Rheumatology Advances in Practice, 2024, **8(4)**, rkae129
https://doi.org/10.1093/rap/rkae129
Advance access publication 9 October 2024
Original Article

British Society for Rheumatology
RHEUMATOLOGY ADVANCES IN PRACTICE
OXFORD

Clinical science

Use of over-the-counter supplements, sleep aids and analgesic medicines in rheumatology: results of a cross-sectional survey

Mehreen Soomro [1], Stephanie Lyons[1], Ramiro Bravo[1], John McBeth [1], Mark Lunt[1], William G. Dixon [1,2,3,4], Meghna Jani [1,2,3,*]

[1]Centre for Epidemiology Versus Arthritis, Centre for Musculoskeletal Research, University of Manchester, Manchester, UK
[2]Department of Rheumatology, Salford Royal Hospital. Northern Care Alliance, Salford, UK
[3]NIHR Manchester Biomedical Research Centre, Manchester University NHS Foundation Trust, Manchester Academic Health Science Centre, Manchester, UK
[4]Division of Informatics, Imaging and Data Science, University of Manchester, Manchester, UK

*Correspondence to: Meghna Jani, Centre for Epidemiology Versus Arthritis, Centre for Musculoskeletal Research, University of Manchester, Oxford Road, Manchester M13 9PT, UK. E-mail: Meghna.jani@manchester.ac.uk

Abstract

Objectives: Pain, fatigue and sleep disturbances are common symptoms in patients with rheumatic and musculoskeletal diseases (RMDs) that may prompt the use of over-the-counter (OTC) supplements, sleep aids and analgesics as self-management strategies. This study evaluated the prevalence of OTC supplements, sleep aids and pain relievers and the financial burden associated with their use in rheumatology.

Methods: A web-based survey developed with patients was administered in rheumatology clinics in an English hospital. Participants shared demographic information and detailed their use of OTC supplements, sleep aids and pain relief in the past week. The data were analysed using descriptive statistics and logistic regression models to identify influencing factors.

Results: A total of 876 people consented to participate in the survey. More than half of patients (54.5%) reported daily supplement intake, typically spending £10/month (interquartile range 5–20), ranging up to £200/month. The most commonly administered supplements were vitamin D, multivitamins, vitamin C, vitamin B/B complex and omega-3/-6 supplements, with multiple overlaps. Prescription, OTC or non-prescription pain relief use was reported by 82% of respondents, with sleep aids being used by 13%. Of the 327 patients who took NSAIDs, 165 (50.4%) also reported taking OTC supplements, while among the 131 patients using opioids (20.5%), 66 (50.3%) reported supplement use, some of which have documented interactions.

Conclusion: The use of OTC supplements, pain relief and sleep aids is common in patients with RMDs. Healthcare professionals should be encouraged to proactively ask about these during consultations, especially from a drug safety perspective, but also to provide timely, reliable advice about such strategies that may be sought by patients.

Lay Summary

What does this mean for patients?

Living with musculoskeletal conditions often means coping with persistent pain, fatigue and sleep disturbances. To manage these symptoms, many people turn to over-the-counter (OTC) medications such as supplements, sleep aids and pain relievers, in addition to their prescribed medications. But how common is this practice and what are the implications for patients and healthcare providers? To understand this, we surveyed patients attending rheumatology clinics. The survey was designed with input from patients and asked participants about their use of these OTC products over the past week. The results revealed that using OTC products to manage symptoms is widespread. More than half of the patients surveyed reported take supplements daily, with vitamin D, multivitamins, vitamin C, B vitamins, omega-3/-6 and turmeric being the most popular. People often took multiple supplements with a financial cost up to £200/week. More than 80% of patients also used some form of pain relief, whether it was prescription, OTC/internet or borrowed from a family member. Concerningly, a considerable number of patients combined OTC supplements with prescription pain medications, including anti-inflammatories and opioids, despite potential interactions. This study highlights the importance of open communication between patients and healthcare providers about OTC product use. Healthcare professionals should proactively ask patients about these products during consultations, not only to ensure safety and manage potential drug interactions, but also to provide evidence-based advice and support patients in making informed decisions about their health.

Keywords: over the counter, supplements, sleep aids, analgesics, opioids, opiates, vitamins, minerals, survey, patient-reported health data.

Received: 21 August 2024. **Accepted:** 25 September 2024

Key messages

- More than half of rheumatology patients surveyed reported taking an over-the-counter (OTC) supplement, with one in three patients using two or more supplements and one in five using five or more supplements daily.
- Prescription, OTC or non-prescription pain relief was used routinely by 82% of rheumatology patients, with sleep aids being used by 13%.
- Patients were often on overlapping supplements and OTC medications, some of which are known to interact or would increase their recommended daily allowance substantially.

Introduction

Over the past few decades, the consumption of supplements has surged, with the global industry now valued at US$300 billion [1]. People turn to supplements for various reasons, with one of the leading motivations being the desire to maintain healthy joints and prevent or ease arthritis [2]. The widespread interest in over-the-counter (OTC) supplements and medicines in rheumatology is to be expected, especially since OA and other common non-inflammatory musculoskeletal (MSK) disorders currently lack approved DMARDs [3–5]. The prevalence of such medicines in these conditions is unknown. Rheumatic and musculoskeletal diseases (RMDs) considerably impair people's quality of life and their ability to perform activities of daily living [6]. Pain can be a predominant issue for those affected by RMDs, which can serve as a catalyst for patients to actively seek solutions to mitigate such symptoms and improve their daily functioning [7].

Alongside pain, poor sleep quality and fatigue are prevalent among rheumatology patients, which may not always be effectively treated following treatment of disease activity [8]. Understandably, patients with RMDs may seek potential alternatives, either OTC or through supplement use to self-manage their symptoms [9, 10]. This may include sleep aids and additional pain relievers available OTC to alleviate their symptoms [11], even more so compared with the general population. While supplements are often perceived as harmless because they can be obtained without a prescription, they are an unregulated industry and may still pose potential adverse effects or drug interactions [10].

The available analgesic options for RMDs pose their own set of issues. NSAIDs are often less suitable for long-term use in individuals >65 years of age, while opioids have been associated with a range of harms [12]. In 2021, the National Institute for Health and Care Excellence in the UK made changes by removing the recommendation to use NSAIDs and opioids for chronic pain management [13]. Non-pharmacological options, such as exercise programs and orthoses, which have good efficacy in clinical trials, have variable adherence among patients, and psychological support or acupuncture may be challenging for patients to access. In the latest EULAR guidelines for hand OA, analgesics such as NSAIDs are recommended for a limited duration only, while placebo-controlled trials of nutraceuticals are on the research agenda but not currently recommended [11].

The cumulative financial expense of OTC supplements, pain relievers and sleep supplements is challenging due to varying prices, brands and personal usage. Persistent pain associated with MSK conditions often impacts those in more deprived populations, where such diseases tend to be more prevalent [14]. The cost of OTC supplements for managing MSK conditions can represent a substantial expense in the limited monthly budgets of those from lower socio-economic backgrounds, exacerbating health inequalities. Sources of supplements and non-prescription medications have now extended to buying over the internet, including through social media channels, which have also become catalysts for wellness trends. There is a lack of research about the frequency of use; types of supplements, sleep aids and pain relief; cost and the characteristics of patients who administer them within rheumatology. Typically, OTC supplements, sleep aids and pain relievers are not consistently recorded or are poorly documented within primary or secondary care electronic health records, underscoring the need to obtain this information directly from patients.

The aims of this study were to evaluate the prevalence of use of OTC supplements, sleep aids and pain reliever in patients with rheumatological conditions and to quantify and describe the subtypes, financial costs and individual factors associated with each in patients attending rheumatology clinics.

Methods

Survey design and administration

A draft web-based patient survey was initially developed collaboratively with two academic consultant rheumatologists, a health informatician and a health psychologist. A patient advisory team ($n = 4$) was recruited via advertisements posted on social media and the university web pages and mailing lists. The final advisory team providing feedback on the draft survey included one occupational therapist and three patients with (collectively) OA, RA and PsA. Two participants identified as Asian and two as White Caucasian. This diverse team provided valuable input on prioritizing essential survey questions, identifying elements that could be excluded to reduce patient burden and offering suggestions for enhancing patient usability. After incorporating this feedback, the survey was finalized and designed using Qualtrics software (version October 2022; Qualtrics, Provo, UT, USA) [15]. The final version is available in the Supplementary Material, available at *Rheumatology Advances in Practice* online.

Patients attending the rheumatology department at Salford Royal Hospital, a large foundation trust in the northwest of England, were invited to participate. The survey web link was shared by their consultants with unselected rheumatology patients using an invitation letter and a printed QR code and, through text messages using the DrDoctor software (DrDoctor, London, UK), a patient engagement platform was used to send reminders regarding hospital appointments. The data collection period spanned from 3 October 2022 to 21 March 2024.

Patients were required to meet specific criteria to participate in the survey, including being an ≥18 years of age, diagnosed with an MSK condition, having had a rheumatology outpatient appointment at the hospital and being under the care of the Salford Royal rheumatology team. Additionally,

they needed access to an internet-connected device and were able to read and understand English independently or with assistance from a caregiver or relative. Prior to answering the survey, informed electronic consent was obtained.

