

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.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get.

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at <https://medicinesauthority.gov.mt/adrportal>, and sent by post or email to;

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000

E: <mailto:postlicensing.medicinesauthority@gov.mt>

Alternatively, you may also report such events promptly to Pfizer Hellas Pharmacovigilance Department contact details: +30 210 67 85 908 and +30 210 67 85 808 (24hour line), via the webportal: <https://genaes.pfizersafetyreporting.com/en> (Pfizersafetyreporting.com) or contact the local representative Vivian Corporation Ltd. Tel. +356 2134 4610/ +356 2258 8600.

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 or if you often get infections. Tell your doctor if you get symptoms such as fever, wounds, feeling more tired than usual or dental problems as these can be signs of infection. - 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.

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 [including but not limited to MMR (for measles, mumps, rubella), vaccines for rubella, yellow fever, varicella or oral vaccines for typhoid fever and poliomyelitis] are not recommended immediately before and while using Litfulo.

RISK OF CANCER:

Non-melanoma skin cancer has been observed in patients taking Litfulo. Your doctor may recommend that you have regular skin examinations while taking Litfulo. If new skin lesions appear during or after therapy or if existing lesions change appearance, tell your doctor.

RISK OF BLOOD CLOTS:

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

- have previously had blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism) or have an increased risk for developing this (for example: if you had recent major surgery, if you use hormonal contraceptives\hormonal replacement therapy, if a coagulation defect is identified in you or your close relatives). Your doctor will discuss with you if Litfulo is appropriate for you. Tell your doctor if you get sudden shortness of breath or difficulty breathing, chest pain or pain in upper back, swelling of the leg or arm, leg pain or tenderness, or redness or discoloration in the leg or arm as these can be signs of blood clots in the veins.

RISK OF HEART DISEASE:

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

- have, or had heart problems

Seek immediate medical attention if you develop severe chest pain or tightness (that may spread to arms, jaw, neck and back), shortness of breath, cold sweat, light headedness or sudden dizziness, as these may be signs of a heart attack.

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.