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AIMS AND SCOPE

The Rheumatology Quarterly is a peer-reviewed periodical journal that publishes quarterly (March, June, September, December) in English electronically. The journal publishes original contributions in the form of experimental and clinical research articles, case reports and literature review, reviews, news, letters to the editor and authors, as well as announcements related to all topics of rheumatology.

The Rheumatology Quarterly aims to constitute a current scientific discussion platform and archive in rheumatology with the contribution of the disciplines related to rheumatology together. The journal intends to share its experiences with the international scientific community in a prestigious way and provide an academic contribution to the development of rheumatology science.

The editorial and publication processes of the journal are shaped in accordance with the guidelines of the International Committee of Medical Journal Editors (ICMJE), World Association of Medical Editors (WAME), Council of Science Editors (CSE), Committee on Publication Ethics (COPE), European Association of Science Editors (EASE), and National Information Standards Organization (NISO). The journal is in conformity with the Principles of Transparency and Best Practice in Scholarly Publishing.

Title: The Rheumatology Quarterly

Journal abbreviation: Rheumatol Q

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INSTRUCTIONS TO AUTHORS

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Peer Review Process

The Rheumatology Quarterly uses an independent, unbiased, double-blind peer review process. Manuscripts are received and reviewed by the editor-in-chief, who directs them to the appropriate section editor. The section editor sends the manuscript to three independent referees. Referees are selected by the editorial board from among national and international experts in the area relevant to the study. The referees accept or reject the invitation to review the manuscript within two weeks. If they accept, they are expected to return their decision within 21 days. The associate editor reviews the referees' decisions, adds their own feedback, and returns the manuscript to the editor-in-chief, who makes the final decision. In case of disagreement among referees, the editor can assign a new referee.

The editor-in-chief, associate editors, biostatistics consultant, and English language editor may make

minor changes to accepted manuscripts before publication, provided they do not fundamentally change the text.

The editorial and publication processes of the journal are shaped in accordance with the guidelines of the International Committee of Medical Journal Editors (ICMJE), World Association of Medical Editors (WAME), Council of Science Editors (CSE), Committee on Publication Ethics (COPE), European Association of Science Editors (EASE), and National Information Standards Organization (NISO). The journal is in conformity with the Principles of Transparency and Best Practice in Scholarly Publishing.

All submissions must be accompanied by a signed statement of scientific contributions and responsibilities of all authors and a statement declaring the absence of conflict of interests. Any institution, organization, pharmaceutical or medical company providing any financial or material support, in whole or in part, must be disclosed in a footnote (ICMJE Disclosure Form for Potential Conflict of Interest(s)).

The manuscript format must comply with the ICMJE-Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals (updated in December 2018).

The presentation of the article types must be designed in accordance with trial reporting guidelines:

Human research: Helsinki Declaration as revised in 2013

Systematic reviews and meta-analyses: PRISMA guidelines

Case reports and literature review: The CARE case report guidelines

Clinical trials: CONSORT

Animal studies: ARRIVE and Guide for the Care and Use of Laboratory Animals

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GENERAL RULES

SUBMISSION REQUIREMENTS

- Cover Letter,
- “ICMJE Conflict of Interest Statement Form” (<http://www.icmje.org/conflicts-of-interest/>) for all contributing authors,
- A separate title page (Title Page should be submitted with all manuscripts and should include the title of the manuscript, name(s), affiliation(s), major degree(s) and ORCID ID of the author(s). The name, address, telephone (including the mobile phone number) and fax numbers and e-mail address of the corresponding author should be clearly listed. Grant information and other sources of support should also be included. Individuals who contributed to the preparation of the manuscript but did not fulfil the authorship criteria should also be acknowledged in the title page),
- Abstract divided into appropriate sections,
- Keywords (For indexing purposes, a list of 4–8 key words in English is essential),
- Article divided into appropriate sections,
- List of references styled according to “journal requirements”,
- A blinded main text (Please exclude all information that may indicate an individual or institution from the main document to ensure a blinded review process),
- The Copyright Agreement and Acknowledgement of Authorship form (Please submit a wet-signed and scanned copy of the Copyright Transfer Form with your submission),
- Upload your title page and forms in the system to Potential Conflict of Interest category to ensure a blinded review process,
- Figures (Figures should be submitted as standalone

images through the submission system in .JPG or .TIFF format),

- Ethics Committee Approval Statement (with decision/ file no, date and name of the institution, for original articles).

Abstract

The research articles should consist of Objectives, Methods, Results and Conclusion sections and should not exceed 250 words. At least 3, a maximum of 6 keywords should be determined on the Abstract page, and the title of the article should be added.

Main Text

The introduction should consist of the Patients / Materials and Methods, Results, Discussion and References sections. Abbreviations should be standard and should be explained in parentheses when they are used first. Internationally accepted units should be used in the measurements.

Tables, Figures and Images

It should be numbered in the order of use in the text, and unnecessary use should be avoided. In the photographs used in the cases, permission should be obtained, and necessary measures should be applied to prevent recognition. Attention should be paid to the quality of photographs and drawings, if any. Editorial Board may request correction or renewal in tables, figures and pictures on the grounds that it is not of sufficient quality. Figures and pictures must be original. For the pictures, figures and graphics used in another publication to be published in our journal, the necessary permissions must be obtained by the authors and before applying for an article. A copy of the document indicating that the permit has been obtained must be sent to the journal with the article.