Patients were asked to complete questions on their demographics and OTC supplement, sleep aid and pain relief use in the last week. For analgesics, information on prescription, OTC and non-prescription use was collected. Non-prescription use was defined in the survey as those medicines borrowed from a family member or purchased over the internet. Patients could select to complete one or multiple sections depending on what was relevant. It was an adaptive questionnaire, meaning more detailed questions were enabled if someone stated they had taken a particular treatment. The study received ethics approval from the UK Health Research Authority (REC reference: 306827).

Analysis

Data from the Qualtrics survey were exported to R version 4.2.1 (R Foundation for Statistical Computing, Vienna, Austria) for analysis and visualization. Detailed descriptive and summary statistics were performed. Patient-reported partial postcodes were used to derive Townsend scores, correlating with UK census data to indicate levels of deprivation—a higher score signifying greater deprivation (https://statistics.ukdataservice.ac.uk/dataset/2011-uk-townsend-deprivation-scores). Participants were then grouped into quintiles based on these Townsend scores [16]. Logistic regression analysis, adjusted for age and sex, assessed factors such as ethnicity, MSK conditions and comorbidities associated with individuals' use of OTC supplements, sleep aids and pain relievers.

Results

O of the 876 individuals who consented to participate in the survey, 785 completed in one or more of the relevant sections (Supplementary Fig. S1, available at *Rheumatology Advances in Practice* online). Of the people who completed the survey, 716 (91.2%) individuals reported using at least one of the

Table 1. Baseline characteristics of patients who completed questions on OTC supplement use

Characteristics	All ($N = 710$)	Yes ($n = 387$)	No ($n = 323$)
Age, years, *n* (%)			
Mean (S.D.)	58.3 (14.5)	58.0 (14.7)	58.7 (14.2)
18–39	93 (13.1)	52 (13.4)	41 (12.2)
40–54	174 (24.5)	97 (25.0)	77 (23.8)
55–69	271 (38.1)	140 (36.1)	131 (40.6)
≥70	172 (24.1)	98 (25.5)	74 (22.9)
Gender, *n* (%)			
Female	521 (73.4)	275 (71.1)	246 (76.2)
Male	185 (26.0)	109 (28.1)	76 (23.5)
Other	NA	NA	NA
Ethnicity			
White British	668 (94.0)	362 (93.7)	306 (94.7)
Other/Mixed ethnic groups	25 (3.5)	17 (3.9)	8 (2.1)
Asian/Asian British	11 (1.5)	5 (1.4)	6 (1.8)
Black/African/Caribbean/Black British	6 (1.0)	3 (0.8)	3 (1.2)
Diagnoses, *n* (%)			
MSK conditions			
Osteoarthritis	233 (32.8)	131 (33.7)	102 (31.7)
RA	222 (32.1)	124 (32.1)	98 (32.0)
FM/chronic widespread pain	171 (24.1)	96 (24.9)	75 (23.2)
Osteoporosis	90 (12.8)	41 (10.6)	49 (15.4)
PsA	81 (11.5)	39 (10.1)	42 (13.2)
Other inflammatory condition	63 (8.9)	37 (9.6)	26 (8.2)
axSpA	55 (7.8)	28 (7.3)	27 (8.5)
Myositis	47 (6.7)	22 (5.7)	25 (7.8)
Comorbidities			
Other health conditions	234 (32.9)	131 (33.8)	101 (31.2)
Anxiety	190 (26.7)	105 (27.1)	83 (25.6)
Depression	153 (21.5)	71 (18.3)	81 (25.0)
Gastrointestinal disease	93 (13.0)	46 (11.8)	47 (14.5)
Heart disease	69 (9.7)	33 (8.5)	36 (11.1)
Systemic sclerosis	62 (8.7)	35 (9.0)	27 (8.3)
Previous cancer	48 (6.7)	28 (7.2)	20 (6.1)
Sjogren's syndrome	47 (6.6)	25 (6.4)	22 (6.8)
Townsend deprivation scores (quintiles), *n* (%)			
1 (least deprived)	105 (14.7)	51 (13.1)	54 (16.7)
2	61 (8.7)	32 (8.3)	29 (9.1)
3	124 (17.6)	74 (19.2)	50 (15.7)
4	109 (15.5)	54 (14.0)	55 (17.2)
5 (most deprived)	311 (44.1)	176 (45.4)	135 (41.7)

NA: not disclosed, as may be classed as sensitive information.
Some participants reported more than one diagnosis, including the MSK diseases above and the chronic diseases listed in the questionnaire. Other health conditions (participants asked to specify) include diabetes type 1 or 2, inflammatory bowel disease, chronic obstructive airway disease, asthma, chronic kidney disease, Crohn's disease, other chronic lung conditions, hypertension and liver disease. Please note that due to missing values, some columns may not add up to the total.

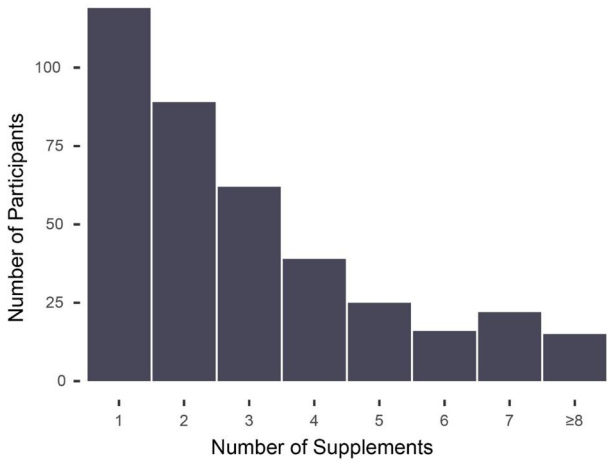

Figure 1. Distribution of the number of OTC supplements used by rheumatology patients

following: supplements, pain relievers or sleep aids. Within this group, 55 (7.0%) respondents indicated that they used all three types of interventions.

OTC supplements

In total, 710 patients completed questions on OTC supplement use. Of those, 521 (73%) were female, with a mean age of 58 years (s.d. 14.5) (Table 1). Most participants self-identified as White British [$n = 668$ (94.3%)], with smaller proportions of Asian/Asian British [$n = 11$ (1.5%)], African/Caribbean [$n = 6$ (1.0%)] and other/mixed/multiple ethnic groups [$n = 25$ (3.5%)]. OA and RA were the most common MSK conditions in 233 (32%) and 226 (32%) patients, respectively, followed by FM in 171 (24%) (see Table 1). Around two-thirds of respondents [$n = 460$ (64%)] also indicated having one or more long-term health conditions, and 221 (31%) indicated having two or more multiple long-term health conditions.

The majority of patients surveyed [$n = 387$ (54.5%)] took one or more supplements daily and 265 (37.3%) reported the use of two or more supplements daily. The median number of supplements taken was 2 [interquartile range (IQR) 1–4], ranging from 1 to 12 (Fig. 1). Of the people who said yes to taking supplements, almost one-fifth of patients [$n = 75$ (19.3%)] used five or more different types of supplements daily. The most common supplements used among patients were vitamin D [$n = 255$ (66%)], multivitamins [$n = 126$ (32%)], vitamin C [$n = 82$ (22%)], vitamin B [$n = 75$ (19.4%)], calcium [$n = 71$ (18.4%)], omega-3/-6 [$n = 70$ (18.1%)], turmeric [$n = 64$ (16.4%)], magnesium [$n = 62$ (16.1%)], zinc [$n = 43$ (11.1%)] and glucosamine [$n = 38$ (9.8%)] (Fig. 2).

In people taking supplements, there was a large overlap between different supplements. Several individuals took an additional supplement alongside a daily multivitamin: 63 (16.2%) took additional vitamin D tablets, 26 (3.7%) took omega-3/-6, 24 (3.4%) took calcium, 19 (4.9%) took vitamin B and 19 (4.9%) took vitamin C (Fig. 3). The five most common combinations of overlap are quantified in Supplementary Fig. S2, available at *Rheumatology Advances in Practice* online. There were also large overlaps between vitamin D and C [$n = 66$ (17.0%)], vitamin D and calcium [$n = 65$ (16.7%)], vitamin D and a multivitamin [$n = 63$ (16.2%)] and vitamin D and B [$n = 62$ (16.0%)] (Fig. 3).

Sleep aids

Of the people who participated, 719 (82%) respondents completed questions on sleep aid use (Supplementary Table S1, available at *Rheumatology Advances in Practice* online). Their demographics were similar to the respondents to the supplement questions, 529 (73%) were female, with a mean age of 58.3 years (s.d. 14.3). Of the 719 respondents, 95 (13%) used sleep aids. Among the sleep aid users, 37 (38.9%) had been diagnosed with OA and 34 (35.1%) had FM. Furthermore, 35 (37%) of the respondents reported having anxiety and depression (Supplementary Table S1, available at *Rheumatology Advances in Practice* online). Of the people on sleep aids, 31 (32%) reported getting them by prescription, 24 (25.2%) by non-prescription, 14 (14.7%) OTC and 4 (4.2%) by a combination of sources (Supplementary Fig. S3, available at *Rheumatology Advances in Practice* online). Additionally, 18 (19%) of the sleep aid users reported taking antihistamine/Benadryl by prescription. Also, 48 (51%) used CBD oil or similar products. The survey also showed that 53 (57%) of the respondents cited pain as the most common reason for taking CBD products.

