Clinical science

Impact of COVID-19 pandemic on the management of patients with RA: a survey of rheumatologists in six European countries

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Abstract

Objective: We aimed to describe, from the perspective of rheumatologists in Europe, how the coronavirus disease 2019 (COVID-19) pandemic has impacted their management of people with RA and the continuing medical education of physicians.

Methods: Rheumatologists participating in the Adelphi RA Disease Specific Programme™ in six European countries were contacted in August and September 2020 for a telephone survey. Rheumatologists were asked seven attitudinal questions on changes to patient management, prescription behaviour and continuing education owing to COVID-19. Results were summarized with descriptive statistics.

Results: The telephone survey was completed by 284 rheumatologists. The most commonly reported changes to patient management were increased utilization of video/telephone consultations (66.5% of respondents), fewer visits (58.5%) and limiting physical contact (58.1%). Furthermore, 67.9% of rheumatologists who indicated that prescribing behaviour had changed switched their patients to self-administered medication, and 60.7% reported not starting patients on targeted synthetic DMARDs, biologic originator DMARDs or biosimilar DMARDs. In total, 57.6% of rheumatologists believed that changes in management would persist. Rheumatologists reported that 38.0% of patients expressed concerns about how COVID-19 would impact treatment, including access to treatment and the risk of infection. The biggest impact on rheumatologist education was a switch to online training and conferences.

Conclusion: All countries saw changes in patient management and prescribing behaviour, including the rapid uptake of telemedicine. It is important that the international rheumatology community learns from these experiences to prepare better for future pandemics and to address ongoing rheumatologist shortages.

Lay Summary

What does this mean for patients?
We asked rheumatologists a series of questions to find out how coronavirus disease 2019 (COVID-19) affected the way they interact with their patients with rheumatoid arthritis. We found that rheumatologists switched to online or telephone appointments in most countries to obey social distancing rules. Rheumatologists also reduced prescription of advanced medicines, most probably as a response to patient fears that such therapies might increase infection risk. There were differences between countries in the changes made to patient treatment, probably caused by differences in COVID-19 case numbers and where patients saw their doctor. We also found that doctor education moved mostly online. These results will help to guide doctors in the event of future pandemics and to plan future studies into how online appointments might best be used, who they are suitable for and how they might be used to ensure that patients can see a rheumatologist when required. They also highlight a need for continued monitoring of patients to ensure that changes to medication do not reduce the effectiveness of treatment in the long term.

Keywords: RA, attitude of health-care professionals, medical education, quality of health care, health policies, COVID-19, pandemic response

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Introduction

RA is a complex long-term condition that requires regular monitoring to inform treatment decisions and balance disease control with patient preferences, side-effects and co-morbidities [1, 2]. The coronavirus disease 2019 (COVID-19) pandemic led to challenges for the management of patients with RA. Public health initiatives forced rheumatologists to cancel or postpone in-person appointments and rapidly take on remote consultations and monitoring (telemedicine) [1, 3, 4]. As updated EULAR recommendations [5] came late in the first wave of the pandemic, rheumatologists had to adapt quickly and flexibly to a changing situation, often with minimal instruction.

Telemedicine is not new. Before the pandemic, telemedicine was a possible method of improving access to rheumatology care and addressing global and regional shortages of rheumatologists [6–8]. Although studies are sparse [7, 9], they indicate that video consultations are accurate, providing a valuable alternative to face-to-face visits when diagnosing, monitoring and following up patients with RA, and are generally well received [7, 9–11]. Historically, uptake of telemedicine has been low owing to difficulties in accessing technology, patients missing face-to-face contact with health-care providers and patients fearing that they might miss important clinical information, and reimbursement issues [10–14]. Significant differences between countries in telemedicine regulation and data protection also pose barriers to uptake [12, 15].

