

## PATIENT MEDICATION INFORMATION

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

<sup>Pr</sup>LITFULO™ (lit-FUL-oh)

#### **ritlecitinib capsules**

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

#### **Serious Warnings and Precautions**

##### **Serious Infections**

- Taking LITFULO increases your risk of getting a serious infection. These infections can lead to hospitalization or death.
- You must not take LITFULO if you have an active infection. This is because LITFULO can make your infection worse. Before you take LITFULO, tell your healthcare professional if you have an infection including one that doesn't go away or often comes back.
- Your healthcare professional will check your risk of tuberculosis before and while you are taking LITFULO.
- Talk to your healthcare professional if you have any symptoms of an infection before you start taking LITFULO and while you are taking it. These include: fever, sweating, chills, muscle aches, cough, shortness of breath, blood in your mucus, weight loss, diarrhea, stomach pain, burning when you urinate, urinating more often than usual, feeling very tired, sore throat.

##### **Cancer**

- LITFULO may increase your risk of getting cancer.

See "**Other warnings you should know about**" for more information.

#### **What is LITFULO used for?**

- LITFULO is used in adults and adolescents aged 12 years and older to treat severe alopecia areata.
- It is not approved for use in children below 12 years of age.

#### **How does LITFULO work?**

LITFULO reduces the activity of certain enzymes in your body called kinases. This changes the way your immune system works and reduces inflammation. This allows for hair regrowth in people with severe alopecia areata.

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

Medicinal ingredient: ritlecitinib tosylate

Non-medicinal ingredients: Crospovidone, FD&C BLUE NO. 1, ferric oxide yellow, glyceryl dibehenate, hypromellose, lactose monohydrate, microcrystalline cellulose, titanium dioxide

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

Capsules, 50 mg ritlecitinib (as ritlecitinib tosylate)

**Do not use LITFULO if you:**

- are allergic to ritlecitinib tosylate or to any of the other ingredients in LITFULO.
- are pregnant or are planning to become pregnant.
- are breast-feeding or are planning to breast-feed. Talk to your healthcare professional about the best way to feed your baby while taking LITFULO.
- have severe liver problems.

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

- have an infection including one that doesn't go away or comes back. You must not take LITFULO if you have an active infection.
- have a weakened immune system due to a medical condition.
- take a medicine that weakens your immune system since it is not recommended to use LITFULO with these medicines.
- have recently had or plan to receive a vaccination with a live or attenuated vaccine. This includes vaccines for shingles.
- have hepatitis virus B or C infection.
- have recently travelled to regions with high rates of fungal infection.
- have low platelet count or white blood cell count.
- have or have had cancer.
- have kidney problems or have had a kidney transplant.
- have diabetes or are aged 65 years or older since people with these conditions have a higher chance of infections.
- have heart problems or have had a stroke or heart attack.
- have had a blood clot in the veins or arteries of your leg, lung or eye.
- have a skin condition called eczema.
- have difficulty digesting or breaking down some sugars, a condition called lactose intolerance.

**Other warnings you should know about:**

**Infections:** Before you take LITFULO, tell your healthcare professional if you have an infection including one that doesn't go away or often comes back. You should not take LITFULO if you have an active infection. LITFULO can make you more likely to get an infection or make an infection worse. Your healthcare professional will closely monitor you for infection during your treatment. They might also stop your treatment with LITFULO until the infection gets better. Talk to your healthcare professional if you have any symptoms of an infection before you start taking LITFULO or while you are taking it. These include: fever, sweating, chills, muscle aches, cough, shortness of breath, blood in your mucus, weight loss, diarrhea, stomach pain, burning when you urinate, urinating more often than usual, feeling very tired, sore throat.

- **Tuberculosis:** Before you take LITFULO, tell your healthcare professional if you have or have ever had tuberculosis (TB). Also tell them if you have recently been in close contact with someone with TB or have recently traveled to regions with high rates of TB infection. You should not take LITFULO if you have an active TB infection. Your healthcare professional may treat you for TB before you take LITFULO if you have TB or have had it before. They may also

treat you for inactive TB, a form of TB in which the TB germs are sleeping and not causing the disease, before you take LITFULO. They will monitor you for TB infection while you are taking LITFULO.

- **Herpes zoster:** Before you take LITFULO, tell your healthcare professional if you have had a herpes infection, because LITFULO may reactivate this condition.
- **Shingles:** Tell your healthcare professional if you develop a painful skin rash with blisters while you are taking LITFULO. These can be signs of shingles.