Pain relievers

Of the participants who consented, 779 (88%) completed questions on the use of pain relievers. Of 779 individuals who experienced pain in the last week, 639 (82%) used some form of pain reliever, either prescription or non-prescription drugs such as paracetamol, NSAIDs or opioids (Supplementary Table S1, available at *Rheumatology Advances in Practice* online).

Non-opioids

Of those who used pain relievers, 470 (73%) reported using paracetamol, 327 (51.1%) reported using NSAIDs, 186 (29%) reported using ibuprofen, 86 (13%) reported using naproxen and 30 (4.6%) reported using diclofenac (Fig. 4). Additionally, 130 (20.5%) respondents reported using ibuprofen OTC, 25 (3.9%) obtained it from non-prescription sources and 14 (2.2%) received it by prescription. For diclofenac, 21 (3.3%) respondents were by prescription, 5 (0.8%) obtained it from non-prescription sources and 4 (0.6%) bought it OTC.

Overlap between NSAIDs and supplements

Of the 639 respondents who took pain relievers, 311 (48.6%) reported taking pain relievers and supplements. Of the 327 individuals who took NSAIDs, 165 (50.4%) also reported taking supplements. Among the people who reported taking ibuprofen, 70 (37.6%) also reported taking vitamin D, followed by vitamin B [$n = 26$ (13.9%)], multivitamins [$n = 33$ (17.7%)] and turmeric [$n = 21$ (11.2%)]. Similarly, of the people who reported taking naproxen, 36 (41.8%) also reported taking vitamin D, followed by vitamin B [$n = 9$ (10.4%)], multivitamin [$n = 14$ (16.2%)] and turmeric [$n = 10$ (11.6%)] (Table 2).

Opioids

A total of 131 (20.5%) respondents took opioids, of whom 80 (12.5%) reported taking codeine and 43 (6.7%) reported taking co-codamol as their most frequently used opioid pain reliever by prescription. This was followed by tramadol

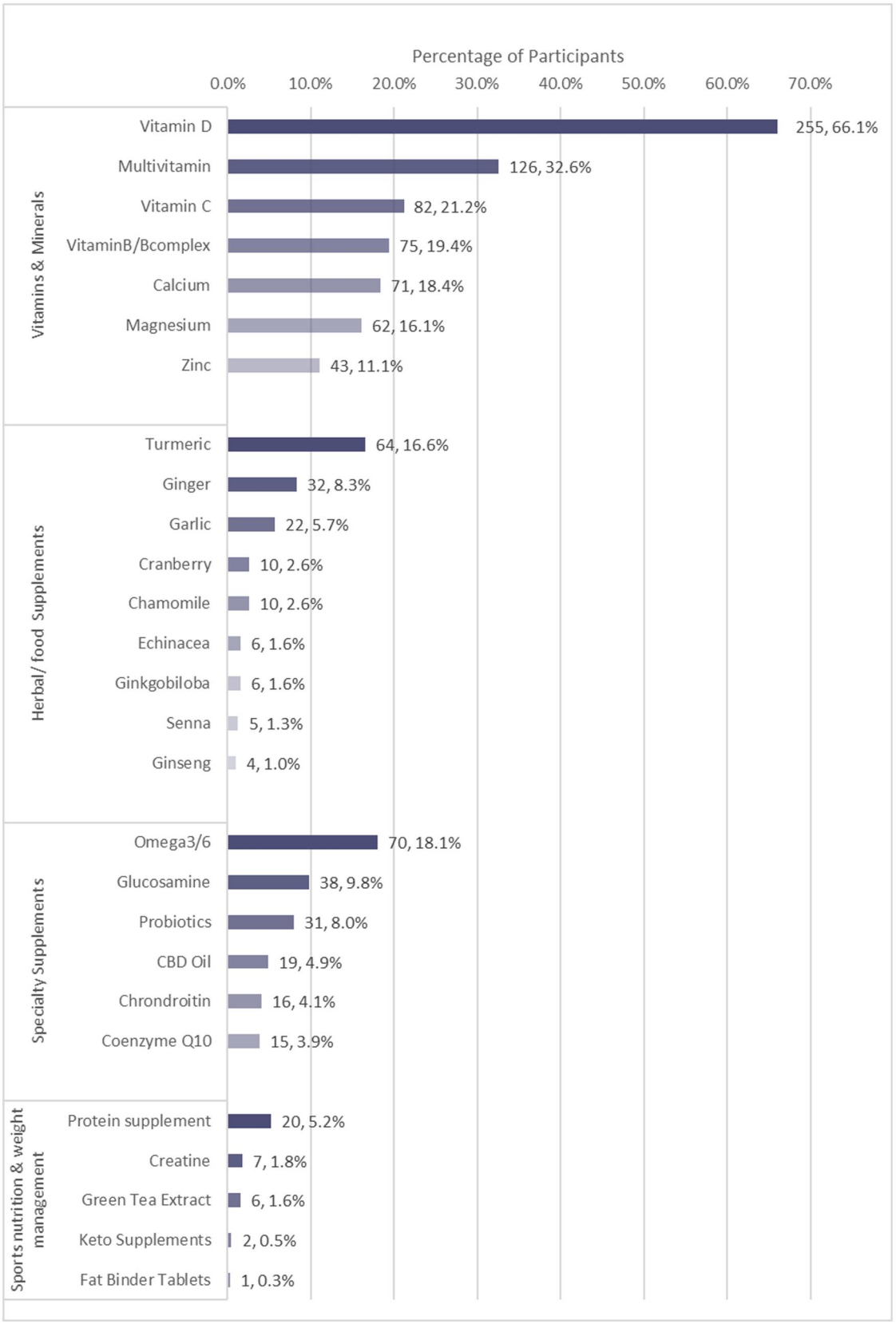

Figure 2. Distribution of OTC supplements used by rheumatology patients by type and specific supplements

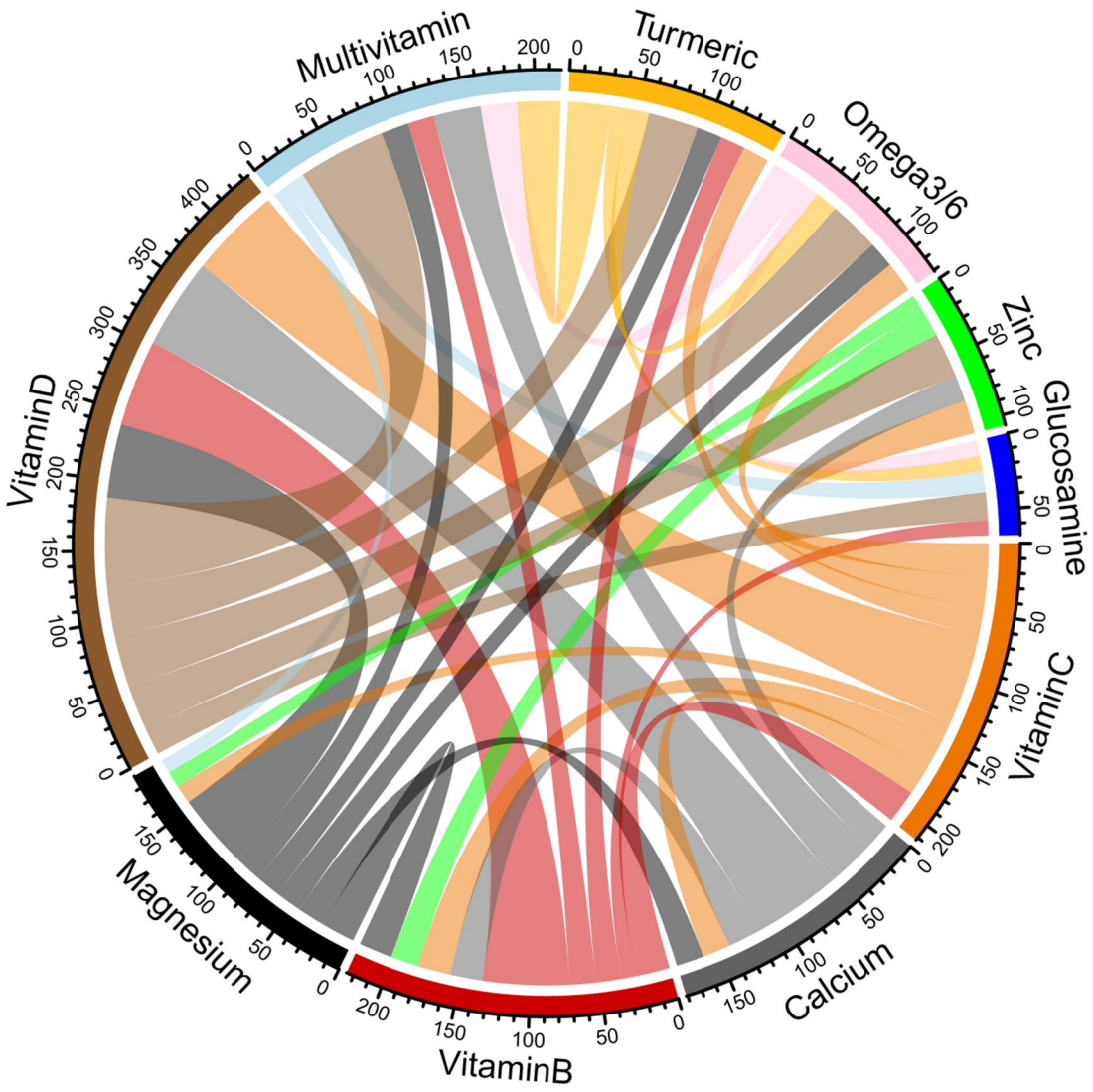

Figure 3. A chord diagram displaying the most common overlaps between the top 10 supplements. The diameter of the chord diagram is divided into groups of the 10 most common supplements, where the length of each arc is proportional to the total overlap count for each supplement. The count around the outer rim of the chord provides the overall count of supplements per group. Based on the diagram, vitamin D has the highest overlap count overall, followed by multivitamins, vitamin C and vitamin B. The thickness of the chord between supplements represents the number of participants who use both supplements. Thicker chords indicate higher numbers of participants using those supplements