References

References should be selected from the ones that are up to date and necessary for the article. References in the text should be indicated in parentheses and numbered

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according to the order of use. The name of the journals should be abbreviated in accordance with PubMed rules, and abbreviations should not be used in the names of journals which are not included here. Citation of proceedings should be avoided. Manuscripts accepted by a journal but not yet published can be documented as required and used as a source. Information other than this, including unaccepted articles, can be used by stating “unpublished observation” in the article. References should be written according to the examples below, and all the authors should be presented in references up to 6 authors, references which have more authors should be arranged in a way that “et al.” abbreviation will be placed at the end of the first three authors. The responsibility for the accuracy of the references belongs to the authors.

Examples:

Periodical publication example:

Wolfe F, Hawley DJ, Cathey MA. Termination of slow-acting antirheumatic therapy in rheumatoid arthritis: a 14-year prospective evaluation of 1017 consecutive starts. *J Rheumatol* 1990;17:994-1002.

Example of periodical publication published in an online journal:

Yurdakul S. Is there a higher risk of infection with anti-TNF-alpha agents, or is there a selection bias? *Lett Ed Rheumatol* 1(1):e110006. doi:10.2399/ler.11.0006

Example of book section:

Buchanan WW, Dequeker J. History of rheumatic diseases. In: Hochberg MC, Silman AJ, Smolen JS, Weinblatt ME, Weisman MH, editors. *Rheumatology*. Edinburgh: Mosby; 2003:3-

Preparation of the Manuscript

Title page: A separate title page should be submitted with all submissions and this page should include;

- The full title of the manuscript as well as a short title (running head) of no more than 50 characters,

- Name(s), affiliations and major degree(s) of the author(s)
- Grant information and detailed information on the other sources of support,
- The name, address, telephone (including the mobile phone number) and fax numbers and e-mail address of the corresponding author,
- Acknowledgement of the individuals who contributed to the preparation of the manuscript but do not fulfil the authorship criteria.

Abstract: An abstract should be submitted with all submissions except for letters to the editor. The abstract of Original Articles should be structured with subheadings (Aim, Materials and Method, Results and Conclusion).

Keywords: Each submission must be accompanied by a minimum of three and a maximum of six keywords for subject indexing at the end of the abstract. The keywords should be listed in full without abbreviations.

Manuscript Types

Original Articles: This is the most important type of article since it provides new information based on original research. The main text of original articles should be structured with Introduction, Materials and Methods (with subheadings), Results, Discussion, Study Limitations, Conclusion subheadings.

Statistical analysis to support conclusions is usually necessary. Statistical analyses must be conducted in accordance with the international statistical reporting standards (Altman DG, Gore SM, Gardner MJ, Pocock SJ. Statistical guidelines for contributors to medical journals. *Br Med J* 1983;7:1489-93). Information on statistical analyses should be provided with a separate subheading under the Materials and Methods section and statistical software that was used the process must certainly be specified. Data must be expressed as mean±standard deviation when parametric tests are used to compare continuous variables. Data

INSTRUCTIONS TO AUTHORS

must be expressed as median (minimum-maximum) and percentiles (25th and 75th percentiles) when non-parametric tests are used. In advanced and complicated statistical analyses, relative risk (RR), odds ratio (OR) and hazard ratio (HR) must be supported by confidence intervals (CI) and p values.

Editorial Comments: Editorial comments aim at providing brief critical commentary by the reviewers having expertise or with high reputation on the topic of the research article published in the journal. Authors are selected and invited by the journal. Abstract, Keywords, Tables, Figures, Images and other media are not included.

Review Articles: Reviews which are prepared by authors who have extensive knowledge on a particular field and whose scientific background has been translated into high volume of publication and higher citation potential are taken under review. The authors may be invited by the journal. Reviews should be describing, discussing and evaluating the current level of knowledge or topic used in the clinical practice and should guide future studies. Please check Table 1 for limitations for Review Articles.

Case reports and literature review: There is limited space for case reports and literature review in the journal and reports on rare cases or conditions that

constitute challenges in the diagnosis and treatment, those offering new therapies or revealing knowledge not included in the books, and interesting and educative case reports and literature review are accepted for publication. The text should include Introduction, Case Report, Discussion, Conclusion subheadings. Please check Table 1 for limitations for case reports and literature review.

Letters to the Editor: This type of manuscripts can discuss important parts, overlooked aspects or lacking parts of a previously published article. Articles on the subjects within the scope of the journal that might attract the readers' attention, particularly educative cases can also be submitted in the form of "Letter to the Editor". Readers can also present their comments on the published manuscripts in the form of "Letter to the Editor". Abstract, Keywords, Tables, Figures, Images and other media are not included. The text should be unstructured. The manuscript that is being commented on must be properly cited within the manuscript.

Images: Authors can submit for consideration an illustration and photos that is interesting, instructive, and visually attractive, along with a few lines of explanatory text. Images can include no more than 200 words of text. No abstract, discussion or conclusion are required but please include a brief title.

Table 1: Limitations for each manuscript type.

