# Litfulo (Ritlecitinib) - PATIENT CARD

**Your Name:**
**Doctor's Name (Who Prescribed Litfulo):**
**Doctor's Phone Number:**
**The Date You Started Litfulo:**

## 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 information leaflet included in each pack of Litfulo.
- Ask your doctor or pharmacist if any of the information is not clear.

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

## What Litfulo Is and What It Is Used for:

Litfulo contains the active substance ritlecitinib. It is used to treat severe alopecia areata in adults and adolescents 12 years of age and older. Alopecia areata is a disease where the body's own immune system attacks hair follicles, causing inflammation that leads to hair loss on the scalp, face and/or other parts of the body.

Litfulo works by reducing the activity of enzymes called JAK3 and TEC kinases, which are involved in inflammation at the hair follicle. This reduces the inflammation, leading to hair regrowth in patients with alopecia areata.

## You should know about certain side effects and topics listed below, talk to your doctor if you get any side effects:

### Risk of Infections:

Talk to your doctor or pharmacist before and during treatment with Litfulo if you:

- Have an infection (possible signs may be fever, sweating, chills, muscle aches, cough, shortness of breath, blood in your phlegm, weight loss, diarrhoea, stomach pain, burning when you urinate, urinating more often than usual, feeling very tired).
- Have, or have had, tuberculosis or have been in close contact with someone with tuberculosis, or if you reside or travel in regions where tuberculosis is very common. Your doctor will test you for tuberculosis before starting Litfulo and may retest you during treatment.
- Have ever had a herpes infection (such as chickenpox or shingles), because Litfulo may allow it to come back. Tell your doctor if you get a painful skin rash with blisters as this can be a sign of shingles.



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### Vaccines:

Talk to your doctor or pharmacist if you have recently had or plan to have a vaccination (immunisation) - this is because certain live vaccines (for example Polio, Hepatitis B, MMR, Varicella, Rotavirus) are not recommended immediately before and while using Litfulo.

### Risk of Cancer:

It is not clear if Litfulo increases the risk of cancer, and your doctor will discuss with you if treatment with this medicine is appropriate and whether check-ups including regular skin checks will be necessary during treatment.

### Risk of Blood Clots in Veins or Lungs:

Talk to your doctor or pharmacist if you:

- Have had blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism). Tell your doctor if you get a painful swollen leg, chest pain, or shortness of breath as these can be signs of blood clots in the veins.
- Have had blood clots in an artery in the eye (retinal occlusion) or heart (heart attack). Tell your doctor if you experience acute changes to your eyesight (blurry vision, partial or complete loss of vision), chest pain, or shortness of breath as these changes may be a sign of blood clots in the arteries.

### Risk of Neurological Symptoms:

Talk to your doctor or pharmacist before and during the treatment if you have unexplained symptoms caused by a problem with the nervous system while taking Litfulo.

### Contraception and Pregnancy

- Litfulo must NOT be used during pregnancy.
- If you are a woman of childbearing potential, you should use an effective method of contraception during treatment with Litfulo and for at least one month after your last dose of Litfulo. Talk to your doctor about suitable methods of contraception.
- Tell your doctor straight away if you become pregnant or think you might have become pregnant during treatment as Litfulo can harm the developing baby.



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**For more information, please refer to the patient information leaflet (PIL).**

**Adverse Event Reporting Details:**

The National Pharmacovigilance & Drug Safety Centre (NPC) at Saudi Food and Drug Authority (SFDA)

**SFDA Call Center: 19999**

**Toll-Free Phone: 8002490000**

**E-mail: npc.drug@sfda.gov.sa**

**Website: http://ade.sfda.gov.sa/**

- **Pharmacovigilance Department in the Company**

**E-mail: SAU.AEReporting@pfizer.com**

***This material is approved by the Executive Directorate of Pharmacovigilance at SFDA***



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