

## PATIENT MEDICATION INFORMATION

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

Pr **FLAGYSTATIN**<sup>®</sup>

**metronidazole and nystatin ovules**

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

#### Serious Warnings and Precautions

- Cases of severe liver failure (including cases leading to death) in patients with Cockayne syndrome have been reported with products containing metronidazole for systemic use. If you have Cockayne syndrome, your doctor should check your liver function many times during and after your treatment.

#### What is Flagystatin used for?

- **Flagystatin** treats and reduces two infections in your vagina at the same time.
- These infections are caused by the following microorganisms or “germs”: *Trichomonas vaginalis* and *Candida albicans*.

Antibacterial and antifungal drugs, like **Flagystatin**, treat only bacterial and fungal infections. They do not treat viral infections. Although you may feel better early in your treatment, **Flagystatin** should be used exactly as directed. Misuse or overuse of **Flagystatin** could lead to the growth of bacteria/fungi that will not be killed by **Flagystatin** (resistance). This means that **Flagystatin** may not work for you in the future. Do not share your medicine.

#### How does Flagystatin work?

**Flagystatin** kills the microorganisms causing the vaginal infection.

#### What are the ingredients in Flagystatin?

Medicinal ingredients: Metronidazole, nystatin.

Non-medicinal ingredients: Glycerides of saturated fatty acid (hard fat).

#### Flagystatin comes in the following dosage form:

- **Flagystatin** comes in vaginal ovules. Each ovule contains metronidazole (500 mg) and nystatin (100,000 IU).

#### Do not use Flagystatin if:

- you are allergic to metronidazole (e.g., Flagyl<sup>®</sup>) or nystatin (e.g., Mycostatin<sup>®</sup>, Nilstat<sup>®</sup>, Nyaderm<sup>®</sup>), or any of the other ingredients in **Flagystatin**. (Read also “**What are the ingredients in Flagystatin?**” above).

- you are allergic to medications in the imidazole group of drugs. This group includes clotrimazole (e.g., Canesten®) and miconazole (e.g., Monistat®). These drugs are used to treat fungal and yeast infections.

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

- are pregnant, think you may be pregnant, or plan to get pregnant.
- are breastfeeding or plan to breastfeed. Metronidazole passes into breast milk and may affect your baby.
- have liver problems.
- have a disease of the nervous system.
- have a blood problem (like leukemia or hemophilia).
- have a thyroid problem.
- have hypoadrenalism (underactive adrenal glands).

**Other warnings you should know about:**

Reproductive Health:

- Condoms or diaphragms may not work well when you are using **Flagystatin**. Please talk to your healthcare professional about choosing a different form of birth control while you are using this medicine.
- Do NOT use other vaginal injection or irrigation products, menstrual tampons, and soaps, douches and washes for your vagina while you are using **Flagystatin**. Your infection may be harder to treat if you use these products.
- If a sexual partner thinks they may be infected, they should go to the healthcare professional for treatment too.

Liver Problems:

- Cases of severe liver toxicity/acute liver failure, including deaths, in patients with Cockayne syndrome have been reported with products containing metronidazole.
- If you are affected by Cockayne syndrome, your doctor should also monitor your liver function frequently while you are being treated with metronidazole and afterwards.
- Tell your doctor immediately and stop taking metronidazole if you develop stomach pain, loss of appetite, nausea, vomiting, fever, malaise, fatigue, jaundice (e.g. yellowing of skin and eyes), dark urine putty or mastic (yellowish to greenish) colored stools or itching.
- Do NOT drink alcohol (beer, wine or liquor) while you are using **Flagystatin**. Do NOT drink alcohol until one day after you finish your treatment. You could have a reaction that could make you throw up (vomit), feel flushed (become red in the face or other part of the body) and have a fast heartbeat.
- Some people being treated with metronidazole can experience mental health problems such as irrational thoughts, hallucinations, feeling confused or feeling depressed, including thoughts of self-harm or suicide. These symptoms can occur even in people who have never had similar problems before.

**Flagystatin** may make your urine darker. You do not need to worry about this.

Do NOT drive any type of vehicle or use any tools or machinery if:

- you feel confused, dizzy or experience vertigo (spinning sensation).
- you see or hear things that are not there (hallucinations).
- you have a seizure.
- you have an eye problem, like blurred or double vision.

Do not use the applicator after the seventh month of pregnancy.

