Litfulo (ritlecitinib): update to product information to revise warnings in line with other Janus kinase inhibitors

14/07/2026 | Circular Number P09/2026

Information on Litfulo (Ritlecitinib)

- Litfulo is a medicine used to treat adults and adolescents over 12 years of age with severe alopecia areata, an autoimmune disease causing hair loss of the scalp or other parts of the body.
- Ritlecitinib, works by blocking the action of certain enzymes called JAK3 and TEC kinases, which play an important role in inflammation.

In Malta the following product is authorised centrally:

Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	MAH/license holder
Ritlecitinib 50mg	Litfulo	Hard capsule	POM	EU/1/23/1755/001 EU/1/23/1755/002 EU/1/23/1755/003	Pfizer Europe MA EEIG

Information from the EMA about the safety concern

- JAK inhibitors have an increased risk of serious side effects, including cardiovascular problems, blood clots, cancer and serious infections, and this increased risk is also considered to apply to Litfulo.
- A boxed warning will be added to the Litfulo product information, stating that the medicine should be used in the following patients only if no suitable treatment alternatives are available:
    - those aged 65 years or above
    - those at increased risk of major cardiovascular problems (such as heart attack or stroke)
    - those who smoke or have done so for a long time in the past and those at increased risk of cancer

- In addition, Litfulo should be used with caution in patients with risk factors for blood clots in the lungs and in deep veins (venous thromboembolism), other than those listed above.
- The boxed warning is already included in the product information for other JAK inhibitors, which are used to treat certain chronic inflammatory disorders, including alopecia areata.
- For Litfulo, the PRAC reviewed available data from clinical trials, the literature and spontaneous post-marketing reports of suspected side effects.
- Based on this review and considering that Litfulo also works by inhibiting a JAK enzyme, the PRAC concluded that the product information and educational material for Litfulo should be amended to include the same information as for other JAK inhibitors.
- The PRAC has agreed on a direct healthcare professional communication (DHPC) to inform healthcare professionals that the warnings on the potential risk of certain serious side effects with the Janus kinase (JAK) inhibitor Litfulo will be strengthened..

For more information visit https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-6-9-july-2026 on the European Medicines Agency's website and the SmPC for Litfulo.

In Malta

For Patients

- If you are taking Litfulo, it is important to speak to your doctor to seek alternative treatment especially if you are 65 years or older, have a history of cardiovascular issues such as heart attack or stroke and if you smoke or have been a smoker for a long time.

For Healthcare Professionals

- Liftulo is only prescribed to the below patients if no suitable treatment alternatives are available:
    - those aged 65 years or above
    - those at increased risk of major cardiovascular problems (such as heart attack or stroke)
    - those who smoke or have done so for a long time in the past and those at increased risk of cancer

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Liftulo (Ritlecitinib). Suspected Adverse Drug Reactions (side effects) may be reported using the

Medicines Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or online to **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate

Malta Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Malta Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Archived Safety Circulars
Archived Direct Healthcare Professional Communications
Archived Risk Minimisation Measures

Feedback Form

The Malta Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Malta Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this formt (address side up), stapling the ends and then posting (no stamp required)

Feedback:

We thank you for your interest and look forward to hearing your opinion.

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Pharmacovigilance Section

Post-Licensing Directorate

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