

## PATIENT MEDICATION INFORMATION

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

#### **PrFREYA 21 and PrFREYA 28 Desogestrel and Ethinyl estradiol Tablets, USP**

Read this carefully before you start taking **FREYA** 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 **FREYA**.

#### **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 over 35 years of age. 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 FREYA.
- Birth control pills **DO NOT PROTECT** against sexually transmitted infections (STIs), including HIV/AIDS. For protection against STIs, it is advisable to use latex or polyurethane condoms AND take your birth control pills.

#### **What is FREYA used for?**

FREYA is used to prevent pregnancy in women who have had their first menstrual period (menarche).

#### **How does FREYA work?**

FREYA 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. Desogestrel/ethinyl estradiol tablets have been shown to be effective in preventing pregnancy when taken as prescribed by your healthcare professional.

Combination hormonal contraceptives like FREYA work in two ways:

- To stop the monthly release of an egg by the ovaries.
- To change the mucus produced by your 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 if

FREYA is not used correctly.

### **Other Ways to Prevent Pregnancy**

There are other methods of birth control available. They are usually less effective than birth control pills. If used properly, the other methods of birth control are effective enough for many women.

The following table lists pregnancy rates for different types of birth control, including no birth control. A pregnancy rate is the number of women out of 100 who would become pregnant in one year.

#### **Reported Pregnancies per 100 Women per Year:**

Subdermal Implant	less than 1
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

There are differences in these pregnancy rates. This is because not all people use birth control as carefully or as regularly as they should. This does not apply to subdermal implants or IUDs since these are implanted under the skin or in the uterus. If you are careful and use your birth control regularly, pregnancy rates should be lower. Some types of birth control will require more effort than taking a single pill every day.

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

Medicinal ingredients: desogestrel and ethinyl estradiol.

#### Non-medicinal ingredients:

Inactive ingredients include anhydrous lactose, colloidal silicon dioxide, polyvinyl pyrrolidone, potato starch, stearic acid and vitamin E.

FREYA 28 also contains 7 green tablets containing the following inactive ingredients: FD&C Blue No. 1, ferric oxide yellow, lactose monohydrate, magnesium stearate and polacrillin potassium.

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

FREYA 21:

white tablets: 0.15 mg desogestrel and 0.03 mg ethinyl estradiol.

FREYA 28:

white tablets: 0.15 mg desogestrel and 0.03 mg ethinyl estradiol.

green tablets: no active ingredients.

**Do not use FREYA if:**

- you are allergic to desogestrel or ethinyl estradiol or any of the non-medicinal ingredients in FREYA (see **What are the ingredients in FREYA?**)
- you have or have had a blood clot in the legs (deep vein thrombosis), lung (pulmonary embolism), eyes or somewhere else in your body, or thrombophlebitis (inflammation of the veins)
- you have the following risk factors for blood clots:
  - severe high blood pressure or blood pressure that is not under control (hypertension)
  - diabetes with complications
  - 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
    - anti-phospholipid-antibodies
  - very high blood cholesterol or triglyceride levels
  - smoke and are above the age of 35
  - a family history of blood clot disorders
  - you have 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 had a 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 a disease of the heart valves with complications
- you have or have had migraine headaches with or without focal aura (flashes or light, blind spots and other vision changes)
- you have or might have breast cancer
- you have a cancer of the uterus, or a cancer that is sensitive to hormones
- you have liver disease

- you have Hepatitis C Virus (HCV) and are taking the combination drug regimen ombitasvir / paritaprevir / ritonavir, with or without dasabuvir, or some other Hepatitis C drug combinations (such as glecaprevir/pibrentasvir)
- you have or have had liver tumors (cancerous or non-cancerous)
- you have or have had jaundice. This is where the skin or whites of the eyes turn yellow. This may have been related to other medicines you were taking or may have happened during pregnancy.
- you have unusual vaginal bleeding without a known reason
- you have loss of vision due to blood vessel disease of the eye
- you have or have had inflammation of the pancreas (pancreatitis) and high levels of fat in your blood (triglycerides)
- you are or think you might be pregnant

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take FREYA. Talk about any health conditions or problems you may have, including if you:**