As the pandemic saw a rapid global shift to telemedicine to comply with regional public health guidelines, physicians and legislators had to find ways to overcome the previous barriers. There is now a unique opportunity to learn from these experiences and identify factors that might still need to be addressed to sustain adoption of telemedicine. Furthermore, understanding how telemedicine negatively affects patient care will inform for whom and when telemedicine might be most suitable. This will allow rheumatologists to plan a better response in future pandemics, while informing future studies into telemedicine uptake and efficacy. Considering the global shortage of rheumatologists [6, 16], it is vital that we learn how COVID-19 has impacted access to ongoing physician education and how this might influence future training.

The objectives of this real-world investigation were to leverage the existing cohort of rheumatologists participating in the Adelphi RA Disease Specific ProgrammeTM (DSP) to investigate the perspective of European rheumatologists on the impact of the COVID-19 pandemic on management of their patients with RA, their prescribing behaviour and their continuing medical education.

Methods

The Adelphi RA DSP was a large, point-in-time survey of physicians and their consulting patients presenting in a real-world clinical setting, which was conducted in Belgium, France, Germany, Italy, Spain and the UK between November 2019 and November 2020. The DSP provided a cohort of physicians to conduct a dedicated survey on how COVID-19 impacted patient management and the prescribing behaviour of physicians. The overall DSP methodology has been published previously [17].

The DSP protocol used to collect the original sample and follow-up interview fulfil the definition of market research as defined by European Pharmaceutical Market Research Association (EphMRA) guidance [18] and are therefore exempt from independent review board/clinical research ethics committee review. To confirm this status, the DSP methodology was submitted to the Western Independent Review Board, who provided a letter of exemption (protocol #AG-8382). Permission to contact physicians for a follow-up survey was provided during the initial DSP data-collection period. The follow-up survey was also classified as market research under EphMRA guidance.

Rheumatologists were re-contacted during August and September 2020 for an additional telephone survey comprising attitudinal questions regarding how COVID-19 impacted their management of patients with RA. Participation in the follow-up interview was voluntary; no personally identifiable or protected data were collected, and all data collected were anonymized. Participating physicians received the equivalent of £20 compensation for their time. The telephone survey asked seven questions, grouped into four themes around changes to clinical practice owing to COVID-19: patient management, prescription behaviour, continuing medical education and patient concerns. The term ‘advanced therapy’ was used to refer collectively to biologic or targeted synthetic DMARDs. The telephone survey questions and mode of answer are provided in Supplementary Table S1, available at Rheumatology Advances in Practice online.

For quantitative data, the number of respondents for each answer were aggregated for all countries and analysed using descriptive statistics. Results were interpreted at an overall European level. In addition, country-specific analyses were carried out, as appropriate. Thematic analysis [19] was carried out on free-text comments from question 6, which asked rheumatologists to describe patient concerns.

Results

Of the 316 rheumatologists who participated in the Adelphi RA DSP, 96% (n = 284) completed the supplemental COVID-19 survey. Country breakdown and demographics are presented in Supplementary Table S2, available at Rheumatology Advances in Practice online.

Changes to clinical practice owing to COVID-19

Effect of COVID-19 on current patient management for RA

Almost all (n = 282, 99.3%) rheumatologists reported that COVID-19 had impacted patient management (Table 1). The most common changes reported were ‘moving to video/telephone consultation and remote completion of questionnaires’ (n = 189; 66.5%), ‘fewer visits made by individual

Key messages

- The COVID-19 pandemic led to rheumatologists conducting more consultations online or via telephone.
- Rheumatologists reported delaying advanced treatments, switching patients to other treatments or discontinuing advanced treatments.
- Concerns of patients and physicians probably drove changes to prescription behaviour during the pandemic.
Effect of COVID-19 on future patient management and prescribing behaviour for RA

When asked whether they thought changes in patient management and prescribing behaviour would continue after the end of lockdown/social distancing, 57.6% (n = 163) of rheumatologists reported that changes would continue in the event of further outbreaks. Furthermore, 65.5% (n = 55) of the 84 rheumatologists who reported changes to prescribing behaviour believed that these would continue in the event of future COVID-19 outbreaks. In Germany and Belgium, however, most rheumatologists (n = 50, 86.2%, and n = 7, 77.8%, respectively) stated that they would revert to previous management patterns after the end of lockdown/social distancing. If Germany and Belgium were excluded, 70.8% (153 of 216) of physicians believed that management changes would continue (Fig. 1).