Type of manuscript	Word limit	Abstract word limit	Reference limit	Table limit	Figure limit
Original Article	5000	200 (Structured)	50	6	7 or total of 15 images
Review Article	5000	200	50	6	10 or total of 20 images
Case reports and literature review	1500	200	10	No tables	10 or total of 20 images
Letter to the Editor	500	N/A	5	No tables	No media
Scientific letter	900	N/A	10	No tables	2 or total of 4 images
Clinical Imaging/Visual Diagnosis	400	N/A	5	No tables	3 or total of 6 images
History	900	N/A	10	No tables	3 or total of 6 images

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REVISIONS

When submitting a revised version of a paper, the author must submit a detailed “Response to the reviewers” that states point by point how each issue raised by the reviewers has been covered and where it can be found (each reviewer’s comment, followed by the author’s reply and line numbers where the changes have been made) as well as an annotated copy of the main document. Revised manuscripts must be submitted within 30 days from the date of the decision letter. If the revised version of the manuscript is not submitted within the allocated time, the revision option may be cancelled. If the submitting author(s) believe that additional time is required, they should request this extension before the initial 30-day period is over.

Accepted manuscripts are copy-edited for grammar, punctuation, and format. Once the publication process of a manuscript is completed, it is published online on the journal’s webpage as an ahead-of-print publication before it is included in its scheduled issue. A PDF proof of the accepted manuscript is sent to the corresponding author, and their publication approval is requested within two days of their receipt of the proof.

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Out of respect to the reviewers, journal staff and the Editorial Board, authors are asked to submit a withdrawal request only if the reasons are compelling

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Please structure your review using the following headings:

A brief summary of manuscript:

- What is the intent of the study?
- What conclusions do the authors reach?
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The Title

- Does the title adequately reflect the content of the manuscript?

Keywords

- Are the keywords appropriate?

The Abstract

- Is it structured?
- Does the Abstract adequately summarize the manuscript?
- Can the Abstract be understood without reading the manuscript?
- Does it specify outcome measures, and provide salient statistics?
- Do any discrepancies exist between the Abstract and the rest of the paper?

The Introduction

- Is the Introduction brief?
- Is the rationale for conducting the study explained based on a review of the medical literature?
- Is the purpose of the study clearly defined? Is there a well-described hypothesis?

Materials and Methods

- Is the design of the methods appropriate to allow the hypothesis to be tested?
- Could another investigator reproduce the study using the Methods as outlined?
- Is the sample or participant recruitment described in detail with the inclusion and exclusion criteria?

- Have the authors obtained Informed Consent and Ethical Committee Approval (if relevant)?
- Do the authors specify the data acquisition and evaluation (e.g., the index test, the reference standard)?
- Are the statistical methods described? Are they appropriate?

Results

- Are the Results clearly explained?
- Is the order of presentation of the Results parallel the order of presentation of the Methods?
- Are the Results convincing and reasonable?
- Are there any Results given that are not preceded by an appropriate discussion in the Methods?

Discussion

- Is the Discussion concise?
- Does it begin with the most important finding and summarize key results?
- Does it relate exclusively to the results of the study?
- Does it compare the results with the relevant literature?
- Are the conclusions justified by the results found in the study?
- Are the unexpected results explained sufficiently?
- Is the clinical applicability of the study findings discussed?
- Are the limitations of the study clearly stated?

Figures and Graphs

- Are all figures referred to in the text?
- Are the figures and graphs correct and appropriately labeled?
- Is the number of Figures within the limitations of the Journal?

(Please check out Table 1 on the Instructions to Authors page)

- Do the figures and graphs adequately show the important results?

INSTRUCTIONS FOR REVIEWERS

- Do arrows need to be added to depict important or subtle findings?
- Are the figure legends self-sufficient and understood without making reference to the remainder of the manuscript?

Tables

- Do the tables appropriately describe the Results?
- Are the abbreviations used in the tables explained at the bottom?

References

- Does the reference list follow the style for the Journal?
- Is the number of references within the limitations of the Journal? (Please check out Table 1 on the Instructions to Authors page)
- Does the reference list contain obvious mistakes?
- Do any important references need to be added?

Final appraisal and decision

- Please summarize the Major strengths and Major weaknesses of the manuscript, and make your decision according to your answer to the following questions;

1. Does the article provide novel information (data, techniques, or idea) that is not already available in the literature?

If **yes**, please describe what you believe is new.

If **no**, ask the authors to explain what they consider new in their work. Otherwise, unless the paper has something else extremely important to present, the manuscript should likely be rejected.

2. Do the authors provide a solid rationale for conducting this study? If no, then the manuscript should likely be rejected.

3. Has the data analysis been performed appropriately? If no, then the manuscript should likely be rejected, or major revisions should be requested.

4. Have the results been clearly and accurately presented? If no, then a major revision should likely be requested.

5. If the article is scientifically acceptable, but the text is poorly written, then a minor revision should likely be requested.

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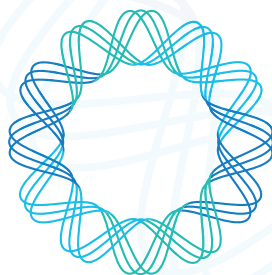
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AS=Ankylosing spondylitis; nr-axSpA=Non-radiographic axial spondyloarthritis without radiographic evidence.

References:

1. Verxant[®] (secukinumab) Summary of Product Characteristics. 2. Marzo-Ortega H, et al. *Lancet Rheumatol*. 2020;2:e339-46. 3. Deodhar A, et al. *Arthritis Rheumatol*. 2021;73(1):110-120. 4. Baraliakos X, et al. *RMD Open*. 2019;5(2):e001005. 5. Deodhar A, et al. *Arthritis Res Ther*. 2019;21(1):111. 6. Schreiber S, et al. *Ann Rheum Dis*. 2019;78(4):473-479. 7. Marzo-Ortega H, et al. *The Lancet Rheumatology*. 2020;June(28):e339-e346. 8. Novartis data on file. Aralık 2021.