- smoke
- are overweight
- have high blood pressure
- have high cholesterol
- have or have a family history of diabetes
- have a family history of stroke, heart attack or blood clot disorders
- have or have a history of heart or kidney problems
- have a history of seizures or have epilepsy
- have a history of depression
- have a history of liver problems
- have cholestasis. This is a condition where bile flow from the liver is decreased.
- wear contact lenses
- have uterine fibroids (benign tumours of the uterus)
- have systemic lupus erythematosus. This is a disease of the immune system that affects your joints, skin, kidneys, blood cells, brain, heart and lungs.
- have inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- have hemolytic uremic syndrome. This is when there is an abnormal breakdown of blood cells, which clogs the kidney.
- have sickle cell disease. This is a disease that affects haemoglobin, a molecule in red blood cells that delivers oxygen throughout the body.
- have problems with the valves in your heart and/or have an irregular heart beat
- have a condition called hereditary or acquired angioedema or if you have had episodes of swelling in body parts such as hands, feet, face, tongue and/or throat, or airway passages, if you experience difficulty swallowing, potentially with difficulty breathing. Products containing estrogens may cause or worsen hereditary and acquired angioedema.
- have porphyria. This is a disease of blood pigment that is passed down in families (inherited).

- have a history of a skin condition called chloasma (hyperpigmentation)

**Other warnings you should know about:**

**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 clots is highest during the first year a woman uses a hormonal birth control. The risk is also high if a woman restarts the same or new hormonal birth control. Clots can occur in many areas of the body and can lead to blindness or impaired vision as well as damage to or loss of a limb and death.

While you are taking FREYA, if you have any of the below symptoms, talk to your healthcare professional right away. These are signs of blood clots.

- sharp pain in your chest
- coughing up blood
- sudden shortness of breath
- crushing chest pain or chest heaviness
- irregular heartbeat
- sudden severe or worsening headache
- feeling full
- vomiting
- dizziness, trouble walking
- fainting, seizures
- anxiety, confusion
- changes in vision
- changes in speech
- pain and / or swelling in your calf
- weakness or numbness in your face, arm or leg
- sudden pain, swelling and slight blue or red discoloration of an arm or leg
- discomfort radiating to your back, jaw, throat or stomach

Blood clots can develop whether or not you are using hormones for birth control. They can also happen if you are pregnant. The risk is higher in users of CHCs, including FREYA than in non-users, but it is not as high as the risk during pregnancy. You should talk to your healthcare professional about the available options.

**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 family history of breast cancer, meaning if your mother or sister have or had breast

cancer. Other factors that increase your risk for breast cancer are being obese, never having children, or having your first full-term pregnancy at a late age.

If you have breast cancer now, or had it in the past, do not use birth control pills. The hormones in these pills can affect some cancers.

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

While you are taking FREYA, 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
- 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 feel severe abdominal pain or find a lump in your abdomen, talk to your healthcare professional right away.

Do not use FREYA if you have a history of liver tumors (cancerous or noncancerous).

### **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.

### **Vaginal Bleeding**

Breakthrough bleeding or spotting sometimes happens in women using birth control pills including FREYA. 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, talk to your healthcare professional.

While you are taking FREYA you may not get your period each month. If you were not taking FREYA 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.

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

**Use in pregnancy:** Birth control pills should not be taken by pregnant women. Stop taking FREYA if you get pregnant. You should talk to your healthcare professional about risks to your unborn child from any medication taken during pregnancy.

**Use after pregnancy, miscarriage or an abortion:** You will be at increased risk for blood clots. Your healthcare professional will tell you when to start using FREYA after childbirth, miscarriage or an abortion.

**Pregnancy after stopping FREYA:** You will have a menstrual period when you stop using FREYA. Wait until after your next period before getting pregnant. This will help to better date the pregnancy. Talk to your healthcare professional about other forms of birth control you can use during this time.

**Breastfeeding:** If you are breastfeeding, talk to your healthcare professional before starting the birth control pill. Other types of birth control, instead of a birth control pill, are recommended until your baby has stopped breastfeeding. The hormones in the pill may lower the amount and quality of your breast milk. This may not happen, however, if you wait until after breastfeeding is established.

### **Skin Conditions**

Chloasma may develop while you are using FREYA. 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 FREYA.

### **Surgery**

Tell your healthcare professional if you are scheduled for surgery. You may need to stop using FREYA four weeks before surgery and during prolonged bed rest. You may need to wait for at least two weeks after surgery before restarting FREYA.

### **Check-Ups and Tests**

Before starting FREYA, 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 FREYA, you will need regular check-ups with your healthcare professional. Your first check-up should be about three months after starting FREYA. Afterward, you will see your healthcare professional at least once a year. At these visits, your healthcare professional will conduct physical and internal exams. They 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 FREYA. If you see a different healthcare professional be sure to tell them that you are taking FREYA. This is because birth control pills can affect some blood tests.

