



## Thank you to the reviewers of *Rheumatology Advances in Practice* 2022

*Rheumatology Advances in Practice* (RAP) continues to be at the forefront of sharing and helping to disseminate knowledge related to rheumatology. In addition to being a fully open access journal, we have the privilege of interviewing authors for the *Talking Rheumatology Research* podcast and, in 2022, we introduced lay summaries with the aim of being even more inclusive. Lay summaries encourage our authors to explain their research and innovative ideas in clear, easily understood language, leading to improved accessibility for everyone, including the public, patients and non-specialists. We believe that the advances developed by our researchers and authors should benefit as many of our readers as possible. To facilitate this, we have provided detailed guidance to authors on how to write the lay summaries, focusing on the question, 'What does this research mean for patients?' [1].

Of course, all that we publish in RAP is made possible by our selfless reviewers. We are humbled by the ever-growing number of experts who, supported by our approachable editorial team, take time to review for us, imparting their knowledge and experience to help ensure that our publications are scientifically robust and relevant. We hope that they enjoy being the first to read new, ground-breaking research and the satisfaction of seeing their efforts come to fruition when these articles are published.

We would therefore like to thank every one of our dedicated reviewers. We truly appreciate your time and expertise. Thank you, all!


### Data availability

All data are included in the article.

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### Reference

1. [https://academic.oup.com/rheumap/pages/General\\_Instructions?login=false#lay](https://academic.oup.com/rheumap/pages/General_Instructions?login=false#lay) (10 January 2023, date last accessed).

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# A 2nd generation, JAK1 preferential inhibitor for moderate to severe RA<sup>1-6</sup>

While 1st generation JAK inhibitors are relatively non-selective,<sup>2-6</sup> JYSELECA has over 5x greater potency for JAK1 over JAK2/3 and TYK2<sup>1\*</sup>

Balancing sustained efficacy<sup>7-11</sup> with acceptable tolerability<sup>1,12</sup>

Indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease modifying anti-rheumatic drugs.<sup>1</sup> May be used as monotherapy or in combination with methotrexate.<sup>1</sup>

\*From biochemical assays, the clinical relevance of which is uncertain. JAK, Janus kinase; RA, rheumatoid arthritis; TYK, tyrosine kinase.

Learn more at  
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Refer to Summary of Product Characteristics (SmPC) before prescribing, and for full prescribing information.

**JYSELECA** <sup>▽</sup> filgotinib 100 mg or 200 mg film-coated tablets.  
**Indication:** Jyseleca is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease modifying anti-rheumatic drugs (DMARDs). Jyseleca may be used as monotherapy or in combination with methotrexate (MTX). **Dosage:** Adults: 200 mg once daily. Taken orally with/without food. It is recommended that tablets are swallowed whole. **Laboratory Monitoring:** Refer to the SmPC for information regarding laboratory monitoring and dose initiation or interruption. **Elderly:** A starting dose of 100 mg once daily is recommended for patients aged 75 years and older as clinical experience is limited. **Renal impairment:** No dose adjustment required in patients with estimated creatinine clearance (CrCl) ≥ 60 mL/min. A dose of 100 mg of filgotinib once daily is recommended for patients with moderate or severe renal impairment (CrCl 15 to < 60 mL/min). Not recommended in patients with CrCl < 15 mL/min. **Hepatic impairment:** Mild/moderate hepatic impairment: no dose adjustment required. Severe hepatic impairment: not recommended. **Children (< 18 years):** Safety and efficacy not yet established. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Active tuberculosis (TB) or active serious infections. Pregnancy. **Warnings/Precautions:** See SmPC for full information. **Immunosuppression:** Combination use, with immunosuppressants e.g., ciclosporin, tacrolimus, biologics or other Janus kinase (JAK) inhibitors is not recommended as a risk of additive immunosuppression cannot be excluded. **Infections:** Infections, including serious infections such as pneumonia and opportunistic infections e.g. tuberculosis (TB), oesophageal candidiasis, and cryptococcosis have been reported. Risk benefit should be assessed prior to initiating in patients with risk factors for infections (see SmPC). Patients should be closely monitored for the development of signs and symptoms of infections during and after filgotinib treatment. Treatment should be interrupted if the patient

