

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using LITFULO?

LITFULO contains the active ingredient ritlecitinib. LITFULO is used to treat severe alopecia areata in adults and adolescents 12 years of age and older.

For more information, see Section [1. Why am I using LITFULO?](#) in the full CMI.

2. What should I know before I use LITFULO?

Do not use if you have ever had an allergic reaction to ritlecitinib or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use LITFULO?](#) in the full CMI.

3. What if I am taking other medicines?

LITFULO may increase the amount of some medicines in your blood..

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use LITFULO?

- The recommended dose of LITFULO is one 50 mg capsule taken once daily with or without food.
- Swallow the capsules whole, do not crush, split or chew.

More instructions can be found in Section [4. How do I use LITFULO?](#) in the full CMI.

5. What should I know while using LITFULO?

Things you should do	• Remind any doctor, pharmacist or dentist you visit that you are using LITFULO. • Keep all your appointments so that your progress can be checked. • Wear sunscreen and sunprotective clothing when outdoors to avoid getting sunburnt. • Have regular skin checks. • If you are of childbearing age, use effective contraception to avoid becoming pregnant including for 1 month after you stop treatment with LITFULO. • Tell your doctor before you receive any vaccine. • Contact your doctor straight away if you develop any signs of shingles (a painful skin rash with blisters with or without fever), or if you develop hives (an itching skin rash).
Things you should not do	• Do not stop using this medicine suddenly without talking to your doctor first. • Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	• LITFULO has no or limited effect on the ability to drive or use machines.
Looking after your medicine	• Store below 30°C in original container to protect from light.

For more information, see Section [5. What should I know while using LITFULO?](#) in the full CMI.

6. Are there any side effects?

Common: infections of the nose, throat or windpipe, inflammation of the hair follicle which may be itchy or painful, dizziness, diarrhoea, acne, rash, increased creatine phosphokinase (enzyme). Serious: Shingles and Hives.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

LITFULO®

Active ingredient(s): ritlecitinib (as tosylate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using LITFULO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using LITFULO.**

Where to find information in this leaflet:

1. [Why am I using LITFULO?](#)
2. [What should I know before I use LITFULO?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use LITFULO?](#)
5. [What should I know while using LITFULO?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using LITFULO?

LITFULO contains the active ingredient ritlecitinib.

LITFULO 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 should I know before I use LITFULO?

Warnings

Do not use LITFULO if:

1. you are allergic to ritlecitinib, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
2. you have a serious ongoing infection, including tuberculosis.
3. you have severe liver problems.
4. you are pregnant or breast-feeding.

Check with your doctor if you:

- have allergies to any other medicines, foods, ingredients (including lactose), preservatives or dyes.
- have or have had any other medical condition.
- 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, 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

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.

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.

Additional monitoring and 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.

Your doctor will test you for tuberculosis before starting LITFULO and may retest you during treatment.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

In particular, tell your doctor or pharmacist before taking LITFULO if you are taking some of the medicines to treat:

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if LITFULO may affect these medicines.

4. How do I use LITFULO?

How much to take / use

- The recommended dose of LITFULO is one 50 mg capsule taken once daily.
- Follow the instructions provided and use LITFULO until your doctor tells you to stop.

When to take / use LITFULO

- LITFULO can be taken once daily with or without food.
- Swallow the capsules whole, do not crush, split or chew.

If you forget to use LITFULO

LITFULO should be used regularly at the same time each day. If you miss your dose at the usual time, take the dose as soon as possible, and then go back to taking LITFULO as you would normally.

If it is almost time (less than 8 hours) for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much LITFULO

If you think that you have used too much LITFULO, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using LITFULO?

Things you should do

- keep all your appointments so that your progress can be checked.
- wear sunscreen and sunprotective clothing when outdoors to avoid getting sunburnt.
- have regular skin checks.
- if you are of childbearing age, use effective contraception to avoid becoming pregnant including for 1 month after you stop treatment with LITFULO.
- tell your doctor before you receive any vaccine.

Call your doctor straight away if you:

- develop any signs of shingles (herpes zoster), a painful skin rash with blisters with or without fever.
- develop any signs of hives (urticaria), an itching skin rash.

Remind any doctor, pharmacist or dentist you visit that you are using LITFULO.

Things you should not do

- Do not stop using this medicine suddenly without talking to your doctor first. 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.
- Do not give your medicine to anyone, even if they have the same condition as you.

Driving or using machines

LITFULO has no or limited effect on the ability to drive or use machines.

Looking after your medicine

- Store below 30°C in original container to protect from light.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
• Infections of the nose, throat or windpipe. • Inflammation of the hair follicle which may be itchy or painful. • Dizziness. • Diarrhoea. • Acne. • Rash (other than hives or shingles). • Increase in an enzyme called creatine phosphokinase (identified by blood test).	Speak to your doctor if you have any of these common side effects and they worry you.

Serious side effects

Serious side effects	What to do
• Shingles (herpes zoster), a painful skin rash with blisters, with or without fever. • Hives (urticaria), an itching skin rash.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. Some of these side effects (increase of liver enzymes in the blood, abnormal blood count results) can only be found when your doctor does blood tests.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What LITFULO contains

Active ingredient (main ingredient)	Ritlecitinib
Other ingredients (inactive ingredients)	Microcrystalline cellulose Lactose monohydrate Crospovidone Glycerol dibehenate Hypromellose Titanium dioxide Iron oxide yellow Brilliant Blue FCF Shellac Propylene glycol Strong ammonia solution Iron oxide black Potassium hydroxide

Do not take this medicine if you are allergic to any of these ingredients.

What LITFULO looks like

LITFULO is supplied as an opaque hard capsule, with a yellow body and blue cap, printed with 'RCB 50' and the cap is printed with 'Pfizer' in black (Aust R 427296).

Who distributes LITFULO

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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