval or after the last "reminder" pill.
- If a vaginal ring or transdermal patch has been used, start using LINESSA on the day of removal. If this is not possible, start LINESSA 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):**

- Switching from a mini-pill: You may start LINESSA any day after the mini-pill.
- Switching from an injectable: Start LINESSA when the next injection would be due.
- Switching from an implant or an IUS: Start LINESSA on the day of removal.

In all of these cases you should use a back-up barrier birth control method (like condoms) for the first 7 days of taking LINESSA.

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

- You may start LINESSA right away. 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 LINESSA 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 you already had sex or intercourse, 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.

### Usual Adult Dose:

- **LINESSA 21:** Take 1 tablet each day for 21 days and off pills for 7 days. Begin a new pack the next day.
- **LINESSA 28:** Take 1 tablet each day for 28 days. Begin a new pack the next day.

### Overdose:

If too many birth control pills are taken at one time, nausea, vomiting, breast tenderness, dizziness, abdominal pain, fatigue/drowsiness and withdrawal bleeding may happen.

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

### Missed Dose:

**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.

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.

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.

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>	
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.	

Sunday Start	Day 1 Start
<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>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 throw away 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 or clinic.</b></p>	<p><b>Third Week:</b></p> <ol style="list-style-type: none"> <li>1. Safely throw away 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 or clinic.</b></p>
<b>Miss 3 or More Pills in a Row</b>	
<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 throw away 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 or clinic.</b></p>	<p><b>Anytime in the Cycle:</b></p> <ol style="list-style-type: none"> <li>1. Safely throw away 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 or clinic.</b></p>

**LINESSA 28 - Day Pack:** If you forget any of the 7 green “reminder” pills in Week 4, just safely throw away 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 ready:**

- An extra full pack of pills;
- Another kind of birth control (such as condoms and spermicidal foam or gel) to use as a back-up in case you miss pills. You will need back-up birth control if you miss pills and in some other situations. Always talk to your healthcare professional if you are not sure whether you need to use back-up birth control.

## 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.

- migraine, severe headaches
- acne
- rash
- skin colour changes, red skin lumps
- hair loss or increase in growth
- nausea, vomiting
- abdominal or back pain
- sleep disorder like insomnia
- dizziness
- diarrhea
- urinary tract infections or inflammation
- painful period cramps
- flu-like symptoms
- bronchitis, runny or stuffy nose, sore throat, common cold
- loss of strength, weakness, fatigue
- feeling of physical discomfort or uneasiness
- cough
- fever
- indigestion
- weight gain
- difficulty wearing contact lenses
- nervousness, anxiety, mood swings

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>Arterial thromboembolism, Myocardial infarction</b> (blood clot in the artery, heart attack): sudden pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the shoulder, chest, arm, or below the breastbone; discomfort radiating to the back, jaw, throat, arm, stomach, feeling of being full, having indigestion or choking; sweating, nausea, vomiting or dizziness; extreme weakness, anxiety, or shortness of breath; rapid or irregular heartbeats, cold sweat, heart burn			√
<b>Behavior and mood changes:</b> agitation including aggressive behavior or hostility, changes in sexual desire or sexual activity, increased eating, stress	√		
<b>Breast changes (breast lumps/breast cancer):</b> pain and tenderness, lumps, nipple discharge		√	
<b>Blood clot on the eye:</b> sudden partial or complete loss of vision or double vision			√
<b>Depression:</b> persistent sad mood accompanied by difficulty in sleeping, weakness, lack of energy, fatigue		√	
<b>Reproductive System Disorders:</b> Pelvic pain, painful intercourse, abdominal bloating or swelling, pain during bowel movements; cysts usually disappear on their own within a few months and may not show symptoms; serious cysts are uncommon		√	



<b>Deep vein thrombosis</b> (blood clot in the deep veins of legs or arms): swelling of one leg or one foot, pain or tenderness in the leg, difficulty standing or walking, feeling of warmth in the leg, red or discolored skin on the leg, sudden pain, swelling and slight blue discoloration of an extremity			√
<b>Hypersensitivity</b> (allergic reaction): rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, feeling sick to your stomach and throwing up; wheezing, drop in blood pressure			√
<b>Liver problems including liver tumour, jaundice:</b> abnormal liver test, yellowing of the skin or eyes, dark urine, nausea, vomiting, severe pain or lump in the abdomen, loss of appetite, fever, light-coloured bowel movements			√
<b>Pulmonary embolism (blood clot in the lung):</b> sharp pain in the chest, coughing blood, sudden shortness of breath			√
<b>Stroke:</b> sudden severe or worsening headache, vomiting, dizziness, fainting, vision or speech problems, weakness or numbness in the arm or leg			√
<b>Edema:</b> swelling of the arms or legs		√	
<b>Vaginal bleeding changes:</b> increased or decreased menstrual bleeding, spotting, infrequent periods or absence of bleeding	√		
<b>Vaginal infection</b> (inflammation of the vagina or surrounding area): itching, or unusual or increased vaginal discharge	√		

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 (15°C – 30°C).
- Keep in a safe place out of reach and sight of children and pets.
- Do not throw away any drugs via wastewater or household waste. Ask your pharmacist how to throw away drugs you no longer use. These measures will help to protect the environment.

## 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/services/drugs-health-products/drug-products/drug-product-database.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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