[$n = 25$ (3.9%)] (as shown Fig. 4). Among the opioid users, 10 (1.5%) reported acquiring them from non-prescription sources. Of the individuals who used co-codamol, 37 (5.8%) obtained it by prescription, while a small proportion, $n = 4$ (0.6%) and $n = 2$ (0.3%), acquired it through non-prescription and OTC routes, respectively.

Overlap between opioids and supplements

Of the 131 (20.5%) people on opioids, 66 (50.3%) also reported taking supplements, followed by 62 (47%) taking vitamin and mineral supplements and 16 (12%) taking herbal or food supplements (Table 2).

Cost

The total median cost was £15/month (IQR 6–30), with a mean value of £24.80/month. Excluding prescribed pain-relieving medications, the median cost for OTC medications, sleep aids, CBD products and supplements was £10/month (IQR 5–20), with a mean value of £19.53/month. The costs for OTC medications, sleep aids, CBD products and supplements ranged from £1/month to £200/month (Supplementary Fig. S4, available at *Rheumatology Advances in Practice* online).

Factors associated with taking OTC supplements, sleep aids and pain relievers

In the logistic regression model, after adjusting for age and sex, no factors were found to be significantly associated with using OTC supplements. Patients diagnosed with axial spondylarthritis (axSpA) and FM had a higher odds ratio (OR) of using sleep aids compared with those without these conditions [OR 2.32 (95% CI 1.13, 4.52) and 1.81 (95% CI 1.10, 2.97), respectively] (Supplementary Tables S2A and S2B, available at *Rheumatology Advances in Practice* online). Individuals diagnosed with RA, OA and FM exhibited higher odds of using pain reliever medications compared with those without these conditions. The adjusted ORs for RA, OA and FM were found to be 1.58 (95% CI 1.04, 2.44), 3.34 (95%

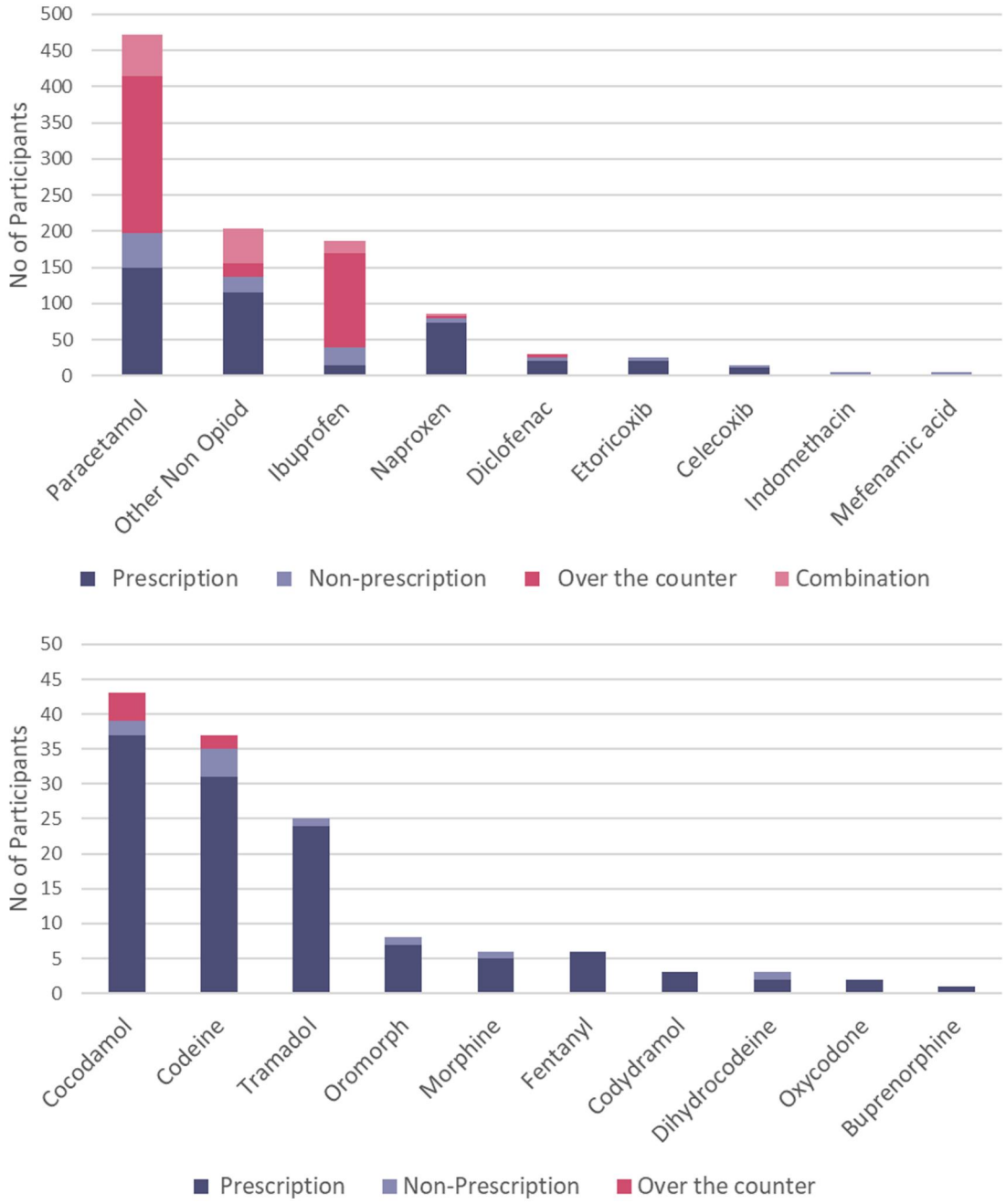

Figure 4. Types of pain relievers reported by rheumatology patients. **(A)** Non-opioid pain relievers. **(B)** Opioid pain relievers. Non-prescription use was defined in the survey as those medicines borrowed from a family member or purchased over the internet

CI 2.03, 5.75) and 3.44 (95% CI 1.95, 6.48), respectively (Supplementary Table S2B, available at *Rheumatology Advances in Practice* online).

Discussion

Our survey results revealed that OTC supplement use is frequent, with >50% of rheumatology patients taking supplements. At least one in three patients was on two or more supplements and one in five took five or more supplements daily. Noting that most respondents were from more socially deprived areas (Table 1), the median cost per patient was £10/month (IQR 5–20), ranging up to £200/month. The most common supplements used among patients were vitamin D, multivitamins, vitamin C, vitamin B/B complex, omega-3/-6 supplements and calcium, followed by turmeric, magnesium, zinc and glucosamine. Additionally, prescription, OTC or non-prescription pain relief was used by up to 82% of respondents, with sleep aids being used by 13%.

