The impact of polymyalgia rheumatica on intimate sexual relationships: findings from the PMR Cohort Study

Sara Muller[1], Samantha L Hider[1,2], Prabath Ranasinghe[3], Toby Helliwell[1], Sarah A Lawton[1], William Protheroe[1], Christian D Mallen[1]

[1] School of Medicine, Keele University, Keele, UK

[2]Haywood Academic Rheumatology Centre, Midlands Partnership Foundation Trust, Stoke on Trent, UK

[3]Health Services Office, Matale, Sri Lanka

Address for correspondence: Dr Sara Muller, School of Medicine, David Weatherall Building, Keele University, Keele Staffordshire, ST5 5BG, UK

E: s.muller@keele.ac.uk, Orcid ID: 0000-0001-6645-5751

Abstract

Objectives: To determine the impact of polymyalgia rheumatica (PMR) on intimate and sexual relationships over time.

Methods: The PMR Cohort study (UKCRN ID16477) is a longitudinal study of patients with incident PMR in English primary care. Participants were sent questions about their PMR symptoms, treatments and overall health, including an item about how their PMR symptoms affected intimate and sexual relationships. The proportion reporting the relevance of intimate and sexual relationships, the effect of PMR on these relationships and the associations with PMR symptoms and general health were explored.

Results: 652/739 patients (response 90.1%) completed the baseline survey, with 446/576 (78.0%) responding at two years. Mean age of responders was 72.4 years. 62.2% were female. 363/640 (56.7%) participants reported that intimate and sexual relationships were not relevant to them at baseline. 113/277 (40.8%) reported that PMR had a large effect on intimate relationships. This proportion decreased over time in those responding to 12- and 24-month surveys, but continued to be associated with younger age, male gender, worse PMR symptoms, poorer physical function and worse mental health.

Conclusion: Intimate and sexual relationships are increasingly recognised as important for healthy ageing and health professionals should consider this as part of a holistic approach to the management of PMR.

Keywords: Polymyalgia rheumatica; Primary Health Care; Cohort study; Sexual relationships

Key points

- PMR impacts the sexual and intimate relationships of 40% of people wanting these relationships.
- PMR-intimate and sexual relationships association was stronger in those with poorer physical and mental health.
- Clinicians should be aware of the potential effect of PMR on intimate and sexual relationships.

Lay summary

What does this mean for patients?

Polymyalgia rheumatica (PMR) is a condition that affects older people. It causes pain and stiffness in the hips and shoulders, as well as making people feel very tired. It can stop people from doing routine things that they previously did with no problem (e.g. walking upstairs, getting out of a car). We know very little about how PMR affects people's personal lives. Therefore, we sent a questionnaire to 652 people in England with newly diagnosed PMR. One question asked people whether their PMR affected their "intimate and sexual relationships". We asked the same question again 1 and 2 years later. Just over half of people said this wasn't relevant for them. For people where it mattered to them, 4 in 10 said PMR had a large effect on their relationships. Men, people who were younger, those with worse PMR symptoms and worse mental health were more likely to report a negative effect of PMR on their relationships. The proportion of people reporting a problem reduced over time, as people's PMR symptoms improved. We suggest that doctors should consider people's intimate and sexual relationships as part of their care for people with PMR.

Introduction

Polymyalgia rheumatica (PMR) is the most common inflammatory rheumatological disorder of older people. It classically affects people over the age of 50 years and is characterised by pain and stiffness in the shoulders and hips (1). Onset can be sudden and can have a dramatic effect on activities of daily living. Whilst many patients respond well to treatment with glucocorticoids, PMR is a long-term condition, with treatment typically continuing for at least two years.

The importance of intimate and sexual relationships is increasingly being recognised as a key component of healthy ageing. Living with any long term illness can have a significant impact on these relationships(2), with research demonstrating that intimate and sexual relationships represent an important component of quality of life and are associated with both mental and physical wellbeing(2,3).

There is evidence for the impact of other rheumatological disorders on intimate and sexual relationships. Fatigue and ageing have specifically been associated with impact on these relationships in people with rheumatoid arthritis(4) and, ankylosing spondylitis (AS) where 40% of people reported moderate/extreme problems with their sexual relationships (4–6). However, there is no published evidence on the impact of PMR on intimate and sexual relationships. The aim of this study is to determine whether intimate and sexual relationships are affected by PMR symptoms in the first two years of the disease course and whether specific subgroups of patients are most at risk of this occurring.

