Package leaflet: Information for the patient

Litfulo® 50 mg hard capsules
ritlecitinib

▼This medicine 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In addition to this leaflet, your doctor will give you a patient card, which contains important safety information that you need to be aware of. Keep this patient card with you.

What is in this leaflet

1. 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.

2. What you need to know before you take Litfulo

Do not take Litfulo
- if you are allergic to ritlecitinib or any of the other ingredients of this medicine (listed in section 6).
- if you have a serious infection ongoing, including tuberculosis.
- if you have severe liver problems.
- if you are pregnant or breast-feeding (see the "pregnancy, contraception, breast-feeding and fertility" section).

Warnings and precautions
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). Litfulo can reduce your body's ability to fight infections and so worsen an existing infection or make it more likely for you to get a new infection.
- have diabetes or are older than 65 years of age, as you may have an increased risk of getting infections.
- 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.
- have ever had hepatitis B or hepatitis C. Your doctor will test you for hepatitis before starting Litfulo and may retest you during treatment.
- have cancer or have had any 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.
- 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, shortness of breath as these changes may be a sign of blood clots in the arteries.
- have recently had or plan to have a vaccination (immunisation) – this is because certain vaccines (live vaccines) are not recommended while using Litfulo. Check with your doctor to see if your vaccinations are up to date and if you require additional vaccinations, including vaccination for shingles, before treatment with Litfulo.
- have unexplained symptoms caused by a problem with the nervous system while taking Litfulo. Your doctor will discuss with you if treatment should be discontinued.

Additional monitoring tests
Your doctor will carry out blood tests to check if you have low white blood cell count or low platelet count before and approximately 4 weeks after starting Litfulo treatment and may adjust your treatment if necessary.

Children
This medicine is not approved for use in children below the age of 12 years because the safety and benefits of Litfulo are not established in this age group.

Other medicines and Litfulo
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist before taking Litfulo if you are taking some of the medicines for:
- anxiety or sleep disorders (such as midazolam),
- heart rhythm problems (such as quinidine),
- gout (such as colchicine),
- immunosuppression to prevent rejection after organ transplantation (such as ciclosporin, everolimus, tacrolimus and sirolimus),
- migraine (such as dihydroergotamine and ergotamine),
- schizophrenia and chronic psychosis (such as pimozide),
- asthma (such as theophylline),
- muscle spasms (such as tizanidine),
- idiopathic pulmonary fibrosis (such as pirfenidone).

Litfulo may increase the amount of these medicines in your blood.

Tell your doctor, pharmacist or nurse before taking Litfulo if you are taking medicines for asthma, rheumatoid arthritis, or atopic dermatitis that may affect your immune system (such as biologic therapies, medicines that control the body's immune response such as ciclosporin, other Janus kinase inhibitors, such as baricitinib, upadacitinib), as they may increase the risk of side effects.

If any of the above apply to you or if you are not sure, talk to your doctor, pharmacist or nurse before taking Litfulo.

Pregnancy, contraception, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine.

Contraception in women
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 treatment dose. Your doctor can advise you on suitable methods of contraception.

Pregnancy
Do not use Litfulo if you are pregnant, think you may be pregnant or are planning to have a baby. This medicine can harm the developing baby. Tell your doctor right away if you become pregnant or think you might have become pregnant during treatment.

Breast-feeding
Do not use Litfulo while breast-feeding as it is not known if this medicine passes into breast milk or if breast-fed babies are affected. You and your doctor should decide if you will breast-feed or use this medicine.

Fertility
It is unknown if Litfulo reduces fertility in women or men of childbearing potential.

Driving and using machines
Litfulo has no or limited effect on the ability to drive or use machines.

Litfulo contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Litfulo

Always take this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The recommended dose is 50 mg once a day taken by mouth.

You should swallow your capsule whole with water. Do not open, crush or chew the capsule before swallowing as it may change how much medicine gets into your body.

You can take the capsule either with or without food.

If you take more Litfulo than you should
If you take more Litfulo than you should, contact your doctor. You may get some of the side effects described in section 4.

If you forget to take Litfulo
- If you miss a dose, take it as soon as you remember, unless your next dose is due in less than 8 hours.
- If there is less than 8 hours before your next dose, just skip the missed dose and take your next dose as usual.
- Do not take a double dose to make up for a forgotten capsule.

If you stop taking Litfulo
You should not stop taking Litfulo without discussing this with your doctor.

If you need to stop taking Litfulo for a short time (not more than 6 weeks), the risk of losing your scalp hair is low. If Litfulo is stopped for more than 6 weeks, the risk of losing your hair increases with the duration that you stopped taking Litfulo.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects
Talk to your doctor and get medical help straight away if you get any signs of:
- Shingles (herpes zoster), a painful skin rash with blisters with or without fever
- Hives (urticaria), an itching skin rash

Other side effects

Common (may affect up to 1 in 10 people)
- Diarrhoea
- Headache
- Dizziness
- Acne
- Rash (other than hives and shingles)
- Inflammation (swelling) of the hair follicles which may be itchy or painful (folliculitis)
- Increase in an enzyme called creatine phosphokinase, shown by blood test (blood creatine phosphokinase increased)

Uncommon (may affect up to 1 in 100 people)
- Low platelet count shown by blood test (platelet count decreased)
- Low white blood cell count shown by blood test (lymphocyte count decreased)
- Increase of liver enzymes in the blood (ALT and AST increased)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Litfulo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, bottle, or blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from light.

Use within 45 days after first opening of the bottle.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Litfulo contains

- The active substance is ritlecitinib.
  Each capsule contains ritlecitinib tosylate equivalent to 50 mg ritlecitinib.

- The other ingredients are:
  Hard capsule content: microcrystalline cellulose, lactose monohydrate, crospovidone, glyceryl dibehenate (see section 2 "Litfulo contains lactose").
  Hard capsule shell: hypromellose (E464), titanium dioxide (E171), yellow iron oxide (E172), brilliant blue FCF-FD&C blue 1 (E133).
  Printing ink: shellac, propylene glycol, strong ammonia solution, black iron oxide, potassium hydroxide.

What Litfulo looks like and contents of the pack

Litfulo 50 mg opaque hard capsules have a yellow body and blue cap approximately 16 mm long and 6 mm wide of which the body is printed with "RCB 50" and the cap is printed with "Pfizer" in black.

The 50 mg hard capsules are provided in high-density polyethylene (HDPE) bottles with polypropylene closure containing 28 hard capsules or in aluminium foil blisters containing 30 or 90 hard capsules. The bottle contains a silica gel desiccant used to keep the capsules dry. Do not swallow the silica gel desiccant.

Not all pack sizes may be marketed.

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