While limited data regarding supplement use across Europe exists, a previous national survey in the USA found that >70% of adults ≥71 years of age used supplements [17]. More women were found to use supplements [18] and their use in the USA has been associated with higher educational and socio-economic status [19]. In our study, we found that the highest proportion, 61%, of supplement users were between the ages of 40 and 69, with a lower proportion, 25%, >70 years of age reporting supplement use. Socio-economic

Table 2. Overlap between the most common supplements and opioids and NSAIDs

Supplements	Opioids									NSAIDs				
	All ($N = 131$)	Co-codamol ($n = 43$)	Codeine ($n = 37$)	Tramadol ($n = 25$)	Oromorph ($n = 8$)	Morphine ($n = 6$)	Fentanyl ($n = 6$)	Dihydrocodeine ($n = 3$)	Codydramol ($n = 3$)	All ($N = 327$)	Ibuprofen ($n = 186$)	Naproxen ($n = 86$)	Diclofenac ($n = 30$)	Etoricoxib ($n = 25$)
Vitamin D	55 (42.0)	17 (39.5)	11 (29.7)	14 (56)	4 (50)	3 (50)	2 (33.3)	3 (100)	1 (33.3)	127 (38.8)	70 (37.6)	36 (41.8)	10 (33.3)	11 (44)
Glucosamine	3 (2.3)	3 (6.9)	–	–	–	–	–	–	–	21 (6.4)	11 (5.9)	8 (9.3)	2 (6.6)	–
Vitamin B/B complex	14 (10.7)	5 (11.6)	5 (13.5)	4 (16)	–	–	–	–	–	38 (11.6)	26 (13.9)	9 (10.4)	2 (6.6)	1 (4)
Multivitamin	29 (22.1)	13 (30.2)	5 (13.5)	5 (20)	2 (25)	1 (16.6)	2 (33.3)	1 (33.3)	–	56 (17.1)	33 (17.7)	14 (16.2)	6 (20)	3 (12)
Magnesium	17 (13.0)	5 (11.6)	3 (8.1)	5 (20)	–	1 (16.6)	–	2 (66.6)	1 (33.3)	43 (13.1)	26 (13.9)	10 (11.6)	4 (13.3)	3 (12)
Calcium	14 (10.7)	4 (9.3)	3 (8.1)	4 (16)	2 (25)	1 (16.6)	–	–	–	34 (10.4)	19 (10.2)	7 (8.1)	4 (13.3)	4 (16)
Vitamin C	17 (13.0)	2 (4.6)	8 (21.6)	4 (16)	1 (12.5)	1 (16.6)	–	1 (33.3)	–	45 (13.8)	28 (15.0)	13 (15.1)	3 (10)	1 (4)
Omega-3/-6	4 (3.1)	2 (4.6)	1 (2.7)	–	–	1 (16.6)	–	–	–	13 (4.0)	7 (3.7)	5 (5.8)	1 (3.3)	–
Zinc	9 (6.9)	3 (6.9)	4 (10.8)	1 (4)	–	–	–	1 (33.3)	–	26 (8.0)	14 (7.5)	8 (9.3)	2 (6.6)	2 (8)
CBD oil	5 (3.8)	1 (2.3)	3 (8.1)	1 (4)	–	–	–	–	–	16 (4.9)	11 (5.9)	4 (4.6)	1 (3.3)	–
Chamomile	2 (1.5)	–	1 (2.7)	1 (4)	–	–	–	–	–	3 (0.9)	3 (1.6)	–	–	–
Turmeric	9 (6.9)	5 (11.6)	2 (5.4)	1 (4)	–	–	–	–	1 (33.3)	37 (11.3)	21 (11.2)	10 (11.6)	3 (10)	3 (12)
Ginkgo biloba	0 (0.0)	–	–	–	–	–	–	–	–	2 (0.6)	2 (1.07)	–	–	–
Garlic	4 (3.1)	–	1 (2.7)	1 (4)	1 (12.5)	–	1 (16.6)	–	–	8 (2.4)	6 (3.2)	1 (1.1)	–	1 (4)
Ginger	7 (5.3)	3 (6.9)	1 (2.7)	1 (4)	1 (12.5)	–	1 (16.6)	–	–	20 (6.1)	12 (6.4)	4 (4.6)	2 (6.6)	2 (8)
Echinacea	2 (1.5)	–	–	1 (4)	–	–	1 (16.6)	–	–	2 (0.6)	1 (0.5)	1 (1.1)	–	–

status was not significantly associated with supplement use, suggesting that its use continues to be popular across all groups.

In the last decade, there have been increasing trends in certain supplements (e.g. vitamin D, calcium, multivitamins, vitamin C and collagen), although the clinical efficacy of several of these remains controversial [20]. Patients may understandably request advice about the efficacy of supplementation from their rheumatology team and healthcare professionals, as they are often faced with conflicting information. Multivitamins remain a popular supplement choice in rheumatology patients. However, research based in the USA across >300 000 patients has demonstrated no long-term benefit of multivitamins or additional benefits on mortality risk [20]. Glucosamine continues to be used in rheumatology patients (10% of those reported supplement use). Its effectiveness in rheumatology, especially OA, has been debated for years. Several studies have investigated the efficacy of glucosamine in OA with mixed results. Currently there is no good evidence to support the use of glucosamine [21]. As per national guidance, vitamin D supplementation is advocated during winter months and throughout the year in those with risk factors [22]. Omega-3 supplementation has been reported to have a modest effect on tender and swollen joints in RA [23], with some potentially beneficial effects in reducing cardiovascular outcomes [24]. In the last few years, turmeric has been tested in different settings, including OA. More recent randomized controlled trials have demonstrated promise in reducing pain in knee OA compared with placebo [25], with a small number of RCTs reporting a benefit similar to that of NSAIDs [26].

There are several drug safety considerations with supplement use that may not be well known among patients, highlighting the importance of health professionals proactively asking about them during visits. The first is that the quality of supplements can be variable, given that they fall under the General Sales List within the legal classification of medicines [27]. Therefore they do not undergo the same safety, quality and efficacy reviews as pharmacological medicines and are not obligated to have warnings on labels. This has led to the recall of certain supplemental products due to concerns regarding toxicity following warnings by drug regulators [28]. The second is interactions between prescribed medications and other OTC drugs. For instance, curcumin, the active ingredient within turmeric, may increase drug levels of sulfasalazine and warfarin, leading to more adverse events [29]. Echinacea is known to affect the hepatic metabolism of certain prescribed medications, such as paracetamol [30]. Both turmeric and echinacea use were commonly reported among patients surveyed. Opioids may increase the risk of respiratory depression when used with other sedative herbal supplements such as chamomile ($n = 10$ in the survey), valerian and kava [30, 31]. Third, herbal supplements may interact with OTC NSAIDs. Some examples include an increase in bleeding risk with aspirin/NSAIDs with garlic, ginkgo biloba, turmeric, ginseng, feverfew and those containing coumarin (chamomile, horse chestnut) [31]. Several examples of such concomitant use were reported in this study, highlighting the importance of asking about them during a rheumatology consultation. Fourth, the prevalent use of vitamin and mineral supplements appears to contribute to an increase in population prevalence of intake above the upper tolerable level in high-income countries. This is a particular safety concern for fat-insoluble vitamins (A, D, K, E), especially when taken with a multivitamin [32]. In our study, multivitamins and vitamin B supplements were some of the most commonly reported supplements, with 19 (4.9%) patients taking both. Large doses of vitamin B3 have been associated with hepatoxicity, while a recent study involving >4300 participants with stable cardiac disease suggested that too much niacin (a type of B vitamin) may increase cardiovascular disease risk by provoking blood vessel inflammation [33]. This may be particularly important in rheumatology patients, who are known to already have a higher baseline cardiovascular risk compared with the general population. Healthcare professionals, where possible, should make themselves aware of reliable resources to direct patients to a variety of reliable self-management support resources [34, 35]. These include evidence-based online platforms, reputable patient advocacy groups and educational materials vetted by trusted health organizations.

In this study, patients with FM and axSpA were more likely to take sleep supplements compared with those without this diagnosis. Sleep disturbances associated with FM are well documented and thought to play a critical role in exacerbating pain symptoms [36]. A recent cross-sectional survey reported a high prevalence (46.6%) of sleep disturbance in patients with axSpA that may be associated with a significant reduction in quality of life [37]. The types of sleep supplements varied substantially (Fig. 3), with a considerable proportion of 45 (47%) patients opting for OTC and non-prescription options.

Pain relief was taken by the majority of patients in this study (82%), of which 51% were on some form of NSAID and 20% were on opioids. The most commonly administered opioids were co-codamol, codeine and tramadol, reflecting current prescribing practices in the UK [38]. Interestingly, however, 32% of patients used NSAIDs and 2.3% used opioids through non-prescription routes, i.e. bought on the internet or borrowed from a family member, suggesting it is especially important to ask about these sources in consultations from a drug safety perspective.

The strengths of the survey include that it was co-designed with patients and clinicians and the survey was anonymous, enabling more honest responses regarding more sensitive questions such as medications bought over the internet. We also sampled a relatively large proportion of rheumatology patients across a wide time frame during different times of the year. The results of the survey need to be considered in the context of its limitations. As this was an electronic survey, there may be issues regarding digital literacy, with some patients being unable to use smartphones or computers. The absence of a sampling strategy, such as random sampling, is a consideration in interpreting and reporting this study's findings. However, the demographics of rheumatology patients in this study in terms of age and gender were similar to our previous study in the same centre in which unselected rheumatology outpatient letters were used to develop a text-mining algorithm to automate national COVID-19 shielding criteria [39]. Additionally, the higher proportion of more deprived patients is in line with the demographics of Salford, and thus it is reassuring that the representativeness is not significantly skewed towards the less deprived. Given that the rheumatology department is a tertiary centre for specific conditions with a more deprived population, it is possible that the case mix is more complex, thus leading to more prevalent use of supplements. While minimal information is known about OTC supplement use in Europe, the pattern of supplement use may be different depending on whether these products/medicines are available via pharmacies or by prescription from their primary care provider. Finally, future work should focus on

comparing OTC supplement use with that of a healthy control group to assess how the use of these supplements/medicines differs from that of an RMD cohort. Despite the limitations, the findings provide valuable insights into the prevalence of OTC supplement use for sleep issues and pain management among rheumatology patients. This was a large survey across a tertiary rheumatology department with an intake of general and complex rheumatology patients.