Materials and methods

Study design

The PMR Study is an inception cohort of people diagnosed with PMR in general practice. The study has been described in detail elsewhere(7–9). Briefly, 739 participants were referred (June 2012 - June 2014) to the study team by their general practitioner when a new diagnosis of PMR was made. Potential participants were sent a baseline questionnaire. Those who did not respond within three weeks were sent a reminder questionnaire. Response to the baseline questionnaire indicated consent to be followed up via postal survey at six further time points over two years (1, 4, 8, 12, 18, 24 months), regardless of response to other follow-ups. Ethical approval for the study was received from the Staffordshire Research Ethics Committee (REC reference number: 12/WM/0021). All participants provided written informed consent.

Data collection

The baseline survey collected information on PMR symptoms at the time of diagnosis, treatments received for PMR, general health, lifestyle, function and socio-demographics(8). The follow-up surveys asked similar questions at six further time points over the next two years. Specific questionnaires in the surveys included numerical rating scales for pain and stiffness, EQ5D(10), mHAQ(11,12), FACIT-Fatigue(13), Insomnia Severity Index(14), PHQ8(15) and GAD7(16).

The impact of PMR on intimate and sexual relationships

Based on a question developed to assess impact of AS on intimate and sexual relationships(6) participants were asked. “In the last **2 weeks**, how much did your PMR

symptoms affect your intimate or sexual relationships?". Response options were "Does not apply to me"; "Not at all", "A little bit"; "Moderately", "Quite a bit" and "Extremely". This question was asked at baseline and at 12- and 24-month follow-ups.

Statistical analyses

Simple descriptive statistics, including means, medians and percentages, as appropriate to the distribution of the data, were used to summarise patient characteristics as at each time point. These statistics were then plotted and compared across responses to the intimate and sexual relationships item. All analyses were carried out in Stata 16.2(17) and Microsoft Excel.

Results

Study response

The baseline questionnaire was completed by 652 people (90.1% adjusted response) and 446 (78.0% adjusted response) people completed the 24-month follow-up. Comparison of responders to non-responders has been presented previously, but in summary, responders were of higher socioeconomic status, had lower levels of pain and higher levels of general health than non-responders and those lost to follow-up(7,8). The mean age of respondents at baseline was 72.4 years and 62.2% were female.

The impact and relevance of PMR on intimate andsexual relationships at diagnosis

The item regarding intimate and sexual relationships were not considered to be relevant by more than half of the cohort at baseline (n=363, 56.7%). This questionnaire item was not completed by 14 people.

Older age, female gender, living alone, not being married or cohabiting were associated with reporting that intimate and sexual relationships were not relevant to an individual (Figure 1).

Factors associated with reporting a larger impact of PMR on intimate and sexual relationships at the time of diagnosis included lower quality of life, worse physical functioning, higher levels of fatigue, insomnia, anxiety and depression. There was much less of an association with pain and with stiffness severity and and duration.

The impact and relevance of PMR on intimate and sexual relationships over time

Of the 221 people reporting that intimate and sexual relationships were not relevant to them at diagnosis and responding to this question at 12- and 24-month follow-up, 177 (80%) continued to report it not to be relevant. Of the 185 to whom it was relevant at diagnosis, 20 (11%) reported it was no longer relevant at 12 and 24 months.

Association of PMR symptoms and health characteristics with intimate and sexual relationships at 12 and 24 months follow-up

In those people who reported that intimate and sexual relationships were relevant to them at each time point, the impact of PMR on these relationships was associated with higher levels of pain and stiffness severity and duration, poorer quality of life and physical functioning, higher levels of fatigue, and with the presence of insomnia, anxiety and depression (Figure 2). These findings were similar across time points in the study, and although improvements were seen in reported pain and stiffness at follow-ups compared to

baseline, those reporting higher levels of pain and stiffness were more likely to report significant impact on intimate and sexual relationships.

Discussion

Intimate and sexual relationships are important aspects of adult life and are increasingly being recognised as a significant aspect of healthy ageing. Interruption or reduction in quality of such relationships can have pronounced effects, including relationship difficulties, anxiety, and impacts on self-esteem and self-image(18). The current study found that almost half of people recently diagnosed with PMR say that intimate and sexual relationships are relevant to them and that two in five of these people feel that their PMR has a substantial negative impact on these relationships.