†This medicinal product is subject to additional monitoring. This triangle will ensure that new safety information is quickly identified. Reporting ensures continuous follow-up of risk-benefit ratio of this medicine. Healthcare professionals are expected to report the suspected adverse reactions to Turkish Pharmacovigilance Center (TUFAM) www.tufam.gov.tr; e-mail: tufam@tufam.gov.tr; tel: 0312 218 30 00, 0800 314 00 08; fax: 0312 218 35 99; and/or related pharmaceutical company officials.

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Axial spondyloarthritis without radiographic evidence (nr-axSpA). VERXANT is indicated for the treatment of adult patients with axial spondyloarthritis who respond inadequately to non-steroidal anti-inflammatory drugs (NSAIDs), have high C-reactive protein (CRP) levels and/or objective signs of inflammation evidenced by magnetic resonance imaging (MRI) without active radiographic evidence. Dosage and administration: Plaque psoriasis. The recommended dose is 300 mg of secukinumab by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Each 300 mg dose is given as two subcutaneous injections of 150 mg. For some patients, a dose of 150 mg may be acceptable. Psoriatic arthritis. For patients with concomitant moderate to severe plaque psoriasis or who are anti-TNF- α inadequate responders (IR), the recommended dose is 300 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Each 300 mg dose is given as two subcutaneous injections of 150 mg. For other patients, the recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Based on clinical response, the dose can be increased to 300 mg. Ankylosing spondylitis. The recommended dose is 150 mg by subcutaneous injection with initial dosing at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. In patients with inadequate response (in patients with ongoing active ankylosing spondylitis), the dose can be increased to 300 mg. Each 300 mg dose is given as two subcutaneous injections of 150 mg. Axial spondyloarthritis without radiographic evidence (nr-axSpA). The recommended dose is 150 mg by subcutaneous injection with initial dosing at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Contraindications: Verxant is contraindicated in patients who have/had severe hypersensitivity reactions to the active substance or to any of the excipients and in patients who have clinically important, active infection (e.g. active tuberculosis). Warnings and precautions: Infections. Caution should be exercised when considering the use of Verxant in patients with a chronic infection or a history of recurrent infection. If a patient develops a serious infection, the patient should be closely monitored and Verxant should not be administered until the infection resolves. Anti-tuberculosis therapy should be considered prior to initiation of Verxant in patients with latent tuberculosis. Verxant should not be given to patients with active tuberculosis. Inflammatory bowel disease. Caution should be exercised when prescribing Verxant to patients with inflammatory bowel disease, including Crohn's disease and ulcerative colitis. Patients should be closely monitored. Hypersensitivity reactions: Rare cases of anaphylactic reactions have been observed during clinical trials. Administration of Verxant should be discontinued immediately and appropriate therapy initiated if an anaphylactic or other serious allergic reaction occurs. Vaccinations: Verxant should not be given concurrently with live vaccines. Pregnancy Category C Breast-feeding: Because of the potential for adverse reactions in nursing infants from secukinumab, a decision on whether to discontinue breast-feeding during treatment and up to 20 weeks after treatment or to discontinue therapy with Verxant must be made taking into account the benefit of breast-feeding to the child and the benefit of Verxant therapy to the woman. Adverse drug reactions: Very common ($\geq 1/10$): Upper respiratory tract infections. Common ($\geq 1/100$ to $< 1/10$): Oral herpes, rhinorrhea, diarrhoea. Uncommon ($\geq 1/1,000$ to $< 1/100$): Oral candidiasis, tinea pedis, otitis externa, neutropenia, conjunctivitis, urticaria. Rare: Anaphylactic reactions. Interactions: Live vaccines should not be given concurrently with Verxant. Overdose: In the event of overdose, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions and appropriate symptomatic treatment be instituted immediately. Contents of container: Verxant is supplied in a colourless glass vial with a grey coated rubber stopper and aluminium cap with a white flip-off component containing 150 mg of secukinumab. Storage: Store in a refrigerator (2°C - 8°C). Shelf Life: 3 years. After reconstitution: Chemical and physical in-use stability has been demonstrated for 24 hours at 2°C to 8°C. From a microbiological point of view, unless the method of reconstitution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user. Marketing Authorization Holder: Farmanova Sağlık Hizmetleri Limited Şirketi Surayip & Akel İş Merkezi, Röportajlar Mah. Şehit Şevan Erolul Cad. No: 8, 34805, Katrak - Beykoz/İstanbul, Türkiye. Manufactured by: Novartis Pharma Stein AG, Schaffhauserstrasse, CH-4332 Stein, Switzerland. This summary of product characteristics is prepared from Verxant (secukinumab) full prescribing information approved on 15.11.2021 in Turkey.

Indications and presentations may vary by country. For detailed information on packages, prices, registration and summary of product characteristics please contact your local Novartis company.