Conclusions

In summary, there is a high prevalence of OTC supplement and non-prescription analgesic use in patients with RMDs. To our knowledge, there have been no recent estimates focusing on the use, types, costs and individual factors associated with each of these drugs across Europe. As patients rely increasingly on such self-management strategies and access health information from a variety of sources online, it is especially important, from a drug safety perspective, for healthcare professionals to proactively ask about such strategies in their consultations. This is especially true as there are concerns about their interactions with other conventional medicines and other OTC supplements, their quality in an unregulated market and their lack of standardized dosages. Healthcare professionals also need to be well equipped to provide reliable advice to patients on the scientific evidence regarding such medicines to help manage symptoms of pain, sleep and fatigue that can greatly impact quality of life.

Supplementary material

Supplementary material is available at *Rheumatology Advances in Practice* online.

Data availability

The data used for the survey are not publicly available without the completion of specific training requirements and information governance checks mandated by the data owners.

Authors' contributions

M.J. and W.G.D. conceived the study and design. M.J., W.G.D., S.L. designed the first draft of the survey and helped coordinate the data acquisition. S.L. led on obtaining feedback from the patient-advisory group and multidisciplinary team. R.B. was responsible for data management. M.S. performed the data preparation and analysis. M.S. and M.J. wrote the first draft of the manuscript. W.G.D., M.J., J.M. and M.L. contributed to funding acquisition. All authors edited and reviewed the final version.

Funding

Assembling the Data Jigsaw has been funded by the Nuffield Foundation's Oliver Bird Fund and Versus Arthritis, but the views expressed are those of the authors and not necessarily the funders. Visit https://www.nuffieldfoundation.org and https://www.versusarthritis.org. M.J. is funded by a National Institute for Health and Care Research (NIHR) Advanced Fellowship (NIHR301413). The views expressed in this publication are those of the authors and not necessarily those of the NIHR, National Health Service or the UK Department of Health and Social Care.

Disclosure statement: The authors have declared no conflicts of interest.

Acknowledgements

We would like to thank all the survey participants for their contributions and the wider study team including Louise Cook and Ginny Mitchell for programme support.

References

1. Djaoudene O, Romano A, Bradai YD *et al.* A global overview of dietary supplements: regulation, market trends, usage during the COVID-19 pandemic, and health effects. Nutrients 2023;15:3320.
2. Bailey RL, Gahche JJ, Miller PE, Thomas PR, Dwyer JT. Why US adults use dietary supplements. JAMA Intern Med 2013; 173:355–61.
3. Persson MSM, Sarmanova A, Doherty M, Zhang W. Conventional and biologic disease-modifying anti-rheumatic drugs for osteoarthritis: a meta-analysis of randomized controlled trials. Rheumatology (Oxford) 2018;57:1830–7.
4. Wandel S, Jüni P, Tendal B *et al.* Effects of glucosamine, chondroitin, or placebo in patients with osteoarthritis of hip or knee: network meta-analysis. BMJ 2010;341:c4675.
5. Gonçalves S, Gowler PRW, Woodhams SG *et al.* The challenges of treating osteoarthritis pain and opportunities for novel peripherally directed therapeutic strategies. Neuropharmacology 2022; 213:109075.
6. Roux CH, Guillemin F, Boini S *et al.* Impact of musculoskeletal disorders on quality of life: An inception cohort study. Ann Rheum Dis 2005;64:606–11.
7. Geenen R, Overman CL, Christensen R *et al.* EULAR recommendations for the health professional's approach to pain management in inflammatory arthritis and osteoarthritis. Ann Rheum Dis 2018; 77:797–807.
8. Dures E, Farisoğulları B, Santos EJF *et al.* 2023 EULAR recommendations for the management of fatigue in people with inflammatory rheumatic and musculoskeletal diseases. Ann Rheum Dis 2023;83:1260–7.
9. Hazes JMW, Luime JJ. The epidemiology of early inflammatory arthritis. Nat Rev Rheumatol 2011;7:381–90.
10. Michos ED, Cainzos-Achirica M. Supplements for the treatment of mild COVID-19—challenging health beliefs with science from A to Z. JAMA Netw Open 2021;4:e210431.
11. Kloppenburg M, Kroon FPB, Blanco FJ *et al.* 2018 update of the EULAR recommendations for the management of hand osteoarthritis. Ann Rheum Dis 2019;78:16–24.
12. Chou R, Turner JA, Devine EB *et al.* The effectiveness and risks of long-term opioid therapy for chronic pain: a systematic review for a national institutes of health pathways to prevention workshop. Ann Intern Med 2015;162:276–86.
13. Zambelli Z, Halstead EJ, Iles R, Fidalgo AR, Dimitriou D. The 2021 NICE guidelines for assessment and management of chronic pain: a cross-sectional study mapping against a sample of 1,000 in the community. Br J Pain 2022;16:439–49.
14. Yu D, Jordan KP, Wilkie R *et al.* Persistent inequalities in consultation incidence and prevalence of low back pain and osteoarthritis in England between 2004 and 2019. Rheumatol Adv Pract 2023; 7:rkac106.
15. Qualtrics^{XM} (2022). https://www.qualtrics.com/ (20 June 2024, date last accessed).
16. Shohaimi S, Welch A, Bingham S *et al.* Area deprivation predicts lung function independently of education and social class. Eur Respir J 2004;24:157–61.

17. Bailey RL, Gahche JJ, Lentino CV *et al.* Dietary supplement use in the United States, 2003–2006. J Nutr 2011;141:261–6.
18. Chen F, Du M, Blumberg JB *et al.* Association among dietary supplement use, nutrient intake, and mortality among U.S. adults: a cohort study. Ann Intern Med 2019;170:604–13.
19. Blumberg JB, Frei B, Fulgoni VL, Weaver CM, Zeisel SH. Contribution of dietary supplements to nutritional adequacy by socioeconomic subgroups in adults of the United States. Nutrients 2017;10:4.
20. Loftfield E, O'Connell CP, Abnet CC *et al.* Multivitamin use and mortality risk in 3 prospective US cohorts. JAMA Netw Open 2024;7:e2418729.
21. Runhaar J, Rozendaal RM, Van Middelkoop M *et al.* Subgroup analyses of the effectiveness of oral glucosamine for knee and hip osteoarthritis: a systematic review and individual patient data meta-analysis from the OA trial bank. Ann Rheum Dis 2017; 76:1862–9.
22. National Institute for Health Care and Excellence. Vitamin D deficiency in adults. Health topics A to Z. 2022. https://cks.nice.org.uk/topics/vitamin-d-deficiency-in-adults/ (15 March 2024, date last accessed).
23. Sigaux J, Mathieu S, Nguyen Y *et al.* Impact of type and dose of oral polyunsaturated fatty acid supplementation on disease activity in inflammatory rheumatic diseases: a systematic literature review and meta-analysis. Arthritis Res Ther 2022;24:100–13.
24. Khan SU, Lone AN, Khan MS *et al.* Effect of omega-3 fatty acids on cardiovascular outcomes: a systematic review and meta-analysis. EClinicalMedicine 2021;38:100997.
25. Wang Z, Jones G, Winzenberg T *et al.* Effectiveness of curcuma longa extract for the treatment of symptoms and effusion-synovitis of knee osteoarthritis. Ann Intern Med 2020;173:861–9.
26. Paultre K, Cade W, Hernandez D *et al.* Therapeutic effects of turmeric or curcumin extract on pain and function for individuals with knee osteoarthritis: a systematic review. BMJ Open Sport Exerc Med 2021;7:e000935.
27. Medicines and Healthcare Products Regulatory Agency. Medicines: reclassify your product. 2024. https://www.gov.uk/guidance/medicines-reclassify-your-product#prescription-only-medicine-pom-to-pharmacy-p-medicine (15 March 2024, date last accessed).
28. Medicines and Healthcare Products Regulatory Agency. Class 2 medicines recall: Asda, St John's Wort, HRI Good Mood and Superdrug St John's Wort tablets. THR 02231/0002. 2016. https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-asda-st-johns-wort-hri-good-mood-and-superdrug-st-john-s-wort-tablets-thr-02231-0002 (15 March 2024, date last accessed).
29. Kusuhara H, Furuie H, Inano A *et al.* Pharmacokinetic interaction study of sulphasalazine in healthy subjects and the impact of curcumin as an in vivo inhibitor of BCRP. Br J Pharmacol 2012;166:1793–803.
30. Abebe W. Herbal medication: potential for adverse interactions with analgesic drugs. J Clin Pharm Ther 2002;27:391–401.
31. Sood A, Sood R, Brinker FJ *et al.* Potential for interactions between dietary supplements and prescription medications. Am J Med 2008;121:207–11.
32. Cheruvattath R, Orrego M, Gautam M *et al.* Vitamin A toxicity: when one a day doesn't keep the doctor away. Liver Transpl 2006; 12:1888–91.
33. Ferrell M, Wang Z, Anderson JT *et al.* A terminal metabolite of niacin promotes vascular inflammation and contributes to cardiovascular disease risk. Nat Med 2024;30:424–34.
34. Nikiphorou E, Santos EJF, Marques A *et al.* 2021 EULAR recommendations for the implementation of self-management strategies in patients with inflammatory arthritis. Ann Rheum Dis 2021; 80:1278–85.
35. Khoo T, Jani M, Chinoy H. Is there a role for novel supplements in the management of fatigue in rheumatic diseases? RMD Open 2024;10:e004529.
36. Bigatti SM, Hernandez AM, Cronan TA, Rand KL. Sleep disturbances in fibromyalgia syndrome: relationship to pain and depression. Arthritis Rheum 2008;59:961–7.
37. Frede N, Rieger E, Lorenzetti R *et al.* Sleep behaviour differs in women and men with psoriatic arthritis and axial spondyloarthritis with impact on quality of life and depressive symptoms. RMD Open 2023;9:e002912.
38. Jani M, Birlie Yimer B, Sheppard T, Lunt M, Dixon WG. Time trends and prescribing patterns of opioid drugs in UK primary care patients with non-cancer pain: a retrospective cohort study. Song Z, ed. PLoS Med 2020 17:e1003270.
39. Jani M, Alfattni G, Belousov M *et al.* Development and evaluation of a text analytics algorithm for automated application of national COVID-19 shielding criteria in rheumatology patients. Ann Rheum Dis 2024;83:1082–91.