is not responding to antimicrobial therapy, until infection is controlled. There is a higher incidence of serious infections in the elderly aged 75 years and older, caution should be used when treating this population. **Tuberculosis:** Patients should be screened for TB before initiating filgotinib, and filgotinib should not be administered to patients with active TB. **Viral reactivation:** Cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical studies (see SmPC). If a patient develops herpes zoster, filgotinib treatment should be temporarily interrupted until the episode resolves. Screening for viral hepatitis and monitoring for reactivation should be performed. **Malignancy:** Immunomodulatory medicinal products may increase the risk of malignancies. Malignancies were observed in clinical studies (see SmPC). **Fertility:** In animal studies, decreased fertility, impaired spermatogenesis, and histopathological effects on male reproductive organs were observed (see SmPC). The potential effect of filgotinib on sperm production and male fertility in humans is currently unknown. **Haematological abnormalities:** Do not start therapy, or temporarily stop, if Absolute Neutrophil Count (ANC) < 1 × 10<sup>9</sup> cells/L, ALC < 0.5 × 10<sup>9</sup> cells/L or haemoglobin < 8 g/dL. Temporarily stop therapy if these values are observed during routine patient management. **Vaccinations:** Use of live vaccines during, or immediately prior to, filgotinib treatment is not recommended. **Lipids:** Treatment with filgotinib was associated with dose dependent increases in lipid parameters, including total cholesterol, and high-density lipoprotein (HDL) levels, while low density lipoprotein (LDL) levels were slightly increased (see SmPC). **Cardiovascular risk:** Rheumatoid arthritis patients have an increased risk for cardiovascular disorders. Patients should have risk factors (e.g., hypertension, hyperlipidaemia) managed as part of usual standard of care. **Venous thromboembolism:** Events of deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving JAK inhibitors including filgotinib. Caution should be used in patients with risk factors for DVT/PE, such as older age, obesity, a medical history of DVT/PE, or patients undergoing surgery, and prolonged

immobilisation. **Lactose content:** Contains lactose; patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take filgotinib. **Pregnancy/Lactation:** Filgotinib is contraindicated in pregnancy. Filgotinib should not be used during breast-feeding. Women of childbearing potential must use effective contraception during and for at least 1 week after cessation of treatment. **Driving/Using machinery:** No or negligible influence, however dizziness has been reported. **Side effects:** See SmPC for full information. **Common (≥1/100 to <1/10):** nausea, upper respiratory tract infection, urinary tract infection and dizziness. **Uncommon (≥1/1000 to <1/100):** herpes zoster, pneumonia, neutropenia, hypercholesterolaemia and blood creatinine phosphokinase increase. **Serious side effects:** See SmPC for full information. **Legal category:** POM. **Pack:** 30 film-coated tablets/bottle. **Price:** UK Basic NHS cost: £863.10. **Marketing authorisation number(s):** Great Britain Jyseleca 100mg film-coated tablets PLGB 42147/0001 Jyseleca 200mg film-coated tablets PLGB 42147/0002 Northern Ireland Jyseleca 100mg film-coated tablets EU/1/20/1480/001 EU/1/20/1480/002 Jyseleca 200mg film-coated tablets EU/1/20/1480/003 EU/1/20/1480/004. **Further information:** Galapagos UK, Belmont House, 148 Belmont Road, Uxbridge UB8 1QS, United Kingdom 0800 7878 1345 [medicalinfo@glpg.com](mailto:medicalinfo@glpg.com) Jyseleca<sup>®</sup> is a trademark. **Date of Preparation:** January 2022 UK-RA-FIL-202201-00019

▽ Additional monitoring required

Adverse events should be reported.

For Great Britain and Northern Ireland, reporting forms and information can be found at [yellowcard.mhra.gov.uk](http://yellowcard.mhra.gov.uk) or via the Yellow Card app (download from the Apple App Store or Google Play Store).

Adverse events should also be reported to Galapagos via email to [DrugSafety.UK.Ireland@glpg.com](mailto:DrugSafety.UK.Ireland@glpg.com) or 0800 7878 1345

**References:** 1. JYSELECA SPC. Available at: [www.medicines.org.uk](http://www.medicines.org.uk). Last accessed: June 2022. 2. Angelini J, et al. Biomolecules 2020;10(7):E1002. 3. Banerjee S, et al. Drugs 2017;77:521-546. 4. O'Shea JJ, et al. Nat Rev Rheumatol 2013;9(3):173-182. 5. Traves PG, et al. Ann Rheum Dis 2021;01-11. 6. McInnes IB, et al. Arthr Res Ther 2019;21:183. 7. Combe B, et al. Ann Rheum Dis 2021;doi:10.1136/annrheumdis-2020-219214. 8. Genovese MC, et al. JAMA 2019;322(4):315-325. 9. Westhovens R, et al. Ann Rheum Dis 2021;doi:10.1136/annrheumdis-2020-219213. 10. Combe B, et al. Arthritis Rheumatol 2021;73(suppl. 10). <https://acrabstracts.org/abstract/clinical-outcomes-up-to-week-48-of-filgotinib-treatment-in-an-ongoing-long-term-extension-trial-of-ra-patients-with-inadequate-response-to-mtx-initially-treated-with-filgotinib-or-adalimumab-during-th/>. Last accessed: June 2022. 11. Buch MH, et al. Arthritis Rheumatol 2021;73(suppl. 10). <https://acrabstracts.org/abstract/clinical-outcomes-up-to-week-48-of-ongoing-filgotinib-ra-long-term-extension-trial-of-biologic-dmard-inadequate-responders-initially-on-filgotinib-or-placebo-in-a-phase-3-trial/>. Last accessed: June 2022. 12. Winthrop K, et al. Arthritis Rheumatol 2021;73(suppl. 10). Available at: <https://acrabstracts.org/abstract/integrated-safety-analysis-update-for-filgotinib-in-patients-with-moderately-to-severely-active-rheumatoid-arthritis-receiving-treatment-over-a-median-of-2-2-years/>. Last accessed: June 2022.

## Galápagos

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