

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Litfulo® 50 mg, capsules

Active ingredient

Each capsule contains ritlecitinib (as tosylate) 50 mg

Inactive ingredients and allergens in the medicine: See section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Further information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

In addition to the patient information leaflet, Litfulo also has a patient safety information card.
This card contains important safety information that you need to know and that you should follow before starting and during treatment with Litfulo. Carefully read the patient safety information card and patient information leaflet before using this medicine. Keep the card in case you need to read it again.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Litfulo is indicated for the treatment of severe alopecia areata in adults and adolescents aged 12 years and older.

Therapeutic group: Litfulo works by reducing the activity of enzymes called JAK3 kinase and TEC kinase, which are involved in hair follicle inflammation. This reduces the inflammation, leading to hair growth in patients with alopecia areata.

Alopecia areata is a disease in which the immune system attacks hair follicles, causing inflammation leading to hair loss on the scalp, face and/or other areas of the body.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to ritlecitinib or to any of the other ingredients in this medicine (see section 6).
- You have a severe infection, including tuberculosis.
- You have severe liver problems.
- You are pregnant or breastfeeding (see 'Pregnancy, contraception, breastfeeding and fertility' section).

Special warnings regarding use of the medicine

Before and during treatment with Litfulo, tell your doctor if:

- You have an infection (possible signs may be fever, sweating, chills, muscle aches, cough, shortness of breath, blood in the 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 making it more likely for you to get a new infection.

- You have diabetes or are older than 65 years of age. You may have an increased risk of getting infections.
- You have, or have had tuberculosis or have been in close contact with someone with tuberculosis, or 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.
- You have 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.
- You have had hepatitis B or hepatitis C. Your doctor will test you for hepatitis before starting Litfulo, and may retest you during treatment.
- You have or have had 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 for you and whether check-ups, including regular skin checks, will be necessary during treatment.
- You have had blood clots in the veins of the 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 may be signs of blood clots in the veins.
- You have had blood clots in an artery in the eye (retinal occlusion) or heart (heart attack). Tell your doctor if you experience acute changes in your eyesight (blurry vision, partial or complete loss of vision), chest pain, shortness of breath, as these may be signs of blood clots in the arteries.
- You are a current or past smoker.
- You experience decreased hearing during Litfulo treatment.
- You have recently had or plan to have a vaccination – 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 starting treatment with Litfulo.
- You have unexplained symptoms caused by a problem with the nervous system while taking Litfulo. Your doctor will discuss with you whether treatment should be discontinued.

Children

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

Tests and follow-up

Your doctor will refer you for 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 as necessary.

Drug interactions

If you are taking or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking medicines to treat:

- anxiety or sleep disorders (such as midazolam)
- heart rhythm problems (such as quinidine)
- gout (such as colchicine)
- rejection in organ transplantation (such as cyclosporine, 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 the blood.

Using this medicine and food

The medicine can be taken with or without food.

Pregnancy, contraception, breastfeeding and fertility

If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, consult your doctor before taking this medicine.

Contraception for 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 additional 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 are pregnant or are planning to become pregnant. This medicine may harm the developing baby. Tell your doctor right away if you become pregnant or think you might have become pregnant during treatment.

Breastfeeding

Do not use Litfulo if you are breastfeeding, as it is not known if this medicine passes into breast milk and affects the baby. You and your doctor should decide if you will breastfeed or take this medicine.

Fertility

It is unknown whether Litfulo reduces fertility in women and men.

Driving and using machines

Litfulo has no or limited effect on the ability to drive or operate machines.

Important information about some of this medicine's ingredients

Litfulo contains lactose

If you have been told by your doctor that you have an intolerance to certain sugars, consult your doctor before starting treatment with this medicine.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.

The dosage and treatment regimen will be determined by your doctor only.

The recommended dose is 50 mg once a day.

Elderly

No dose adjustment is required for patients 65 years of age and older.

There is a higher incidence of infections in patients 65 years of age and older. Consult your doctor as soon as you see any signs or symptoms of infections.

Do not exceed the recommended dose.

After starting treatment, you should consult your doctor at regular time intervals for re-assessment of the treatment.

If there is no improvement in your condition after 36 weeks of treatment, contact your doctor.

Swallow the medicine whole with water. Do not open, split, crush or chew the capsule before swallowing, as it may change the amount of medicine entering into the body.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. You may experience some of the side effects described in section 4.

If you forget to take the medicine at the scheduled time

- 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, skip the missed dose and take the next dose at the usual time.
- Do not take a double dose to make up for a missed dose.

If you stop taking Litfulo

Even if your health improves, do not stop treatment with this medicine without consulting your doctor or pharmacist.

Adhere to the treatment as recommended by your doctor.

If you need to stop taking Litfulo for a short time (no more than 6 weeks), the risk of losing your scalp hair is low.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Litfulo may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Serious side effects

Talk to your doctor to get medical help straight away if you develop any signs of:

- Shingles (herpes zoster), a painful skin rash with blisters with or without fever
- Hives (urticaria), an itching skin rash

Additional side effects

Common side effects (may affect up to 1 in 10 people):

- Infections of the nose, throat or the windpipe
- Diarrhoea
- Dizziness
- Acne
- Rash (other than hives and shingles)
- Inflammation (swelling) of the hair follicles which may be itchy or painful (folliculitis)
- Increase in creatine phosphokinase enzyme in blood tests

Uncommon side effects (may affect up to 1 in 100 people):

- Low platelet counts in blood tests
- Low white blood cell counts in blood tests
- Increase in the liver enzymes ALT and AST in the blood

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

There are no special storage conditions. It is recommended to store at room temperature. Store in the original package.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

Capsule content:

microcrystalline cellulose, lactose monohydrate, glycerol dibehenate, crospovidone

Capsule shell:

hypromellose (E464), titanium dioxide (E171), yellow iron oxide (E172), brilliant blue FCF (E133).

Ink:

black iron oxide, shellac, dehydrated alcohol, purified water, propylene glycol, buthyl alcohol, isopropyl alcohol, strong ammonia solution, potassium hydroxide.

What the medicine looks like and contents of the pack:

Litfulo 50 mg:

A capsule with a blue cap with "Pfizer" printed in black ink, and a yellow body with "RCB 50" printed in black ink. The capsule contains a white/off-white/light pink powder.

The medicine is marketed in a bottle containing 28 capsules.

Registration holder and address: Pfizer Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
Litfulo 50 mg: 176-18-37835-99

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