FREYA 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
- are taking certain medicines

If this happens, you should use another method of birth control, like condoms (barrier method). Do this while taking FREYA and until you start a new pack of FREYA.

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

Certain drugs may interact with birth control pills (including FREYA) and prevent them from working properly. This can make them less effective in preventing pregnancy or cause unexpected bleeding (spotting or breakthrough bleeding). Birth control pills may also interfere with how other drugs work.

**The following may interact with FREYA:**

- drugs used for the treatment of epilepsy including primidone, phenytoin, barbiturates (e.g., phenobarbital, carbamazepine, oxcarbazepine, lamotrigine, topiramate, felbamate)
- drugs used for the treatment of tuberculosis including rifampicin, rifabutin
- drugs used for the treatment of HIV infections or AIDS including ritonavir, nelfinavir, nevirapine, efavirenz
- drugs for Hepatitis C Virus infections including ombitasvir, paritaprevir, ritonavir, with or without dasabuvir, boceprevir, telaprevir, and some other Hepatitis C drug combinations (such as glecaprevir / pibrentasvir)
- drugs used to treat bacterial infections including nitrofurantoin, erythromycin, clarithromycin, chloramphenicol, neomycin, sulfonamides, troleandomycin
- drugs used to treat fungal infections including griseofulvin fluconazole, itraconazole, ketoconazole
- drugs used to lower cholesterol including clofibrate
- drugs used to prevent blood clots
- St. John's wort, an herbal product used to treat depression and other conditions



- drugs used to treat high blood pressure including guanethidine, methyldopa, beta-blockers, diltiazem
- drugs used to treat high blood pressure in the blood vessels between the heart and lungs (pulmonary hypertension) including bosentan
- drugs used to treat diabetes including insulin and oral drugs that lower blood sugar
- drugs used to treat fever, pain or inflammation including prednisone, phenylbutazone, acetaminophen, ASA, antipyridine, meperidine
- drugs used to help you relax or sleep including barbiturates, glutethimide, meprobamate, chlorthalidone, lorazepam, oxazepam, diazepam, phenothiazines, reserpine
- drugs used to treat depression including clomipramine
- drugs used to treat allergies including antihistamines
- drugs used to treat migraine headaches
- some nutritional supplements including Vitamin E, Vitamin B12, folic acid
- drugs used to help prevent organ rejection including cyclosporine
- alpha-II adrenoreceptor agents including clonidine
- a drug used to help treat bleeding called aminocaproic acid
- drugs used to treat lung diseases such as asthma and COPD (bronchitis, emphysema) including beta-mimetic agents (e.g. isoproterenol), theophylline

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

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

If you are taking medicines or herbal products that might make FREYA less effective, a barrier method of birth control should also be used. Since the effect of other medicines on FREYA may last up to 28 days after stopping the medicine, you must use the additional barrier method of birth control for that long.

Do not use FREYA if you have Hepatitis C and are being treated with ombitasvir / paritaprevir / ritonavir, with or without dasabuvir or some other Hepatitis C drug combinations (such as glecaprevir/pibrentasvir). Using these drugs at the same time as FREYA can cause problems with your liver, such as an increase in the ALT liver enzyme. You can usually start FREYA about 2 weeks after finishing treatment with these combination drugs used for Hepatitis C, but talk to your healthcare professional before taking FREYA.

### **How to take FREYA:**

#### **1. Be sure to read these directions:**

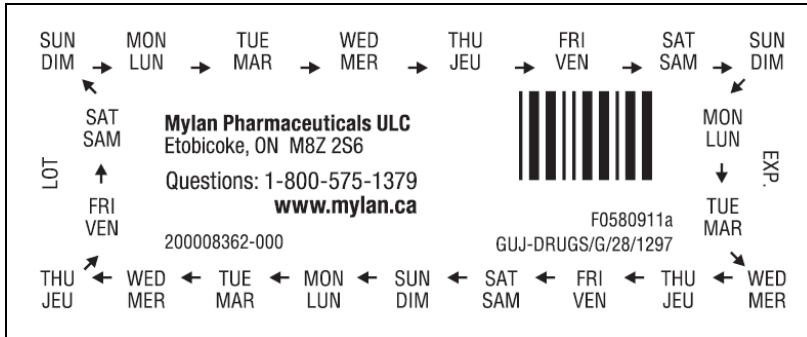
- before you start taking your pills, and
- any time you are not sure what to do.