The likelihood of this key aspect of life being relevant to people with PMR was largely associated with general life circumstances, such as age, marital status and overall quality of life that did not tend to change over time. However, in those reporting intimate and sexual relationships to be relevant, the impact of PMR on relationship was greater in those reporting more physical and emotional symptoms. This was the case at baseline and over time. Age at diagnosis was lowest in those reporting a moderate impact of PMR symptoms on intimate and sexual relationships and higher in those reporting smaller and larger impacts.

Nicolosi et al (19) found 70% of men and 60% of women aged 40 to 80 years in the UK reported themselves to be sexually active. Sexual relationships therefore appear to be less relevant in our sample, but the age groups and definitions of sexual activity are not directly

comparable. In those reporting being sexually active or that sexual relationships were relevant, the proportions reporting an impact were higher in the current study than in the general population in men (46% vs 31%), but lower in women (35% vs 43%), although again definitions were not directly comparable.

The frequency of PMR related impact on intimate and sexual relationships is lower than reported estimates in RA patients (e.g. 54% of men and 46% of women (20)). This may be expected, due to the life-long, chronic nature of RA, along with RA presenting more frequently in younger people, who are more likely to be sexually active.

A strength of this study was in recruiting participants from primary care with incident PMR and following them prospectively. This reduces the potential for recall bias and mean they are more likely to be representative of the general PMR population than cohorts recruited from specialist settings. In asking about the impact of PMR on relationships over time, we were able to better understand how PMR is associated with intimate and sexual relationships throughout the disease course. Finally, by asking participants to report the effect of PMR on intimate and sexual relationships rather than to report sexual satisfaction, avoided subjectivity, as people's expectations and response to sex can vary significantly (21). However, the item used to ask about this was taken from a previous study of people with ankylosing spondylitis(6) but has not undergone specific psychometric testing and we allowed the study participant to define "intimate or sexual relationships" as they chose. This may have introduced heterogeneity in the way participants responded and in future studies, as more rigorously tested method of assessing impact could be used.

Whilst a GP diagnosis of PMR could be seen as a limitation, the sample has similar age and gender distributions to those seen in other PMR cohorts in secondary care, giving credence to GPs' diagnoses. Regardless of potential misdiagnosis, this sample can be seen to represent those diagnosed with and treated for PMR in real world primary care settings. Some participants may have been referred to specialist services either at diagnosis or during treatment.

It remains unclear exactly how PMR symptoms, physical functioning and mental health are related to intimate and sexual relationships in PMR and it is likely that, particularly for mental health, there is a bidirectional relationship. In the context of continuing PMR symptoms for many people beyond their initial diagnosis and treatment the value in delineating these relationships further is questionable. It may be more prudent to ensure individuals with PMR are offered a holistic approach to disease management considering all aspects of life they consider relevant.

In conclusion, a sizable proportion of participants reported that PMR symptoms had a significant impact on their intimate and sexual relationships, which in turn may have effects on physical and mental wellbeing and vice versa. The association of intimate and sexual relationships with pain and stiffness was similar to that observed in other inflammatory conditions. The continued association with symptoms and measures of function over time suggests that control of underlying disease activity could improve patients' relationships. Our findings suggest that considering the impact on intimate and sexual relationships could form part of a broader management plan and that problems in this important area of life are likely to be related to poor symptom control, physical functioning and/or mental health.

Acknowledgements

This project was undertaken with the support of the Keele Clinical Trials Unit, Keele University, UK. The authors would like to thank the staff at Keele University's Primary Care Centre Versus Arthritis and the staff and patients of the participating practices and National Institute for Health Research Clinical Research Networks.

Funding: This work was supported by Arthritis Research UK Clinician Scientist Award to CDM [grant number 19634); National Institute for Health and Care Research (NIHR) Applied Research Collaboration (West Midlands) to CDM and SM; and NIHR School for Primary Care Research to CDM. This article presents independent research funded by the National Institute for Health and Care Research (NIHR). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health. The study funders had no role in the study design; data collection, analysis, or interpretation; in the writing of the paper; or in the decision to submit the paper for publication.

Disclosure statement: The School of Medicine has received funding from Bristol Myers Squibb to support recruitment to a non-pharmacological study screening for atrial fibrillation. SM is a trustee at the charity PMRGCAuk. The remaining authors have declared no conflicts of interest.