Rheumatology Advances in Practice, 2024, 8, 1–11
https://doi.org/10.1093/rap/rkae129
Original Article

Biologics may be **less effective** in patients who are **overweight**[1,2]

Eligible patients, weighing ≥90kg with PsA and concomitant moderate to severe PsO, may need an individualised treatment approach[4,5]

>6 in 10 adults over the age of 18 years in England are estimated to be overweight or living with obesity[3]

Click here to visit our HCP portal and learn more

Cosentyx® (secukinumab) provides **flexible dosing** based on your eligible patients' needs*[4,5]

Loading dose

Week **0**	Week **1**	Week **2**	Week **3**	Week **4**
300 mg	300 mg	300 mg	300 mg	300 mg

Maintenance dosing

Body weight **<90 kg**: 300 mg Monthly

Based on clinical response, consider up-titration
≥90 kg patients not responding to monthly maintenance dosing: 300 mg every **2 weeks**

Adapted from Cosentyx® (secukinumab) SmPC.[4,5]

*For adult patients with PsA and concomitant moderate to severe PsO, the recommended dose of Cosentyx is 300 mg with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by **monthly maintenance dosing**. Based on clinical response, a maintenance dose of 300 mg **Q2W** may provide additional benefit for patients with a body weight of **90 kg or higher**.[4,5]

Cosentyx is indicated for the treatment of moderate to severe plaque psoriasis in adults, children and adolescents from the age of 6 years who are candidates for systemic therapy; active psoriatic arthritis in adult patients (alone or in combination with methotrexate) when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate; active ankylosing spondylitis in adults who have responded inadequately to conventional therapy; active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs; active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic therapy; active enthesitis-related arthritis in patients 6 years and older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy; active juvenile psoriatic arthritis in patients 6 years and older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy.[4,5]

PsA, psoriatic arthritis; PsO, plaque psoriasis; Q2W, every 2 weeks.

References: 1. Warren RB, et al. *J Invest Dermatol* 2015;135:2632–2640; **2.** Warren RB, et al. *Br J Dermatol* 2019;180(5):1069–1076; **3.** Office for Health Improvement and Disparities. Obesity profile: short statistical commentary May 2024. Available at: https://www.gov.uk/government/statistics/update-to-the-obesity-profile-on-fingertips/obesity-profile-short-statistical-commentary-may-2024 [Accessed August 2024]; **4.** Cosentyx® (secukinumab) GB Summary of Product Characteristics; **5.** Cosentyx® (secukinumab) NI Summary of Product Characteristics.

NOVARTIS

UK | September 2024 | FA-11257948

Cosentyx® (secukinumab) Great Britain Prescribing Information.

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Indications: Treatment of: moderate to severe plaque psoriasis in adults, children and adolescents from the age of 6 years who are candidates for systemic therapy; active psoriatic arthritis in adults (alone or in combination with methotrexate) who have responded inadequately to disease-modifying anti-rheumatic drug therapy; active ankylosing spondylitis in adults who have responded inadequately to conventional therapy; active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs; active enthesitis-related arthritis and juvenile psoriatic arthritis in patients 6 years and older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy; active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. **Presentations:** Cosentyx 75 mg solution for injection in pre-filled syringe; Cosentyx 150 mg solution for injection in pre-filled syringe; Cosentyx 150 mg solution for injection in pre-filled pen; Cosentyx 300 mg solution for injection in pre-filled pen. **Dosage & Administration:** Administered by subcutaneous injection at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Consider discontinuation if no response after 16 weeks of treatment. Each 75 mg dose is given as one injection of 75 mg. Each 150 mg dose is given as one injection of 150 mg. Each 300 mg dose is given as two injections of 150 mg or one injection of 300 mg. If possible avoid areas of the skin showing psoriasis. *Plaque Psoriasis:* Adult recommended dose is 300 mg. Based on clinical response, a maintenance dose of 300 mg every 2 weeks may provide additional benefit for patients with a body weight of 90 kg or higher. Adolescents and children from the age of 6 years: if weight ≥ 50 kg, recommended dose is 150 mg (may be increased to 300 mg as some patients may derive additional benefit from the higher dose). If weight < 50 kg, recommended dose is 75 mg. *Psoriatic Arthritis:* For patients with concomitant moderate to severe plaque psoriasis see adult plaque psoriasis recommendation. For patients who are anti-TNFα inadequate responders, the recommended dose is 300 mg, 150 mg in other patients. Can be increased to 300 mg based on clinical response. *Ankylosing Spondylitis:* Recommended dose 150 mg. Can be increased to 300 mg based on clinical response. *nr-axSpA:* Recommended dose 150 mg. *Enthesitis-related arthritis and juvenile psoriatic arthritis:* From the age of 6 years, if weight ≥ 50 kg, recommended dose is 150 mg. If weight < 50 kg, recommended dose is 75 mg. *Hidradenitis suppurativa:* Recommended dose is 300 mg monthly. Based on clinical response, the maintenance dose can be increased to 300 mg every 2 weeks. **Contraindications:** Hypersensitivity to the active substance or excipients. Clinically important, active infection. **Warnings & Precautions:** *Infections:* Potential to increase risk of infections; serious infections have been observed. Caution in patients with chronic infection or history of recurrent infection. Advise patients to seek medical advice if signs/symptoms of infection occur. Monitor patients with serious infection closely and do not administer Cosentyx until the infection resolves. Non-serious mucocutaneous candida infections were more frequently reported for secukinumab in the psoriasis clinical studies. Should not be given to patients with active tuberculosis (TB). Consider anti-tuberculosis therapy before starting Cosentyx in patients with latent TB. *Inflammatory bowel disease (including Crohn's disease and ulcerative colitis):* New cases or exacerbations of inflammatory bowel disease have been reported with secukinumab. Secukinumab, is not recommended in patients with inflammatory bowel disease. If a patient develops signs and symptoms of inflammatory bowel disease or experiences an exacerbation of pre-existing inflammatory bowel disease, secukinumab should be discontinued and appropriate medical management should be initiated. *Hypersensitivity reactions:* Rare cases of anaphylactic reactions have been observed. If an anaphylactic or serious allergic reactions occur, discontinue immediately and initiate appropriate therapy. *Vaccinations:* Do not give live vaccines concurrently with Cosentyx; inactivated or non-live vaccinations may be given. Paediatric patients should receive all age appropriate immunisations before treatment with Cosentyx. *Latex-Sensitive Individuals:* The removable needle cap of the 75mg and 150 mg pre-filled syringe and 150mg pre-filled pen contains a derivative of natural rubber latex. *Concomitant immunosuppressive therapy:* Combination with immunosuppressants, including biologics, or phototherapy has not been evaluated in psoriasis studies. Cosentyx was given concomitantly with methotrexate, sulfasalazine and/or corticosteroids in arthritis studies. Caution when considering concomitant use of other immunosuppressants. **Interactions:** Live vaccines should not be given concurrently with secukinumab. No interaction between Cosentyx and midazolam (CYP3A4 substrate) seen in adult psoriasis study. No interaction between Cosentyx and methotrexate and/or corticosteroids seen in arthritis studies. **Fertility, pregnancy and lactation:** *Women of childbearing potential:* Use an effective method of contraception during and for at least 20 weeks after treatment. *Pregnancy:* Preferably avoid use of Cosentyx in pregnancy. *Breast feeding:* It is not known if secukinumab is excreted in human breast milk. A clinical decision should be made on continuation of breast feeding during Cosentyx treatment (and up to 20 weeks after discontinuation) based on benefit of breast feeding to the child and benefit of Cosentyx therapy to the woman. *Fertility:* Effect on human fertility not evaluated. **Adverse Reactions**: *Very Common (≥1/10):* Upper respiratory tract infection. *Common (≥1/100 to <1/10):* Oral herpes, headache, rhinorrhoea, diarrhoea, nausea, fatigue. *Uncommon (≥1/1,000 to <1/100):* Oral candidiasis, lower respiratory tract infections, neutropenia, inflammatory bowel disease. *Rare (≥1/10,000 to <1/1,000)*: anaphylactic reactions, exfoliative dermatitis (psoriasis patients), hypersensitivity vasculitis. *Not known:* Mucosal and cutaneous candidiasis (including oesophageal candidiasis). *Infections:* Most infections were non-serious and mild to moderate upper respiratory tract infections, e.g. nasopharyngitis, and did not necessitate treatment discontinuation. There was an increase in mucosal and cutaneous (including oesophageal) candidiasis, but cases were mild or moderate in severity, non-serious, responsive to standard treatment and did not necessitate treatment discontinuation. Serious infections occurred in a small proportion of patients (0.015 serious infections reported per patient year of follow up). *Neutropenia:* Neutropenia was more frequent with secukinumab than placebo, but most cases were mild, transient and reversible. Rare cases of neutropenia CTCAE Grade 4 were reported. *Hypersensitivity reactions:* Urticaria and rare cases of anaphylactic reactions were seen. *Immunogenicity:* Less than 1% of patients treated with Cosentyx developed antibodies to secukinumab up to 52 weeks of treatment. *Other Adverse Effects:* The list of adverse events is not exhaustive, please consult the SmPC for a detailed listing of all adverse events before prescribing. **Legal Category:** POM. **MA Number & List Price:** PLGB 00101/1205 – 75 mg pre-filled syringe x 1 - £304.70; PLGB 00101/1029 - 150 mg pre-filled pen x2 £1,218.78; PLGB 00101/1030 - 150 mg pre-filled syringe x2 £1,218.78; PLGB 00101/1198 – 300 mg pre-filled pen x 1 £1218.78. **PI Last Revised:** June 2023. Full prescribing information, (SmPC) is available from: Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Telephone: (01276) 692255.