2. Decide with your healthcare professional what the best day is for you to start taking your first pill. Pick a time of day that will be easy to remember.

3. **Look at your pill pack:**

- There are two types of pill packs for FREYA:

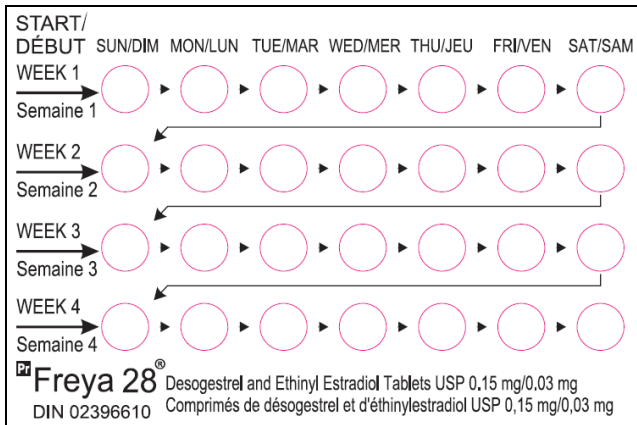
**A. FREYA 21**



The FREYA 21 pill pack has:

- 21 white pills that contain hormones

**B. FREYA 28**



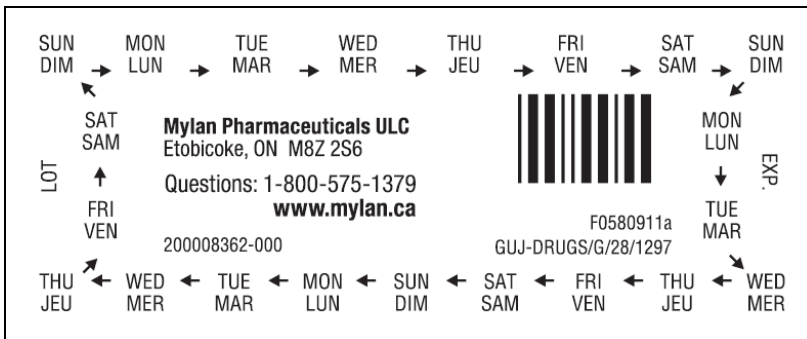
The FREYA 28 pill pack has:

- 21 white pills that contain hormones
- 7 green pills that contain no hormones

- Check the pill pack for:

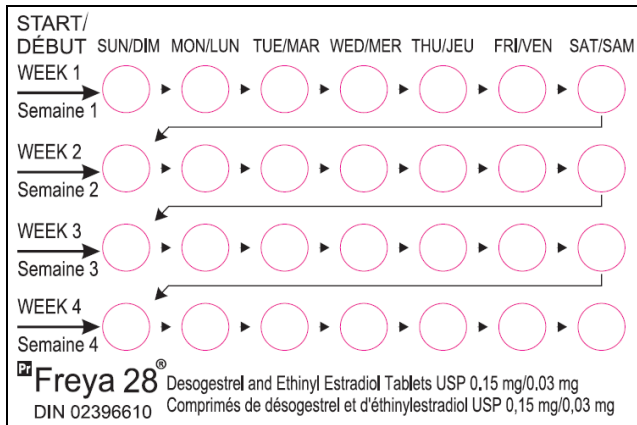
- where to start taking pills; and
- the order to take the pills. Follow the arrows.

4. **The first day of your menstrual period (bleeding) is day 1 of your cycle.** Your healthcare professional may tell 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.
  
5. **A. FREYA 21:**  
 Take one white pill at approximately the same time every day for 21 days. Then take no pills for 7 days. Begin a new pack after 7 days of no pills. Your period should occur during the 7 days that you are not taking pills. You must not be off the pills for more than seven days in a row.
  
- B. FREYA 28:**  
 Take one pill at approximately the same time every day for 28 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, while you are taking the green pills.
  
6. Select the appropriate day-of-the-week label strip. It starts with Day 1 of your menstrual period (for Day 1 starts) or Sunday (for Sunday starts). Apply it to the blister pack above the first row of tablets. This can help remind you to take your pill every day.
  
7. **Taking FREYA:**
  - Take FREYA exactly as directed by your healthcare professional.
  - Take FREYA with or without food.
  - Take your pill at approximately the same time every day. Try to associate taking your pill with a regular activity like eating a meal or going to bed. This will help you remember to take it.
  - Start taking FREYA on either:
    - Day 1 of your period. This is called “Day 1 Start”; or
    - The first Sunday after your period starts. This is called “Sunday Start”. If your period starts on Sunday, start that same day.
  