Patient concerns about COVID-19 impact

Rheumatologists estimated that, on average, 38.0% of patients had expressed concerns about their treatment regimen owing to COVID-19, ranging from 7.3% in Germany to 55.1% in Spain (Fig. 2A). Four concern themes were identified: ‘lockdown and access to treatment and care’; ‘infection risk—medication’ (e.g. increased risk of COVID-19 owing to immunosuppression or method of medicine administration); ‘infection risk—health-care setting’ (e.g. risk of infection from attending hospital); and ‘infection risk—general’ (e.g. infection risk from having to leave the house or travel).

Thematic analysis showed that the most frequent patient concern reported by rheumatologists was infection risk owing to medication, which was reported by 140 of 264 (53.0%) rheumatologists. This was also the case in all individual countries, except Germany, where the main patient concern (70.2%, 33 of 47) was the risk of contracting COVID-19 from a health-care setting (Fig. 2).
Effect of COVID-19 on continuing medical education

Finally, when asked how COVID-19 had affected continuing medical education, most rheumatologists reported some changes (Fig. 3). Half (n = 142 of 284) reported increased attendance of webinars, 48.9% (n = 139) reported scheduled training hosted online instead of face to face, and 46.1% (n = 131) reported attending e-congresses in lieu of face-to-face congresses. These rates were higher in Italy and Spain. Furthermore, around half of rheumatologists in Germany and Italy (46.6%, n = 27 of 58, and 55.9%, n = 33 of 59, respectively) reported attending e-congresses that they would not normally have attended face to face (Fig. 3).

Discussion

Overall, rheumatologists across all countries made changes to the way in which they managed patients with RA and their prescribing behaviour; most believed that these changes would continue in the event of future outbreaks. There was significant variation between countries in the nature and extent of these changes, with Germany showing fewer adaptations compared with other countries. Furthermore, rheumatologists in all countries undertook ongoing medical education and conferences online. Here, we consider these findings in the context of pandemic responses in each country to understand their implications and produce future guidance for rheumatology practice.

Patient management decisions during the COVID-19 pandemic

Rheumatologists across all countries surveyed saw increased use of telemedicine during the pandemic. Most reported some reduction in the frequency of appointments, prioritizing in-person appointments for severe patients and reducing new referrals from primary care. These findings were reflected in a recent survey of 1286 health-care professionals in rheumatology [20], wherein 82% indicated cancellation/postponement of in-person appointments for new patients, with 84% offering remote consultation. Furthermore, 91% of physicians cancelled/postponed follow-up visits, with 96% offering remote follow-ups [20]. Only Germany reported no changes to patient priority or referral numbers, with only minimal changes to visit frequency reported. The main change made to patient management in Germany was to decrease physical contact.

At the time of our survey, countries had different infection rates and public health responses. All countries showed an increase in COVID-19 cases from August to September 2020, but only France, Spain and the UK saw high case numbers, with Italy, Germany and Belgium keeping daily case numbers <2000. At survey initiation, only Germany, France and the UK were not in a lockdown. The UK had strong recommendations to stay home in place, and France was already seeing a rapid increase in COVID-19 cases, which might explain why Germany reported fewer changes in patient contact than other countries [21]. This is potentially supported by our finding that German physicians believed that management changes would not persist, because changes might have begun to revert by the time of our survey. Surveys in Latin America and the UK that showed similar telemedicine utilization during the pandemic to our study showed that lower proportions of rheumatologists believed that telemedicine would continue [22, 23]. In particular, a UK study conducted during August–December 2020 showed that the majority of rheumatologists believed that <50% of follow-up appointments post-pandemic would be conducted remotely; although still high, this could potentially indicate a cooling of opinions about telemedicine after the initial pandemic peak [22]. These differences might also indicate that, in our survey, rheumatologists believed other changes besides remote consultation might continue (i.e. decreased physical contact or wearing face masks).