UK | 290802 | June 2023

Adverse Event Reporting:

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis via uk.patientsafety@novartis.com or online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report.

If you have a question about the product, please contact Medical Information on 01276 698370 or by email at medinfo.uk@novartis.com

Cosentyx® (secukinumab) Northern Ireland Prescribing Information.

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Indications: Treatment of: moderate to severe plaque psoriasis in adults, children and adolescents from the age of 6 years who are candidates for systemic therapy; active psoriatic arthritis in adults (alone or in combination with methotrexate) who have responded inadequately to disease-modifying anti-rheumatic drug therapy; active ankylosing spondylitis in adults who have responded inadequately to conventional therapy; active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs; active enthesitis-related arthritis and juvenile psoriatic arthritis in patients 6 years and older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy; active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. **Presentations:** Cosentyx 150 mg solution for injection in pre-filled pen; Cosentyx 300 mg solution for injection in pre-filled pen. **Dosage & Administration:** Administered by subcutaneous injection at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Consider discontinuation if no response after 16 weeks of treatment. Each 150 mg dose is given as one injection of 150 mg. Each 300 mg dose is given as two injections of 150 mg or one injection of 300 mg. If possible avoid areas of the skin showing psoriasis. *Plaque Psoriasis:* Adult recommended dose is 300 mg monthly. Based on clinical response, a maintenance dose of 300 mg every 2 weeks may provide additional benefit for patients with a body weight of 90 kg or higher. Adolescents and children from the age of 6 years: if weight ≥ 50 kg, recommended dose is 150 mg (may be increased to 300 mg as some patients may derive additional benefit from the higher dose). If weight < 50 kg, recommended dose is 75 mg. However, 150mg solution for injection in pre-filled pen is not indicated for administration of this dose and no suitable alternative formulation is available. *Psoriatic Arthritis:* For patients with concomitant moderate to severe plaque psoriasis see adult plaque psoriasis recommendation. For patients who are anti-TNFα inadequate responders, the recommended dose is 300 mg, 150 mg in other patients. Can be increased to 300 mg based on clinical response. *Ankylosing Spondylitis:* Recommended dose 150 mg. Can be increased to 300 mg based on clinical response. *nr-axSpA:* Recommended dose 150 mg. *Enthesitis-related arthritis and juvenile psoriatic arthritis:* From the age of 6 years, if weight ≥ 50 kg, recommended dose is 150 mg. If weight < 50 kg, recommended dose is 75 mg. However, 150mg solution for injection in pre-filled pen is not indicated for administration of this dose and no suitable alternative formulation is available. *Hidradenitis suppurativa:* Recommended dose is 300 mg monthly. Based on clinical response, the maintenance dose can be increased to 300 mg every 2 weeks. **Contraindications:** Hypersensitivity to the active substance or excipients. Clinically important, active infection. **Warnings & Precautions:** *Infections:* Potential to increase risk of infections; serious infections have been observed. Caution in patients with chronic infection or history of recurrent infection. Advise patients to seek medical advice if signs/symptoms of infection occur. Monitor patients with serious infection closely and do not administer Cosentyx until the infection resolves. Non-serious mucocutaneous candida infections were more frequently reported for secukinumab than placebo in the psoriasis clinical studies. Should not be given to patients with active tuberculosis (TB). Consider anti-tuberculosis therapy before starting Cosentyx in patients with latent TB. *Inflammatory bowel disease (including Crohn's disease and ulcerative colitis):* New cases or exacerbations of inflammatory bowel disease have been reported with secukinumab. Secukinumab, is not recommended in patients with inflammatory bowel disease. If a patient develops signs and symptoms of inflammatory bowel disease or experiences an exacerbation of pre-existing inflammatory bowel disease, secukinumab should be discontinued and appropriate medical management should be initiated. *Hypersensitivity reactions:* Rare cases of anaphylactic reactions have been observed. If an anaphylactic or serious allergic reactions occur, discontinue immediately and initiate appropriate therapy. *Vaccinations:* Do not give live vaccines concurrently with Cosentyx; inactivated or non-live vaccinations may be given. Paediatric patients should receive all age appropriate immunisations before treatment with Cosentyx. *Latex-Sensitive Individuals:* The removable needle cap of the 150mg pre-filled pen contains a derivative of natural rubber latex. *Concomitant immunosuppressive therapy:* Combination with immunosuppressants, including biologics, or phototherapy has not been evaluated in psoriasis studies. Cosentyx was given concomitantly with methotrexate, sulfasalazine and/or corticosteroids in arthritis studies. Caution when considering concomitant use of other immunosuppressants. **Interactions:** Live vaccines should not be given concurrently with secukinumab. No interaction between Cosentyx and midazolam (CYP3A4 substrate) seen in adult psoriasis study. No interaction between Cosentyx and methotrexate and/or corticosteroids seen in arthritis studies. **Fertility, pregnancy and lactation:** *Women of childbearing potential:* Use an effective method of contraception during and for at least 20 weeks after treatment. *Pregnancy:* Preferably avoid use of Cosentyx in pregnancy. *Breast feeding:* It is not known if secukinumab is excreted in human breast milk. A clinical decision should be made on continuation of breast feeding during Cosentyx treatment (and up to 20 weeks after discontinuation) based on benefit of breast feeding to the child and benefit of Cosentyx therapy to the woman. *Fertility:* Effect on human fertility not evaluated. **Adverse Reactions**: *Very Common* (≥1/10): Upper respiratory tract infection. *Common* (≥1/100 to <1/10): Oral herpes, headache, rhinorrhoea, diarrhoea, nausea, fatigue. *Uncommon (≥1/1,000 to <1/100):* Oral candidiasis, lower respiratory tract infections, neutropenia, inflammatory bowel disease. *Rare (≥1/10,000 to <1/1,000)*: anaphylactic reactions, exfoliative dermatitis (psoriasis patients), hypersensitivity vasculitis. *Not known:* Mucosal and cutaneous candidiasis (including oesophageal candidiasis). *Infections:* Most infections were non-serious and mild to moderate upper respiratory tract infections, e.g. nasopharyngitis, and did not necessitate treatment discontinuation. There was an increase in mucosal and cutaneous (including oesophageal) candidiasis, but cases were mild or moderate in severity, non-serious, responsive to standard treatment and did not necessitate treatment discontinuation. Serious infections occurred in a small proportion of patients (0.015 serious infections reported per patient year of follow up). *Neutropenia:* Neutropenia was more frequent with secukinumab than placebo, but most cases were mild, transient and reversible. Rare cases of neutropenia CTCAE Grade 4 were reported. *Hypersensitivity reactions:* Urticaria and rare cases of anaphylactic reactions were seen. *Immunogenicity*: Less than 1% of patients treated with Cosentyx developed antibodies to secukinumab up to 52 weeks of treatment. *Other Adverse Effects:* The list of adverse events is not exhaustive, please consult the SmPC for a detailed listing of all adverse events before prescribing. **Legal Category:** POM. **MA Number & List Price:** EU/1/14/980/005 - 150 mg pre-filled pen x2 £1,218.78; EU/1/14/980/010 – 300 mg pre-filled pen x 1 £1218.78. **PI Last Revised:** May 2023. Full prescribing information, (SmPC) is available from: Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Telephone: (01276) 692255.

UK | 284832 | May 2023

Adverse Event Reporting:

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis via uk.patientsafety@novartis.com or online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report

If you have a question about the product, please contact Medical Information on 01276 698370 or by email at medinfo.uk@novartis.com