**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 Flagystatin:**

- alcohol (e.g., beer, wine or liquor).
- drugs containing alcohol.
- anticoagulants (blood thinners), like warfarin.
- busulfan (e.g., Myleran<sup>®</sup>), a drug used to treat cancer.
- cyclosporine (e.g. Neoral<sup>®</sup>), a drug used to suppress the immune system.
- disulfiram, a drug used to treat drinking problems.
- 5-fluorouracil (e.g., fluorouracil or “5-FU” injection), a drug used to treat cancer.
- lithium (e.g., Carbolith<sup>®</sup>, Lithane<sup>®</sup>, Lithmax<sup>®</sup>), a drug used to treat bipolar disorder.
- phenobarbital, a drug used to treat anxiety or to control seizures.
- phenytoin (e.g., Dilantin<sup>®</sup>), a drug used to control seizures.
- medications that may cause heart rhythm changes (QT prolongation), like certain anti-arrhythmics (medicines for heart rhythm disorders), certain antibiotics, and psychotropic medicines.

**Flagystatin** may interact with some blood tests. Tell your healthcare professional if you have any upcoming blood tests while you are taking **Flagystatin**.

### How to take Flagystatin:

Insert one vaginal ovule deep into your vagina. Do this at bedtime.

### Flagystatin ovule applicator

1. The applicator in this package is especially designed to be used with **Flagystatin** ovules.
2. The applicator will help you to properly insert **Flagystatin** ovules into your vagina.

### How to use the Flagystatin ovule applicator

1. Pull back the applicator plunger about 2.5 centimetres (1 inch).
2. Remove an ovule from its plastic wrapping by pulling the tabs apart. Insert the ovule into the cup at the end of the hollow tube (applicator).
3. Lie on your back with your knees drawn up. Insert the applicator into your vagina as far as it will comfortably go. Do NOT try to force it to go further.
4. **BE SURE** the applicator is in the correct position in your vagina **BEFORE** you push the plunger.
5. Then, push the plunger to place the ovule in your vagina.
6. Remove the applicator. Wash with mild soap and warm water. Rinse thoroughly and dry.



### Usual dose:

Insert one vaginal ovule deep into your vagina at bedtime each day. Do this for 10 days in a row, or as prescribed by your doctor.

Further general directions:

- Tell your healthcare professional if you still have the infections after you finish the 10 days of treatment.

### Overdose:

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

### Missed dose:

If you miss a dose of **Flagystatin**, ask your healthcare professional for advice. Do NOT insert two doses at the same time. Do NOT make up for a missed dose.

### What are possible side effects from using Flagystatin?

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

- slight burning or grainy feeling in your vagina
- darker urine
- constipation
- dry mouth

- bitter or metallic taste in your mouth
- indigestion (stomach upset)
- loss of appetite
- nausea
- vomiting
- depression
- headache
- trouble sleeping
- hearing loss
- noise such as buzzing, ringing, or whistling heard in the ear.

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>Diarrhea</b>	✓		
<b>Irritation in or around your vagina</b>		✓	
<b>Liver problems:</b> yellowing of your skin and eyes (jaundice), right upper stomach area pain or swelling, nausea or vomiting, unusual dark urine, unusual tiredness.			✓
<b>Nervous system problems:</b> trouble moving, seizures, tingling feeling on the skin.			✓
<b>Mental health problems:</b> irrational thoughts, hallucinations, feeling confused or feeling depressed.			✓
Thoughts or actions of self-harm or suicide.			✓
<b>Vertigo</b> (spinning sensation)		✓	
<b>Decrease in some blood cells:</b> fever, other sign of infection such as chills, body aches, sore throat; or extreme tiredness.		✓	
<b>Allergic reaction:</b> difficulty swallowing or breathing, wheezing; drop in blood pressure; feeling sick to your stomach and throwing up; hives or rash; swelling of the face, lips, tongue or throat.			✓
<b>Severe Cutaneous Adverse Reactions (SCAR)</b> (severe skin			✓

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	
reactions that may also affect other organs): - Skin peeling, scaling, or blistering (with or without pus) which may also affect your eyes, mouth, nose, or genitals, itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish). - Swelling and redness of the eyes or face. - Flu-like feeling, fever, shills, body aches, swollen glands, cough. - Shortness of breath, chest pain, or discomfort.			
<b>Meningitis</b> (inflammation of the thin tissue that surrounds the brain and spinal cord): sudden, high fever, severe headache, stiff neck, confusion, nausea and vomiting.			✓
<b>Heart Problems:</b> very fast or uneven heartbeat, chest pain, dizziness, weakness, blurred vision, fainting.  This may also happen when FLAGYSTATIN is taken with drugs that can cause QT prolongation (a heart rhythm condition).			✓

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.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 the vaginal ovules at room temperature, between 15°C and 25°C.

Protect them from light.

Keep out of the reach and sight of children.

### **If you want more information about Flagystatin:**

- 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.sanofi.ca](http://www.sanofi.ca)), or by calling 1-800-265-7927.

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