An Established Treatment for RA

Statistical superiority with UNAMITY[®] + MTX vs adalimumab + MTX as measured by ACR20 ($p \leq 0.05$) and change from baseline in DAS28-hsCRP ($p \leq 0.01$) at Week 12 (both major secondary endpoints).^{1,2}



An Established Treatment for adult patients with moderate to severe RA who are cDMARD-IR^{1,2}



Sustained efficacy

Up to 39% of patients in remission (SDAI ≤ 3.3) at 3 years; remission response at Year 1 sustained for an additional 2 years³



Consistent, long-term safety

Well-tolerated safety profile across 9 randomised clinical trials and 1 LTE study including 3,770 patients treated up to 9 years⁴

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▼ This medicinal product is subject to additional monitoring. This triangle will allow quick identification of new safety information. Healthcare professionals are encouraged to report suspected adverse reactions to TÜFAM (Turkish Pharmacovigilance Center).

ACR20 = American College of Rheumatology 20% improvement criteria; cDMARD = conventional disease-modifying antirheumatic drug; DAS28-hsCRP = Disease Activity Score for 28 joints with high sensitivity C-reactive protein; IR = inadequate responder; JAK = janus kinase; LTE = long-term extension; MTX = methotrexate; RA = rheumatoid arthritis; SDAI = Simplified Disease Activity Index.

References: 1. Taylor PC et al. N Engl J Med 2017;376:652–62 (including supplementary appendix). 2. UNAMITY[®], SmPC 2022. 3. Smolen JS et al. Rheumatology (Oxford) 2021;60:2256–66. 4. Taylor PC et al. Ann Rheum Dis 2021 Oct 27;annrheumdis-2021-221276. doi: 10.1136/annrheumdis-2021-221276.

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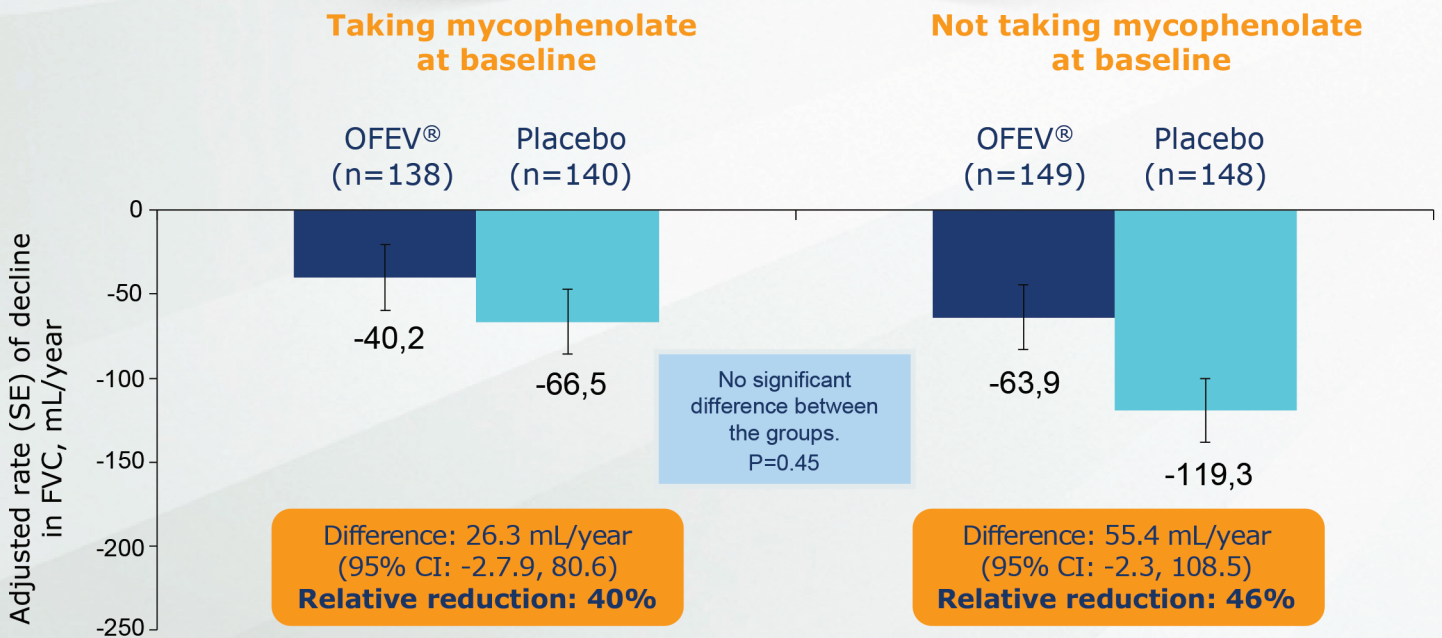
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SLOW DISEASE PROGRESSION¹⁻⁴

Reduce ILD progression by slowing lung function decline with OFEV^{®1-4}

Consistent efficacy and safety profile in IPF, progressive pulmonary fibrosis and SSc-ILD¹⁻⁴

OFEV[®] reduced the rate of FVC decline when used alone or in combination with MMF in patients with SSc-ILD³



References: 1. OFEV[®] Summary of Product Characteristics. 2. Flaherty KR, et al. N Engl J Med. 2019;381(18):1718-1727. 3. Distler O, et al. N Engl J Med. 2019;380:2518-2528. 4. Richeldi L, et al; for the INPULSIS[®] Trial Investigators. N Engl J Med. 2014;370(22):2071-2082.