We must also consider differences in telemedicine regulations and remuneration between countries [15]. Only several months into the pandemic did legislation begin to change in countries to allow greater uptake of telemedicine. The countries that reported the lowest levels of switching to telemedicine were also those with the lowest remuneration for teleconsultations: German rheumatologists received no teleconsultation remuneration until legislation in April 2020 [24]; in Belgium, rheumatologists received only a small remuneration of €20 [25]; and in Italy, remuneration was limited

Table 2. Percentage of physicians in each country who selected each response option in response to the question, ‘How has COVID-19 impacted the way you prescribe medicine?’

<table>
<thead>
<tr>
<th>Response</th>
<th>Base (n = 84)</th>
<th>Belgium (n = 2)</th>
<th>France (n = 12)</th>
<th>Germany (n = 8)</th>
<th>Italy (n = 14)</th>
<th>Spain (n = 33)</th>
<th>UK (n = 15)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency of response selection (%) physicians</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Changed medication to self-administration</td>
<td>67.9 –</td>
<td>–</td>
<td>58.3 –</td>
<td>87.5</td>
<td>64.3</td>
<td>57.6</td>
<td>100.0</td>
</tr>
<tr>
<td>Not starting new patients on an advanced therapy treatment</td>
<td>60.7 100.0</td>
<td>58.3 –</td>
<td>–</td>
<td>28.6</td>
<td>87.9</td>
<td>60.0</td>
<td></td>
</tr>
<tr>
<td>Changed medication to a treatment with less frequent dose</td>
<td>32.1 –</td>
<td>16.7 –</td>
<td>62.5</td>
<td>7.1</td>
<td>33.3</td>
<td>40.0</td>
<td></td>
</tr>
<tr>
<td>Prescribed a longer course of treatment</td>
<td>31.0 –</td>
<td>25.0 –</td>
<td>–</td>
<td>35.7</td>
<td>36.4</td>
<td>40.0</td>
<td></td>
</tr>
<tr>
<td>Changed advanced therapy (biologic or JAK inhibitor treatment) to different advanced therapy (biologic or JAK inhibitor treatment)</td>
<td>28.6 –</td>
<td>16.7 –</td>
<td>–</td>
<td>–</td>
<td>42.4</td>
<td>53.3</td>
<td></td>
</tr>
<tr>
<td>Halted advanced therapy treatment, switched to different treatment class</td>
<td>22.6 –</td>
<td>8.3 –</td>
<td>–</td>
<td>–</td>
<td>27.3</td>
<td>60.0</td>
<td></td>
</tr>
<tr>
<td>Halted advanced therapy treatment, no replacement treatment prescribed</td>
<td>20.2 –</td>
<td>25.0 –</td>
<td>–</td>
<td>–</td>
<td>21.2</td>
<td>46.7</td>
<td></td>
</tr>
<tr>
<td>Other (specify)</td>
<td>13.1 –</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>15.2</td>
<td>40.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6.0 –</td>
<td>8.3 –</td>
<td>–</td>
<td>–</td>
<td>3.0</td>
<td>20.0</td>
<td></td>
</tr>
</tbody>
</table>

to a small number of specific services [26]. A survey of rheumatologists in the Middle East and North Africa showed that, for all regions, only 12% of telemedicine appointments were reimbursed; in this case, only 54% fully agreed to using telemedicine, with a further 24% saying that they would agree if it is reimbursed [27]. These findings, alongside our own, indicate that if telemedicine is to become part of regular practice, reimbursement must be the same as that for in-person appointments.

