

LITFULO[®] 50 MG HARD CAPSULES

Ritlecitinib (50 mg)

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What Litfulo is used for

Litfulo is used to treat severe alopecia areata in adults and adolescents 12 years of age and older.

How Litfulo works

Litfulo contains the active substance ritlecitinib.

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.

Before you use Litfulo

- When you must not use it

Do not take Litfulo

- If you are allergic to ritlecitinib or any of the other ingredients of this medicine.
- If you have a serious infection ongoing, including tuberculosis.
- If you have severe liver problems.
- If you are pregnant or breastfeeding. (see the "pregnancy and lactation" section).

Pregnancy and lactation

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist 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.

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

Do not use Litfulo while 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 use this medicine.

- Before you start to use it

Talk to your doctor, pharmacist or nurse before taking Litfulo:

- If you have an infection (shown by signs such as 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 make an existing infection worse or make it more likely for you to get a new infection.
- If you have diabetes or are elderly (65 years of age and older), you may have an increased risk of getting infections.
- If you have, or have had, tuberculosis or have been in close contact with someone with tuberculosis. Your doctor will test you for tuberculosis before starting Litfulo and may retest you during treatment.
- If you have ever had a herpes zoster infection (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.
- If you have ever had hepatitis B or hepatitis C. Your doctor will test you for hepatitis before starting Litfulo and may retest you during treatment.
- If you 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.

- 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.
- If you have recently had or plan to have a vaccination (immunisation) – this is because certain vaccines (live vaccines) are not recommended while using Litfulo.
- If you 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.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. You should inform your doctor or pharmacist if you are taking any of the following:

- anxiety or sleep disorders (such as midazolam)
- heart rhythm problems (such as quinidine)
- gout (such as colchicine)
- rejection in 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)

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Ritlecitnib (50 mg)

- idiopathic pulmonary fibrosis (such as pirfenidone)

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

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

How to use Litfulo

- How much to use

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist 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.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Litfulo for as long as your doctor recommends.

If you forget to use it

- 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 when it is due.
- Do not take a double dose to make up for a forgotten capsule.

- If you use too much (overdose)

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

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Litfulo.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

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

- Things to be careful of

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.

Side Effects

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

Visit your doctor or pharmacist immediately if you experience any allergic reaction like severe rash or shortness of breath after taking this medicine.

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 ($\geq 1/100$ to $< 1/10$)

- Infections of 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 an enzyme called creatine phosphokinase, shown by blood test (blood creatine phosphokinase increased)

Uncommon ($\geq 1/1000$ to $< 1/100$)

- 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)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Litfulo

Storage

Store below 30°C.

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

- Disposal

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.

Product Description

What it looks like

Litfulo 50 mg hard capsules have opaque 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.

Ingredients

- Active ingredient:

LITFULO[®] 50 MG HARD CAPSULES

Ritlecitinib (50 mg)

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

- Inactive ingredients:

Hard capsule content:

- cellulose microcrystalline
- lactose monohydrate
- crospovidone
- glycerol dibehenate

Hard capsule shell:

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

Printing ink:

- shellac
- propylene glycol
- ammonia solution concentrated
- black iron oxide (E172)
- potassium hydroxide

MAL number:

MAL24106010ARZ

Manufacturer

Manufactured by
Pfizer Manufacturing Deutschland GmbH
Mooswaldallee 1,
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Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.
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