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**WITH ITS DEMONSTRATED EARLY RESPONSES,
AND THE LARGEST DATASET A JAKi IN RA,
EXPERIENCE THE DIFFERENCE XELJANZ[®]
CAN MAKE FROM THE START^{1-3*}**

[Link to XELJANZ Prescribing Information – Turkey](#)

*Includes data on patients with inadequate response to methotrexate and TNF blockers. Details of these studies can be found in the XELJANZ[®] XR product information. XELJANZ XR[®] is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis, active psoriatic arthritis, and active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF inhibitor.

References: 1. Strand V ve ark. Arthritis Res Ther. 2020 Oct 15;22(1):243. 2. Cohen SB ve ark. RMD Open 2020;6:e001395. 3. Xeljanz[®] XR Kısa Ürün Bilgisi.

▽ This medicinal product is subject to additional monitoring. This inverted triangle is dedicated to bringing new information related to safety. Health care providers are obligated to report suspected adverse reactions to TÜFAM.



Trust in¹ Brand Power² in behind!

1. Burmester GR et al. Adv Ther 2020 37, 364-380 2. Saurat JH et al, Br J Dermatol 2008.;158(3):558-66

▼ This medication is subject to additional monitoring. This triangle will allow the rapid identification of new security information. Health care professionals are expected to report suspected adverse reactions to TUFAM. See SPMC Section 4.8 How are adverse reactions reported?

You can access the HUMIRA SPMC link.

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cimzia®
(certolizumab pegol)

Approved for the treatment of patients with



**CIMZIA® has 14+ years of
postmarketing experience with
20 years of total clinical use^a
and over 80 clinical trials
across indications^{1,2ab}**

MORE THAN

>1.000.000

patient-years of worldwide cumulative
exposure across previously approved
indications^{2c}

REFERENCES: 1. CIMZIA® Summary of Product Characteristics. 2. Data on file. UCB, Inc.

^a CIMZIA® was first approved by the FDA in April 2008 for adults with moderate to severe Crohn's disease.

^b Human trials initiated in July 1998. First patient, first dose in rheumatoid arthritis December 1998. Clinical studies investigated patients with rheumatoid arthritis, Crohn's disease, psoriatic arthritis, and other diseases, as well as healthy patients.

^c Patient exposure was estimated using the available sales data in rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, and psoriatic arthritis from 01 Sep 2007 to 28 Feb 2022 for the cumulative time interval. The exposure of CIMZIA was calculated using the following formula: Patient-years = [(total mg of product distributed)/(monthly maintenance dose)]/12 months in year.

▼ This medicine is subject to additional monitoring. The triangle will allow quick identification of new safety information. Healthcare professionals are required to report any suspected adverse reactions to TÜFAM. (www.titck.gov.tr; e-mail: tufam@titck.gov.tr; tel: 0 800 314 00 08; fax: 0 312 218 35 99).

