

LITFULO (ritlecininib) – Patient Card

Your name: _____

Doctor's name (who prescribed LITFULO): _____

Doctor's phone number: _____

The day you started LITFULO: _____

This material was developed by Pfizer as part of the risk minimization plan for LITFULO. This material is not intended for promotional use.

Safety Information for Patients about LITFULO:

- This card contains important safety information you should be aware of before and during treatment with LITFULO.
- For more information, read the Patient Medication Information leaflet provided with your LITFULO.
- Ask your doctor or pharmacist if any of the information is not clear.

Keep this card with you and show it to any healthcare professional involved in your medical care – for example, your pharmacist or an emergency doctor.

What is LITFULO used for?

LITFULO is used in adults and adolescents aged 12 years and older to treat severe alopecia areata (AA). 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.

Do not use LITFULO if you:

- are allergic to ritlecininib 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 these people 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 travelled 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, or 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 your 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 cell or low blood platelet 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.