In most countries surveyed, patients were seen in public hospitals (Supplementary Table S2, available at Rheumatology Advances in Practice online). The COVID-19 pandemic led to many hospitals redeploying staff from chronic disease care to COVID-19 care [22, 28]. Many countries saw closure of rheumatology services owing to staff redeployment, meaning that appointments were cancelled or postponed and/or switched to telemedicine [20, 22]. A perceived higher risk of COVID-19 infection in hospitals might...
also have led to cancellation of appointments, both by physicians and at the request of patients [29, 30]. Health funding is also likely to have influenced appointment cancellation; rheumatologists who were paid based on the number of consultations would have been disincentivized to cancel appointments because this would have led to reduced income. In summary, the structure and location of health-care delivery and its funding seem likely, and not surprisingly, to have influenced rheumatology care during the pandemic.

There is still inadequate empirical evidence to guide clinical practice via telemedicine in rheumatology. Recent updates to EULAR recommendations for pandemic responses removed several recommendations revolving around telemedicine, in favour of addressing the issue via a recently formed taskforce, indicating that there are still lessons to be learned [31]. The Asia Pacific League of Associations for Rheumatology recently released recommendations highlighting the need to assess the suitability of telemedicine for each patient on a case-

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Figure 2. Patient concerns for each country, as reported by their physicians. (A) Proportion of patients who expressed concerns owing to coronavirus disease 2019 (COVID-19) about their treatment regimen as estimated by rheumatologists. (B) The percentage of rheumatologists who mentioned each of the four major themes identified by thematic analysis when asked to describe patient concerns.
by-case basis [32]. Telemedicine might be a mechanism for addressing the global shortage and maldistribution of rheumatologists, and it has already been shown to improve access to rheumatologists for more remote patients in Australia and rural New England [33, 34]. Although it is clear that there is a patient-led demand for telemedicine [8, 16], studies indicate that telemedicine is underutilized by ethnic minorities and patients with lower socioeconomic status, with issues such as literacy, access to new technologies and willingness to embrace them leading to disparities in patient outcome and access to health care [35]. A possible solution to access issues is the approach adopted by the Alaska Native Medical Center, in which patients travel to local clinics, with technology in place for remote consultations and clinicians on hand to assist [14]. It is clear, however, that although telemedicine might be suitable for any patient at any time, it is unlikely to be suitable for all patients, all the time. It is key, therefore, that telemedicine does not replace traditional face-to-face appointments but is integrated on a case-by-case basis and tailored to individual patient needs [36].

Physician prescribing behaviour during the pandemic

In our survey, rheumatologist-reported changes to prescribing behaviour largely consisted of changing medication to self-administration, avoiding the initiation of advanced therapies and, in some countries, reducing the dose of or discontinuing already prescribed advanced therapies. German rheumatologists, however, did not change advanced therapy prescribing behaviour. A previous study found that treatment decisions were often postponed (34%), and most health-care professionals in rheumatology (74%) stated that it was less likely for patients to start a biological/targeted synthetic DMARD during the first wave of the pandemic, mainly owing to patients’ fear of starting such treatments, limited availability of screening procedures and decreased availability of rheumatological services [20].

In the early stages of the pandemic there were fears that patients with RA were more at risk of infection owing to their condition, particularly for those taking immunosuppressant medication [5]. Physicians and patients feared that immunosuppression could lead to more severe COVID-19 infection, particularly before vaccine development. EULAR recommended that advanced therapy prescriptions be adjusted on a case-by-case basis, considering patient concerns, probably reflecting the experiences of rheumatologists during the first wave [5, 20]. We found that physicians estimated that more than one-third of patients expressed concerns about the impact of COVID-19 on their treatment and that three of the four main concerns revolved around increased infection risk (whether from having to attend a hospital or from their medication). In a UK study, 50% of discontinuations were at the request of patients [22]. Improving patient education and communication, particularly via telemedicine, could be vital in assuaging fears and ensuring that patients maintain optimal treatment in future practice; physicians suggest that unified and consistently applied guidance could help in this [26].