**Cancer:** Before you take LITFULO, tell your healthcare professional if you have or have ever had cancer. LITFULO may increase your risk of getting cancer including skin cancer. Follow your healthcare professional's advice on having your skin checked for skin cancer during treatment with LITFULO.

**Blood clots:** Tell your healthcare professional if you have had blood clots in your legs, lungs, eyes or have been told you are at risk of blood clots. Get emergency help right away if you have any symptoms of clots in blood vessels. These may include: swelling or pain in your leg, chest pain, shortness of breath or sudden changes to your vision (blurry vision, partial or complete loss of vision).

**Heart Problems and Stroke:** Before you take LITFULO, tell you healthcare professional if you have a heart problem or have had a heart attack or stroke in the past. LITFULO may increase your risk of heart attack and stroke. Get emergency help right away if you have any symptoms of a heart attack or stroke while using LITFULO. These may include new or worsening chest pain, shortness of breath, weakness in one part or on one side of your body or slurred speech.

**Nervous System Problems:** Tell your healthcare professional if you develop unexplained symptoms of nervous system problems while taking LITFULO as your treatment may have to be stopped. These include headache, burning or tingling sensation in the hands, arms, legs, or feet and altered sense of touch. Your healthcare professional will discuss with you if the treatment should be discontinued.

**Blood tests and monitoring:** LITFULO may decrease your white blood cell and platelet counts. Your healthcare professional will test your blood before you take LITFULO and while you are taking it. They will check for low white blood cell and low platelet counts. You will not be treated with LITFULO if these levels are low. Your healthcare professional will stop your treatment with LITFULO if your white blood cell and platelet counts are too low. Tell your healthcare professional if you develop symptoms of a low white blood cells or low blood platelets level while taking LITFULO. These include getting infections more easily, bruising or bleeding.

**Birth control in women:** You must not take LITFULO if you are pregnant or are planning to become pregnant. You must use effective birth control while you are taking LITFULO and for one month after you stop taking it. Talk to your healthcare professional about effective birth control methods.

**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 LITFULO:**

- Sumatriptan, used to treat migraine.
- Midazolam, used to treat anxiety or sleep disorders.
- Rifampin, used to treat tuberculosis.
- Medicines containing caffeine.

**How to take LITFULO:**

- Always take LITFULO exactly as your healthcare professional tells you to take it.

- LITFULO will be prescribed to you and managed by a healthcare professional with experience in treating alopecia areata.
- Swallow LITFULO capsules whole with water. Do not split, crush, or chew the capsules.
- You can take LITFULO with or without food.
- Check with your healthcare professional if you are not sure how to take LITFULO.
- Your healthcare professional may stop your treatment depending on your response to LITFULO after 36 weeks of treatment.

**Usual dose:**

Take one capsule once a day.

**Overdose:**

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

**Missed Dose:**

If you forget to take LITFULO, take the dose as soon as possible. But if it is less than 8 hours before the next dose, skip the missed dose. Take the next dose at your usually scheduled time.

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

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

**Side effects may include:**

- Diarrhea
- Acne
- Rash
- Dizziness
- Increase in an enzyme called creatine phosphokinase, shown by blood test
- Folliculitis (inflammation of the hair follicles or pores)

LITFULO can cause abnormal blood test results. Your healthcare professional may do blood tests before you start taking LITFULO and while you take it. They will check your liver enzymes. Your healthcare professional will decide when to perform blood tests and will interpret the results.

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>COMMON</b>			
<b>Infection:</b> fever, sweating, chills, muscle aches, cough, shortness of breath, blood in your mucus, weight loss, diarrhea, stomach pain, burning when you urinate, urinating more often than usual, feeling tired, sore throat.		X	
<b>Herpes Zoster (Shingles):</b> a painful skin rash of fluid-filled blisters, blisters appear along a strip of skin (sometimes involving more than one body area), itching, headache, feeling tired, fever, chills.		X	
<b>Allergic reaction:</b> hives, rash, swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing.			X
<b>UNCOMMON</b>			
<b>Lymphopenia</b> (low white blood cells): get infections more easily.		X	
<b>Thrombocytopenia</b> (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself.		X	

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 LITFULO at room temperature (15°C to 30°C). Keep in original package. Keep out of reach and sight of children.

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

- 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.pfizer.ca](http://www.pfizer.ca), or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC.

17,300 TransCanada Highway

Kirkland, Quebec, H9J 2M5

Last Revised NOV 29, 2023