  - Take FREYA 21 according to this schedule:



- Take 1 white pill each day for 21 days in a row.
- Then, take no pills for 7 days.

- Start the next pack after 7 days of no pills.
- You must not be off the pills for more than 7 days in a row.
- Take FREYA 28 according to this schedule:



- Take 1 white pill each day for 21 days in a row. You should always begin a pack by starting with the white pills. You should always take the white pills first.
- Then, take 1 green pill each day for 7 days in a row.
- Start the next pack on the day after your last green pill. Do not wait any days between packs.
- Be sure to use all the pills in each pack.
- Do not skip any of the pills even if you are spotting or bleeding between monthly periods or feel sick to your stomach.
- Do not skip pills even if you do not have sex very often.
- If you start FREYA after Day 1 of your period (Sunday Start), use an extra barrier method of birth control (such as a condom) for the first 7 days of your first cycle of FREYA.

You might notice bleeding 2 to 4 days after the last white pill. The bleeding might not finish before you start the next pack. This is normal. If this happens, do not stop taking FREYA. These symptoms will usually go away. If they remain for a long time, talk to your healthcare professional.

You may miss your period while you are taking FREYA. If you have been having regular periods and then do not have a period for two or more cycles, you may be pregnant. Talk to your healthcare professional if this happens.

If you vomit within 4 hours after taking a white pill, take **a new pill as soon as possible**. A new pill should be taken within 24 hours of the usual dose time. Take the next pill at the usual dose time. If it has been more than 24 hours since the last pill was taken, see "**Missed Dose**" below for more instructions.

**Switching to FREYA from a different type of birth control:**

- For any switch, always use a second barrier method of birth control (such as condoms) for the first 7 days of taking FREYA.
- If you are switching from another combined oral birth control pill, talk to your healthcare professional about when to start taking FREYA.
- If you are switching from minipill (progestogen only) birth control, start taking FREYA on the next day.
- If you are switching from a type of birth control that is implanted, start taking FREYA on the day the implant is taken out.
- If you switch from a type of birth control that is injected into your body, start taking FREYA on the day the next injection would happen.

**Usual dose:****FREYA 21:** 21 white pills (active)

Take one (1) pill per day for 21 days. Then take no pills for 7 days.

**FREYA 28:** 21 white pills (active), 7 green pills (inactive)

Take one (1) white pill per day. When all 21 white pills are done, take one (1) green pill per day for 7 days.

**Overdose:**

If too many birth control pills are taken at one time, nausea, vomiting, breast tenderness, dizziness, abdominal pain, fatigue, drowsiness and vaginal bleeding in women are possible.

If you think you, or a person you are caring for, have taken too much FREYA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you miss white pills, you could get pregnant. The more pills you miss, the more likely you are to get pregnant. This is especially true if you miss taking the first few or the last few white pills in a pack.

Missing pills can cause you to have some spotting or light bleeding, even if you take the missed pills.

If you forget more than one pill two months in a row, talk to your healthcare professional about ways to make pill-taking easier or about using another method of birth control.

The following chart tells you what to do if you miss taking one or more birth control pills. Match the number of pills missed with the appropriate starting time for the type of pill pack. If you miss one or more white pills and do not have a period that month, you may be pregnant. If

this happens talk to your healthcare professional.