Data availability statement: Keele University is a member of the UK Reproducibility Network and committed to the principles of the UK Concordat on Open Research Data. The School of Medicine and Keele Clinical Trials Unit have a longstanding commitment to sharing data from our studies to improve research reproducibility and to maximise benefits for

patients, the wider public, and the health and care system. We encourage collaboration with those who collected the data, to recognise and credit their contributions.

The School of Medicine and Keele Clinical Trials Unit make data available to bona-fide researchers upon reasonable request via open or restricted access through a strictly controlled access procedure. The release of data may be subject to a data use agreement (DUA) between the Sponsor and the third party requesting the data. In the first instance, data requests and enquiries should be directed to medicine.datasharing@keele.ac.uk.

Figure 1: Associations between patient characteristics and reported effect of PMR intimate and sexual relationships at diagnosis.

Figure 2: Association between concurrent patient characteristics and reported impact on intimate and sexual relationships over time.

References

1. Mackie SL, Mallen CD. Polymyalgia rheumatica. BMJ. 2013 Dec 3;347:f6937.

2. Mitchell KR, Mercer CH, Ploubidis GB, Jones KG, Datta J, Field N, et al. Sexual function in Britain: findings from the third National Survey of Sexual Attitudes and Lifestyles (Natsal-3). The Lancet. 2013 Nov 30;382(9907):1817–29.

3. McCabe MP, Connaughton C. Psychosocial Factors Associated with Male Sexual Difficulties. J Sex Res. 2014 Jan 1;51(1):31–42.

4. Östlund G, Björk M, Valtersson E, Sverker A. Lived Experiences of Sex Life Difficulties in Men and Women with Early RA – The Swedish TIRA Project. Musculoskeletal Care. 2015;13(4):248–57.

5. Blake DJ, Maisiak R, Alarcon GS, Holley HL, Brown S. Sexual quality-of-life of patients with arthritis compared to arthritis-free controls. J Rheumatol. 1987 Jun;14(3):570–6.

6. Healey EL, Haywood KL, Jordan KP, Garratt AM, Ryan S, Packham JC. Ankylosing spondylitis and its impact on sexual relationships. Rheumatol Oxf Engl. 2009 Nov;48(11):1378–81.

7. Muller S, Whittle R, Hider SL, Belcher J, Helliwell T, Morton C, et al. Longitudinal clusters of pain and stiffness in polymyalgia rheumatica: 2-year results from the PMR Cohort Study. Rheumatology. 2020 Aug 1;59(8):1906–15.

8. Muller S, Hider SL, Helliwell T, Lawton S, Barraclough K, Dasgupta B, et al. Characterising those with incident polymyalgia rheumatica in primary care: results from the PMR Cohort Study. Arthritis Res Ther. 2016 Sep 7;18(1):200.

9. Muller S, Hider S, Helliwell T, Bailey J, Barraclough K, Cope L, et al. The epidemiology of polymyalgia rheumatica in primary care: a research protocol. BMC Musculoskelet Disord. 2012 Jun 15;13:102.

10. EuroQol Group. EuroQol--a new facility for the measurement of health-related quality of life. Health Policy Amst Neth. 1990 Dec;16(3):199–208.

11. Pincus T, Summey JA, Soraci SA, Wallston KA, Hummon NP. Assessment of patient satisfaction in activities of daily living using a modified stanford health assessment questionnaire. Arthritis Rheum. 1983;26(11):1346–53.

12. Kirwan JR, Reeback JS. Stanford health assessment questionnaire modified to assess disability in British patients with rheumatoid arthritis. Rheumatology. 1986 May 1;25(2):206–9.

13. Yellen SB, Cella DF, Webster K, Blendowski C, Kaplan E. Measuring fatigue and other anemia-related symptoms with the Functional Assessment of Cancer Therapy (FACT) measurement system. J Pain Symptom Manage. 1997 Feb;13(2):63–74.

14. Morin CM. Insomnia: Psychological Assessment And Management. 1st edition. New York: Guilford Press; 1996. 238 p.

15. Kroenke K, Strine TW, Spitzer RL, Williams JBW, Berry JT, Mokdad AH. The PHQ-8 as a measure of current depression in the general population. J Affect Disord. 2009 Apr;114(1–3):163–73.