Cimzia 200 mg/ml solution for s.c. injection in pre-filled syringe **Qualitative & Quantitative composition:** Each pre-filled syringe of 1ml contains 200 mg certolizumab pegol. **List of excipients:** Sodium acetate; 1.36mg Sodium chloride; 7.31 mg and Water for injection. **Therapeutic indications:** **Rheumatoid arthritis:** Cimzia, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe, active rheumatoid arthritis (RA) in adult patients when the response to disease-modifying antirheumatic drugs (DMARDs) including methotrexate, has been inadequate. Cimzia can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Cimzia, in combination with methotrexate (MTX), is indicated for the treatment of severe, active and progressive RA in adults not previously treated with MTX or other DMARDs. Cimzia has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with methotrexate. **Psoriatic arthritis:** Cimzia, alone or in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate. **Axial spondyloarthritis:** Cimzia is indicated for the treatment of adult patients with axial spondyloarthritis, comprising: **Ankylosing spondylitis (AS):** Cimzia is indicated for treatment of severe active ankylosing spondylitis in adults who have had an inadequate response to conventional treatment. **Axial spondyloarthritis without radiographic evidence of AS:** Cimzia is indicated in adult patients with severe axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by MRI (accompanied with elevated CRP or not), who have had an inadequate response to, or are intolerant to NSAIDs **Crohn's Disease:** Reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy. **Plaque psoriasis:** Treatment of adults with moderate to severe plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy, including ciclosporin, methotrexate or psoralen and ultraviolet A light (PUVA). **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Active tuberculosis or other severe infections such as sepsis or opportunistic infections. Moderate to severe heart failure (NYHA classes III/IV). **Special warnings and precautions for use:** Infections; Patients must be monitored closely for signs and symptoms of infections including tuberculosis before, during and after treatment with Cimzia. Treatment with Cimzia must not be initiated in patients with the response to previous DMARD therapy has been inadequate. Autoimmunity: Treatment with Cimzia may result in the formation of antinuclear antibodies (ANA) and uncommonly, in the development of a lupus-like syndrome. Vaccinations: Patients treated with Cimzia may receive vaccinations, except for live vaccines. If a surgical intervention is planned, Certolizumab's half life of 14 days should be considered. Cimzia may cause erroneously elevated aPTT assay results in patients without coagulation abnormalities. Serious infection risk which may be fatal is higher in patients ≥65 years of age compared to patients below 65 years of age. **Pregnancy and lactation:** Pregnancy category: B The use of adequate contraception should be considered for women of childbearing potential. For women planning pregnancy, continued contraception may be considered for 5 months after the last Cimzia dose due to its elimination rate, but the need for treatment of the woman should also be taken into account. For women planning pregnancy, related with CIMZIA's elimination rate, continuing a contraception method for 5 months after the last CIMZIA injection can be considered however, Pregnancy period; Data from more than 500 prospectively collected pregnancies exposed to Cimzia with known pregnancy outcomes, including more than 400 pregnancies exposed during the first trimester, does not indicate a malformative effect of Cimzia. However, the available clinical experience is too limited to, with a reasonable certainty, conclude that there is no increased risk associated with Cimzia administration during pregnancy. Cimzia should only be used during pregnancy if clinically needed. Lactation period; Cimzia can be used during breastfeeding. **Effects on ability to drive and use machines:** Cimzia may have a minor influence on the ability to drive and use machines. Dizziness (including vertigo, vision disorder and fatigue) may occur following administration of Cimzia. **Undesirable effects:** Common (≥ 1/100 to < 1/10); Uncommon (≥ 1/1000 to < 1/100) Infections and infestations; bacterial infections (including abscess), viral infections (including herpes, papillomavirus, influenza), sepsis, tuberculosis, fungal infections. Neoplasms benign, malignant and unspecified (including cysts and polyps); blood and lymphatic system malignancies (including lymphoma and leukaemia), solid organ tumours, non-melanoma skin cancers, pre-cancerous lesions (including oral leukoplakia, melanocytic nevus), benign tumours and cysts (including skin papilloma), gastrointestinal tumours, melanoma. Blood and the lymphatic system disorders; eosinophilic disorders, leukopenia (including neutropenia, lymphopenia), anaemia, lymphadenopathy, thrombocytopenia, thrombocytosis, pancytopenia, splenomegaly, erythrocytosis, white blood cell morphology abnormal. Immune system disorders; vasculitis, lupus erythematosus, drug hypersensitivity, allergic disorders, autoantibody positive, angioneurotic oedema, sarcoidosis, serum sickness, panniculitis. Endocrine disorders; thyroid disorders. Metabolism and nutrition disorders; electrolyte imbalance, dyslipidaemia, appetite disorders, weight change, haemolysis. Psychiatric disorders; anxiety and mood disorders (including associated symptoms), suicide attempt, delirium, mental impairment. Nervous system disorders; headaches (including migraine), sensory abnormalities, peripheral neuropathies, dizziness, tremor, seizure, cranial nerve inflammation, impaired coordination or balance multiple sclerosis, Guillain-Barré syndrome. Eye disorders; visual disorder, eye and eyelid inflammation, lacrimation disorder. Ear and labyrinth disorders; tinnitus, vertigo. Cardiac disorders; cardiomyopathies (including heart failure), ischaemic coronary artery disorders, arrhythmias, palpitations, pericarditis, atrioventricular block. Vascular disorders; hypertension, haemorrhage or bleeding (any site), hypercoagulation, syncope, oedema, ecchymoses, cerebrovascular accident, arteriosclerosis, Raynaud's phenomenon, livedo reticularis, telangiectasia. Respiratory, thoracic and mediastinal disorders; asthma and related symptoms, pleural effusion and symptoms, respiratory tract congestion and inflammation, cough, interstitial lung disease, pneumonitis. Gastrointestinal disorders; nausea, ascites, gastrointestinal ulceration and perforation, gastrointestinal tract inflammation (any site), stomatitis, dyspepsia, abdominal distension, oropharyngeal dryness, odynophagia, hypermotility. Hepatobiliary disorders; hepatitis, hepatopathy, cholestasis, blood bilirubin increased, cholelithiasis. Skin and subcutaneous tissue disorders; rash, alopecia, new onset or worsening of psoriasis and related conditions, dermatitis and eczema, sweat gland disorder, skin ulcer, photosensitivity, acne, skin discoloration, dry skin, nail and nail bed disorders, skin exfoliation and desquamation, hair texture disorder. Musculoskeletal, connective tissue and bone disorders; muscle disorders, blood creatine phosphokinase increased. Renal and urinary disorders; renal impairment, blood in urine, bladder and urethral symptoms, nephropathy. Reproductive system and breast disorders; menstrual cycle and uterine bleeding disorders, breast disorders, sexual dysfunction. General disorders and administration site conditions: pyrexia, pain, asthenia, pruritus, injection site reactions, chills, influenza-like illness, altered temperature perception, night sweats, flushing, fistula. Investigations: blood alkaline phosphatase increased, coagulation time prolonged, blood uric acid increased. Injury, poisoning and procedural complications: skin injuries, impaired healing. The additional following ADRs have been observed uncommonly with Cimzia in other indications: gastrointestinal stenosis and obstructions, general physical health deterioration, abortion spontaneous and azoospermia. **Interaction with other medicinal products and other forms of interaction:** Concomitant treatment with methotrexate, corticosteroids, nonsteroidal anti-inflammatory drugs and analgesics showed no effect on the pharmacokinetics of certolizumab pegol based on a population pharmacokinetics analysis. The combination of Cimzia and anakinra or abatacept is not recommended. **Posology and method of administration:** Posology, Loading dose: The recommended starting dose of Cimzia for adult patients is 400 mg (given as 2 subcutaneous injections of 200 mg each) at weeks 0, 2 and 4. For rheumatoid arthritis and psoriatic arthritis, MTX should be continued during treatment with Cimzia where appropriate. Maintenance dose; Rheumatoid arthritis: After the starting dose, the recommended maintenance dose of Cimzia for adult patients with rheumatoid arthritis is 200 mg every 2 weeks. Once clinical response is confirmed, an alternative maintenance dosing of 400 mg every 4 weeks can be considered. Psoriatic arthritis: After the starting dose, the recommended maintenance dose of Cimzia for adult patients with psoriatic arthritis is 200 mg every 2 weeks. Once clinical response is confirmed, an alternative maintenance dosing of 400 mg every 4 weeks can be considered. Axial spondyloarthritis: After the starting dose, the recommended maintenance dose of Cimzia for adult patients with axial spondyloarthritis is 200 mg every 2 weeks or 400 mg every 4 weeks. After at least 1 year of treatment with Cimzia, in patients with sustained remission, a reduced maintenance dose of 200 mg every 4 weeks may be considered. Crohn's Disease: The recommended initial adult dose of Cimzia is 400 mg (given as two subcutaneous injections of 200 mg) initially, and at Weeks 2 and 4. In patients who obtain a clinical response, the recommended maintenance regimen is 400 mg every four weeks. After the starting dose, the maintenance dose of Cimzia for adult patients with plaque psoriasis is 200 mg every 2 weeks. A dose of 400 mg every 2 weeks can be considered. Method of administration: The total content (1 ml) of the pre-filled syringe should be administered as a subcutaneous injection only. Suitable sites for injection would include the thigh or abdomen. **Renal and hepatic impairment:** Cimzia has not been studied in these patient populations. No dose recommendations can be made. **Paediatric population:** The safety and efficacy of Cimzia in children and adolescents below age 18 years have not yet been established. No data are available. Geriatric population: In elderly patients (≥65 years old) no dose adjustment is required. Population pharmacokinetic analyses showed no effect of age. **Overdose:** No dose-limiting toxicity was observed during clinical trials. Multiple doses of up to 800 mg subcutaneously and 20 mg/kg intravenously have been administered. In cases of overdose, it is recommended that patients are monitored closely for any adverse reactions or effect, and appropriate symptomatic treatment initiated immediately. **Special precautions for storage:** Store in a refrigerator (2°C - 8°C). Do not freeze. Keep the pre-filled syringe in the outer carton in order to protect from light. Keep it in its original package, out of reach and sight of children. **Nature and contents of container:** 2 one ml pre-filled syringe (type I glass) with a plunger stopper (bromobutyl rubber), containing 200 mg of certolizumab pegol and 2 alcohol wipes. **Registration date and number:** 13.12.2012 ve 135/01. **Retail price including VAT and approval date:** 11654.64 TL / 25.07.2023. This abbreviated summary of product characteristics has been prepared in accordance with the Summary of Product Characteristics approved by TR MOH on 16.02.2023. TR-P-CZ-AS-2300017 July 2023 **Legal Category:** Sell by prescription. Call our company for detailed information **UCB Pharma A.Ş. Palladium Tower Barbaros Mah. Karden Sok. No:2 Kat:24/80 34746 Ataşehir, İstanbul Tel: 0 216 538 00 00**