As with patient management, German rheumatologists showed the least change in prescribing behaviour. Unlike other countries in the Adelphi cohort, whose rheumatologists were based in hospitals, German rheumatologists were based in public offices (non-private outpatient practices; Supplementary Table S2, available at Rheumatology Advances in Practice online). Staff redeployment was less likely in public offices, and infection risk might have been perceived to be lower by authorities, allowing rheumatologists to maintain in-person appointments. This might have bolstered both physician and patient confidence in the monitoring and safety of advanced therapies, leading to fewer changes. The highest anxiety was reported for infection risk from a health-care setting, consistent with public clinics remaining open. Rheumatologists in Spain and the UK reported the highest levels of patient concern and the highest levels of prescription changes. Moving more rheumatology services to public offices and ensuring that they remain open could be key to relieving hospital burden and ensuring the continuation of treatment in future pandemics.

Several drugs used to treat RA, including tocilizumab, were identified as possible treatments for COVID-19 early in the pandemic [27, 37, 38]. Increased demand for these drugs led to global shortages, meaning that physicians might have been forced to switch treatments [27, 39]. The reduced prescribing of and switching of advanced therapies might have been
pandemics [40–42]. Although self-training for injection via video has generally been well received, rheumatologists might have postponed initiation until in-person training could take place [41]. Even with training, self-injection is not suitable for some patients owing to limited dexterity or patient preference [42–44]. Given that it has been found that delays between symptom onset and initiating DMARDs lead to lower remission rates and worse outcomes in patients [46, 47], ensuring that patients are on the most appropriate RA drug/drugs to begin with and prioritizing access to treatments based on patient needs are important to prevent treatment disruption in future. Diversification of treatment options and working with health authorities to improve supply lines could also be key to maintaining treatment in future pandemics [27].

Effects of COVID-19 on physician education
In addition to the impacts on patient management and prescribing behaviour, this survey showed that COVID-19 had a marked effect on continuing health-care professional education in all countries, particularly in Italy. Increased attendances at online training, webinars and e-congresses were the three most common changes, with online training consistently ranking within the top three across all countries. Rheumatologists also reported the benefit of increased attendance at conferences that they would not normally have attended. Studies into the effectiveness of more traditional medical education online regularly cite increased accessibility, comfort and a greater ability to meet individual learning needs as major benefits [45, 46]. Conversely, these same studies have shown that online education struggles to find a balance between practical and theoretical learning; communication is often ineffective, and lessons are poorly optimized to the online environment. Furthermore, doctors in training report missing out on face-to-face interaction and networking opportunities and that some balance of online and in-person education would be optimal for future education [4, 45, 47].

It is not only the way education is accessed that has been altered by COVID-19, but also the type of education needed. A recent international report highlighted new training needs in telemedicine, only 39% of rheumatology trainees received telemedicine training, and many reported feeling less comfortable when evaluating new patients or making treatment changes using telemedicine [4]. If telemedicine is to be incorporated into future models of care, appropriate training in virtual clinical skills will be necessary. Some suggest that this could include simulated virtual consultations and lessons in telemedicine-specific legislation [4]. Indeed, the United States Accreditation Council of Graduate Medical Education has already added telemedicine-specific competencies to its list of core competencies for medical training [4, 14, 48].