<b>Sunday Start</b>	<b>Day 1 Start</b>
<b>Miss 1 pill</b>	<b>Miss 1 pill</b>
<ol style="list-style-type: none"> <li>1. Take the missed pill as soon as possible and take the next pill at the usual time. This means that you might take 2 pills in one day.</li> <li>2. Keep taking one pill a day until the pack is finished.</li> </ol>	<ol style="list-style-type: none"> <li>1. Take the missed pill as soon as possible and take the next pill at the usual time. This means that you might take 2 pills in one day.</li> <li>2. Keep taking one pill a day until the pack is finished.</li> </ol>
<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. <b>Use a back-up barrier method of birth control (such as a condom) if you have sex in the 7 days after you miss the pills.</b></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>2. Then take 1 pill a day until you finish the pack.</li> <li>3. <b>Use a back-up barrier method of birth control (such as a condom) if you have sex in the 7 days after you miss the pills.</b></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. <b>Use a back-up barrier method of birth control (such as a condom) if you have sex in the 7 days after you miss the pills.</b></li> <li>4. You may not have a period this month.</li> </ol> <p><b>If you miss two periods in a row, you might be pregnant. Talk to your healthcare professional right away.</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. <b>Use a back-up barrier method of birth control (such as a condom) if you have sex in the 7 days after you miss the pills.</b></li> <li>3. You may not have a period this month.</li> </ol> <p><b>If you miss two periods in a row, you might be pregnant. Talk to your healthcare professional right away.</b></p>
<b>Miss 3 or more pills in a row</b>	<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 discard the rest of the pack and start a new pack that day.</li> <li>3. <b>Use a back-up barrier method of birth control (such as a condom) if you have sex in the 7 days after you miss the pills.</b></li> <li>4. You may not have a period this month.</li> </ol>	<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. <b>Use a back-up barrier method of birth control (such as a condom) if you have sex in the 7 days after you miss the pills.</b></li> <li>3. You may not have a period this month.</li> </ol>

Sunday Start	Day 1 Start
If you miss two periods in a row, you might be pregnant. Talk to your healthcare professional right away.	If you miss two periods in a row, you might be pregnant. Talk to your healthcare professional right away.

**FREYA 28:** If you forget any of the seven green "reminder" pills (inactive) 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 barrier method of birth control.

**If you are not sure about the number or the colour of pills missed:**

Talk to your healthcare professional right away.

**Always be sure you have on hand:**

- Back-up methods of birth control. These are types that do not include hormones, like latex or polyurethane condoms and spermicidal foam or gel. 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.
- An extra, full pack of pills.

**Non-contraceptive benefits of hormonal birth control:**

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 possible side effects from using FREYA?**

These are not all the possible side effects you may have when taking FREYA. If you experience any side effects not listed here, tell your healthcare professional.

The following side effects may occur:

- headache
- painful menstrual cramps
- abdominal (stomach) pain
- nausea
- upper respiratory tract infections (bronchitis, runny or stuffy nose, sore throat, etc.)

- back pain
- breast tenderness
- sore throat
- diarrhea
- vomiting
- loss of strength, weakness, fatigue
- feeling of physical discomfort or uneasiness
- cough
- influenza (flu-like symptoms, fever)
- migraine, severe headaches
- dizziness
- indigestion
- urinary tract infections or inflammation
- 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>Arterial thromboembolism, myocardial infarction (blood clot in the artery, heart attack):</b> 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			✓
<b>Blood clot in the eye:</b> sudden partial or complete loss of vision			✓
<b>Breast lumps, breast tumour,</b>			✓



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>breast cancer</b>			
<b>Deep vein thrombosis (blood clot in the leg):</b> 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>Depression:</b> persistent sad mood accompanied by difficulty sleeping, weakness, lack of energy, fatigue			✓
<b>Edema:</b> unusual swelling of the extremities			✓
<b>Gallbladder disease:</b> nausea, vomiting, pain on the upper right side of the abdomen, especially after meals, loss of appetite, fever		✓	
<b>High blood pressure:</b> chest pain, headaches, vision problems, nosebleeds, irregular heartbeat		✓	
<b>Jaundice:</b> yellowing of the skin or eyeballs, accompanied frequently by fever, fatigue, loss of appetite, dark-coloured urine or light-coloured bowel movements			✓
<b>Liver tumour:</b> lump in the abdomen or severe pain			✓
<b>Pulmonary embolism (blood clot in the lung):</b> coughing blood, sharp pain in chest, or sudden shortness of breath			✓
<b>Stroke:</b> sudden severe			✓

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	
headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness or numbness in an arm or leg			
<b>Vaginal bleeding changes:</b> increased or decreased menstrual bleeding, spotting or bleeding between periods, infrequent periods or absence of bleeding	✓		
<b>Vaginal infection:</b> itching or unusual or increased vaginal discharge	✓		
<b>Unknown Frequency</b>			
<b>Allergic reaction (hypersensitivity, angioedema):</b> rash or hives, swelling of the face, lips, tongue and/or throat, difficulty in breathing or swallowing, feeling sick to your stomach and throwing up			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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 between 15-30°C. Keep in a safe place out of the reach of children and pets.

## If you want more information about FREYA:

- 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>); the manufacturer's website [www.mylan.ca](http://www.mylan.ca), or by calling 1-844-596-9526.

This leaflet was prepared by Mylan Pharmaceuticals ULC.

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