29-Jul-2026

Litfulo▼ (ritlecitinib): Updated recommendations to minimise the risks of major adverse cardiovascular events, malignancy, venous thromboembolism, serious infections, and mortality

Dear Healthcare Professional,

Pfizer Europe MA EEIG, in agreement with the European Medicines Agency (EMA) and the Medicines Authority (MMA), would like to inform you of the following:

Summary

- **Based on the review of latest available data, risks of JAK inhibitors, i.e. major adverse cardiovascular events (MACE), malignancy, serious infections, and venous thromboembolism (VTE) are relevant for Litfulo in its approved indication.**
- **Litfulo should only be used if no suitable treatment alternatives are available in patients:**
    - **65 years of age and older;**
    - **with history of atherosclerotic cardiovascular disease or other cardiovascular risk factors (such as current or past long-time smokers);**
    - **with malignancy risk factors (e.g., current malignancy or history of malignancy).**
- **Litfulo should be used with caution in patients with VTE risk factors other than those listed above.**
- **Periodic skin examinations are recommended for all patients.**

Background on safety concerns and updated risk minimisation measure

Litfulo (ritlecitinib) is a selective JAK3 and TEC family kinase inhibitor, authorised in September 2023 for the treatment of severe alopecia areata (AA) in adults and adolescents 12 years of age and older.

In March 2023, a DHPC[1] for Cibinqo (abrocitinib), Jyseleca (filgotinib), Olumiant (baricitinib), Rinvoq (upadacitinib) and Xeljanz (tofacitinib) was disseminated to healthcare professionals, informing them that an increased incidence of malignancy, major adverse cardiovascular events (MACE), serious infections, venous thromboembolism (VTE) and mortality was observed in patients with rheumatoid arthritis (RA) with certain risk factors using JAK inhibitor treatment compared to TNFα inhibitor[2]. These risks were considered class effects and relevant across all approved indications for JAK inhibitors in inflammatory and dermatologic diseases; class-wide risk minimisation measures were therefore implemented to minimise these risks[3].

As part of EMA's routine assessment of the benefit-risk balance of Litfulo, based on cumulative evidence from clinical trials and post-marketing data, and in the absence of definitive data establishing that JAK3/TEC selectivity abrogates these risks, it was concluded that the precautionary measures recommended in the Article 20 procedure for JAKis used in chronic inflammatory disorders are also relevant for Litfulo. Measures to minimise these risks have therefore been implemented, as outlined in the summary above.

The product information of Litfulo will be updated accordingly. Overall, EMA concluded that the benefit-risk profile of Litfulo remains positive. The updated recommendations are intended to support and reinforce risk minimisation measures.

Call for reporting

Healthcare professionals and patients are encouraged to report any suspected adverse reactions. Please report adverse events in accordance with your national spontaneous reporting system:

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Malta Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to;

P: Pharmacovigilance Section at Post-Licensing Directorate, Malta Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000

E: postlicensing.medicinesauthority@gov.mt

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[1] https://www.ema.europa.eu/en/documents/dhpc/direct-healthcare-professional-communication-dhpc-updated-recommendations-minimise-risks-malignancy-major-adverse-cardiovascular-events-serious-infections-venous-thromboembolism-and-mortality-use_en.pdf

[2] Ytterberg SR, Bhatt DL, Mikuls TR, et al. Cardiovascular and Cancer Risk with Tofacitinib in Rheumatoid Arthritis. N Engl J Med. 2022;386(4):316-326.

[3] European Medicines Agency. EMA confirms measures to minimise risk of serious side effects with Janus kinase inhibitors for chronic inflammatory disorders. EMA/142279/2023. Published March 10, 2023. Accessed July 2, 2026. https://www.ema.europa.eu.

Company contact point

If you have any questions or require further information, please contact Pfizer Hellas Pharmacovigilance Department, contact details: +30 210 67 85 908 and +30 210 67 85 808 (24-hour line), or via the webportal: https://genaes.pfizersafetyreporting.com/en (Pfizersafetyreporting.com), or contact the local representative Vivian Corporation Ltd. Tel. +356 2134 4610/ +356 2258 8600. Medical information inquiries may be submitted in: medical.information@pfizer.com.

Sincerely,

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