Limitations
Several key limitations need to be considered when interpreting our results. The data presented here are >2 years old and might not reflect current attitudes to telemedicine. Low sample size in some cases means that certain results might not be representative; in such cases (e.g. prescribing behaviour in Belgium) we have presented the data but drawn limited conclusions from those samples. Furthermore, questions on whether changes to practice would continue are based on the opinions of rheumatologists; ultimately, the choice might fall to hospitals and policy-makers rather than rheumatologists. Rheumatologist opinion might influence policy decisions, meaning that our data remain key to understanding the direction that policy might take in future. Despite these limitations, our study reflects a snapshot of rheumatological practice across multiple countries, representing a broad sample of rheumatologists and providing valuable insight into responses to the pandemic and the opinions of rheumatologists at that time.

Conclusion
Rheumatologists made changes to their prescribing behaviour and the way in which they manage patients, probably to accommodate public health initiatives and to assuage both their own fears and those of patients surrounding medication. We saw differences between countries, owing, in combination, to the pandemic impact and response in each country, treatment setting, and the variability of legislation and remuneration surrounding telemedicine consultations. One key benefit has been the impact on medical education, with opportunities to learn remotely being expanded. Given the potential benefits of remote consultations, it is vital that guidance on telemedicine is harmonized and that issues with reimbursement and patient education around the risks of treatment and remote treatment devices highlighted above are addressed.

Supplementary data
Supplementary data are available at Rheumatology Advances in Practice online.

Data availability
All data that support the findings of this study are the intellectual property of Adelphi Real World. All requests for access should be addressed directly to James Piercy at: james.piercy@adelphigroup.com.

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Data collection was undertaken by Adelphi Real World as part of an independent follow-up survey using the Adelphi RA DSP cohort. Galapagos did not influence the additional survey through either contribution to the design of questionnaires or data collection. The analysis described here used additional data collected after the original Adelphi RA DSP. The DSP is a wholly owned Adelphi product. Galapagos is one of multiple subscribers to the DSP.

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References


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^{7,8} with acceptable tolerability^{9,10}

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.\(^{5}\) May be used as monotherapy or in combination with methotrexate.\(^{2,6}\)

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

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

JYSELECA\(^{1}\) filgotinib 100 mg or 200 mg film-coated tablets.

Indications: 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). Dose: Adult: 200 mg once daily. Taken orally with/without food. It is recommended that tablets are swallowed whole.

Warnings/Precautions: Refer to the SmPC for information regarding routine monitoring and dose initiation or interruption. Edema: 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. Warning/Precautions: See SmPC for full information. Immunosuppression: Combination use, with immunosuppressants (e.g. cyclosporin, tacrolimus, biologics or other Janus kinase (JAK) inhibitors is not recommended. In case of additive immunosuppression cannot be excluded infections). Infections, including serious infections such as pneumonia and opportunistic infections (e.g. tuberculosis (TB), herpes zoster, candidiasis, and cryptoccocosis) have been reported. Risk benefit should be assessed prior to starting 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. Volt reaction: Cases of herpes zoster reaction (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, if a neutrophil count <4.0 × 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. Jyseleca 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, hyperlipidemia) managed as part of usual standard of care. Veno-occlusive events: 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 distrazes has been reported. Side Effects: See SmPC for full information. Common (≥1/100 to <1/10): headache, fatigue, dizziness. Serious side effects include infection and dizziness. Uncommon (≥1/1000 to <1/100): herpes zoster, pneumonitis, meningitis, hypertension, 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 PB 54174/0001. Jyseleca 200mg film-coated tablets PB 54174/0002. Further information: Galapagos UK, Belmont House, The Belmont Road, Burgess Hill, West Sussex. UK: 0800 778 1345. Medicalinfo@galapagos.com. Jyseleca is a trademark of Galapagos NV. Further information can be found at yellowcard.mhra.gov.uk. Adverse events should also be reported to Galapagos via email to DrugSafety.UK@lrg.com or via the Yellow Card app (download from the Apple App Store or Google Play Store). 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@lrg.com or via the Yellow Card app (download from the Apple App Store or Google Play Store). Adverse events should be reported.