16. Spitzer RL, Kroenke K, Williams JBW, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006 May 22;166(10):1092–7.

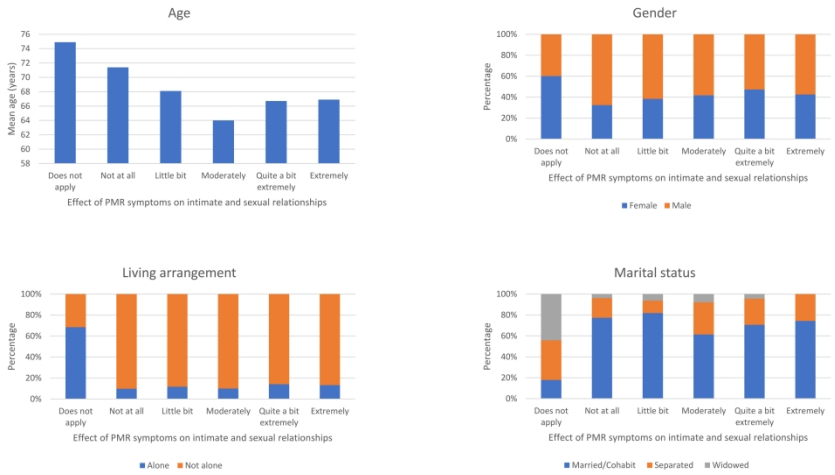
17. Stata. College Station, TX: StataCorp; 2019.

18. Areskoug-Josefsson K, Oberg U. A literature review of the sexual health of women with rheumatoid arthritis. Musculoskeletal Care. 2009 Dec;7(4):219–26.

19. Nicolosi A, Laumann EO, Glasser DB, Brock G, King R, Gingell C. Sexual Activity, Sexual Disorders and Associated Help-Seeking Behavior among Mature Adults in Five Anglophone Countries from the Global Servey of Sexual Attitudes and Behaviors (GSSAB). J Sex Marital Ther. 2006 Sep 1;32(4):331–42.

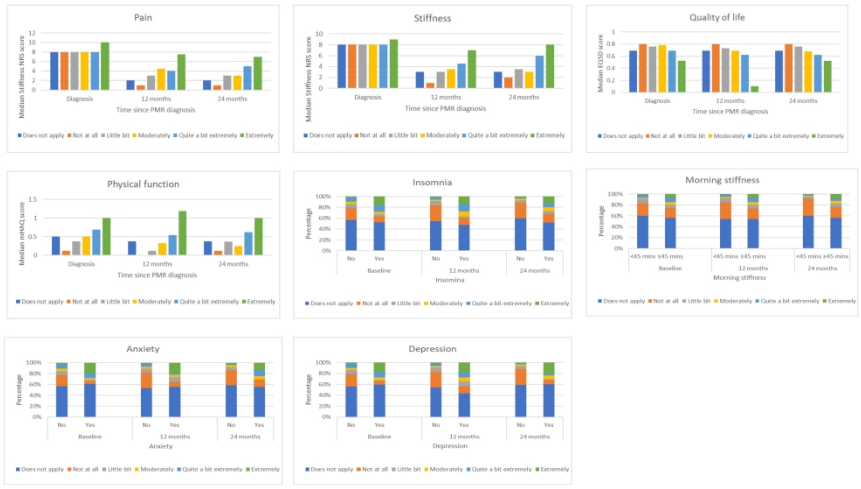
20. El Miedany Y, El Gaafary M, El Aroussy N, Youssef S, Ahmed I. Sexual dysfunction in rheumatoid arthritis patients: arthritis and beyond. Clin Rheumatol. 2012 Apr;31(4):601–6.

21. Brandenburg U, Bitzer J. The challenge of talking about sex: the importance of patient-physician interaction. Maturitas. 2009 Jun 20;63(2):124–7.



Associations between patient characteristics and reported effect of PMR intimate and sexual relationships at diagnosis

338x190mm (300 x 300 DPI)



Association between concurrent patient characteristics and reported impact on intimate and sexual relationships over time

338x190mm (300 x 300 DPI)

A 2nd generation, JAK1 preferential inhibitor for moderate to severe RA[1-6]

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

Balancing sustained efficacy[7-11] with acceptable tolerability[1,12]

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.[1] May be used as monotherapy or in combination with methotrexate.[1]

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

Learn more at strengthofbalance.co.uk

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

JYSELECA® ▽ 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 (< 18years): 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 × 10^9 cells/L, ALC <0.5 × 10^9 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 creatine 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 00800 7878 1345 medicalinfo@glpg.com Jyseleca® 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 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 or 00800 7878 1345

References: 1. JYSELECA SPC. Available at: 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;0:1–11. **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

June 2022 GB-RA-JY-202205-00033