Please refer to the full Prescribing Information in your country before prescribing

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ANOTHER CHAPTER IN SANDOZ BIOSIMILARS IMMUNOLOGY PORTFOLIO

- ✓ Confirmed efficacy and safety in two Phase 3 clinical trials: Rheumatoid arthritis and plaque psoriasis^{*1-4}
- ✓ Proven in first Sandoz-etanercept multiple-switch study to match reference etanercept^{*3-4}
- ✓ Low immunogenicity and a favourable tolerability profile¹⁻⁴
- ✓ Consistent effectiveness in a real-world setting⁵⁻⁷
- ✓ Enhanced patient experience with the SensoReady[®] pen⁸⁻¹⁰



▼ This medicinal product is subject to additional monitoring. This triangle will ensure that new safety information is quickly identified. Reporting ensures continuous follow up of risk benefit ratio of this medicine. Healthcare professionals are expected to report the suspected adverse reactions to Turkish Pharmacovigilance Center TUFAM www.titck.gov.tr; e-mail: tufam@titck.gov.tr; tel: 0312 218 30 00, 0800 314 00 08; fax: 0312218 35 99) and/or related pharmaceutical company officials.

*Erelzi[®] was compared with reference etanercept in the EQUIRA study in adult patients with moderate-to-severe rheumatoid arthritis,⁵ and in the EGALITY study in adult patients with chronic moderate-to-severe plaque psoriasis.^{3,4}

References: 1. Matucci-Cerinic M, et al. RMD Open 2018;4:e000757 & Supplementary material. 2. Jaworski J, et al. Arthritis Res Ther. 2019;21(1):130. 3. Griffiths CEM, et al. Br J Dermatol. 2017; 176:928-38 & Supplementary data. 4. Gerdes S, et al. J Eur Acad Dermatol Venerol. 2018;32:420-27. 5. Colaci M, et al. Ann Rheum Dis. 2021;80:1135. 6. Schmalzing M, et al. Ann Rheum Dis. 2021;80:540. 7. Schmalzing M, et al. Presented at EULAR 2022 Virtual Congress. Abstract 1110. 8. Paul C, et al. J Eur Acad Dermatol Venereol. 2015;29(6):1082-1090. 9. Nash P, et al. Arthritis Res Ther. 2018;20(1):47. 10. Schmalzing M, et al. German Society for Rheumatology (DGRh) 2020.

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