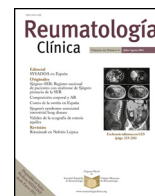




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## Special Article

## Recommendations for the Use of Methotrexate in Psoriatic Arthritis<sup>☆</sup>

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### ABSTRACT

**Objectives:** To develop recommendations for the management of methotrexate (MTX) in psoriatic arthritis (PsA), based on best evidence and experience.

**Methods:** A group of 12 experts on MTX use was selected. The coordinators formulated 14 questions about the use of MTX in PsA patients (indications, efficacy, safety and cost-effectiveness). A systematic review was conducted to answer the questions. Using this information, inclusion and exclusion criteria were established, as were the search strategies (Medline, EMBASE and the Cochrane Library were searched). Two different reviewers selected the articles. Evidence tables were created. At the same time, European League Against Rheumatism and American College of Rheumatology abstracts were evaluated. Based on this evidence, the coordinators proposed 12 preliminary recommendations that the experts discussed and voted on in a nominal group meeting. The level of evidence and grade of recommendation were established using the Oxford Center for Evidence Based Medicine and the level of agreement with the Delphi technique (two rounds). Agreement was established if at least 80% of the experts voted yes (yes/no).

**Results:** A total of 12 preliminary recommendations on the use of MTX were proposed, 9 of which were accepted. One was included in a different recommendation and other two were not voted on and were thereafter clarified in the main text.

**Conclusions:** These recommendations aim to answer frequent questions and help in decision making strategies when treating PsA patients with MTX.

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## Recomendaciones sobre el uso de metotrexato en pacientes con artritis psoriásica

### R E S U M E N

*Palabras clave:*  
Metotrexato  
Artritis psoriásica  
Recomendaciones

**Objetivos:** Desarrollar recomendaciones sobre el uso de metotrexato (MTX) en pacientes con artritis psoriásica (APs) basadas en la mejor evidencia y experiencia.

**Métodos:** Se seleccionó un grupo de 12 expertos reumatólogos en el manejo de MTX. Los coordinadores generaron 14 preguntas sobre el uso de MTX en pacientes con APs (perfiles de indicación, eficacia y seguridad) para ser contestadas mediante una revisión sistemática de la literatura. En función de las preguntas se definieron los criterios de inclusión y exclusión y las estrategias de búsqueda (para interrogar Medline, Embase y la Cochrane Library). Dos revisores seleccionaron los artículos resultantes de la búsqueda. Se generaron tablas de evidencia. Paralelamente se evaluaron abstracts de congresos de EULAR y ACR. Con toda esta evidencia los coordinadores generaron 12 recomendaciones preliminares que se evaluaron, discutieron y votaron en una reunión de grupo nominal con el resto de expertos. Para cada recomendación se estableció el nivel de evidencia, grado de recomendación, y grado de acuerdo mediante un Delphi. Se definió acuerdo si al menos el 80% de los participantes contestan sí a la recomendación (sí o no).

**Resultados:** De las 12 recomendaciones preliminares se aceptaron 9 recomendaciones sobre el uso de MTX en la APs. Una se englobó en otra y otras 2 no se llegaron a votar porque se decidió no incluirlas, pero se comentan en el texto final.

**Conclusiones:** Estas recomendaciones pretenden resolver algunos interrogantes clínicos habituales y facilitar la toma de decisiones con el uso de MTX en la APs.

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## Introduction

Psoriatic arthritis (PsA) is a chronic inflammatory disease that commonly affects patients with psoriasis. The prevalence of psoriasis is around 2%–3% of the general population,<sup>1</sup> and 20%–30% of those patients will develop PsA.<sup>2</sup> Musculoskeletal involvement in PsA can be highly varied, including the axial skeleton, peripheral joints, enthesitis and dactylitis.<sup>3</sup> The course of this disease is also variable, there being very aggressive forms, with considerable joint damage and disability.<sup>2,4</sup>

Concerning treatment, there are now a number of drugs, both for the skin manifestations and the musculoskeletal involvement, that pursue the complete control of the inflammation and an improvement in the quality of life of the patients.<sup>5,6</sup>

Despite the broad consensus on the efficacy of methotrexate (MTX) in PsA in clinical practice, its inclusion as the preferred disease-modifying antirheumatic drug (DMARD) in the recommendations of the European League Against Rheumatism (EULAR)<sup>7</sup> and the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA),<sup>8</sup> and its widespread use among rheumatologists, the scientific evidence is limited in certain aspects. Moreover, in the setting of spondyloarthritides (including PsA), in Spain, we have observed a great variability in the use of DMARDs, including MTX.<sup>9</sup>

Taking into account the above uncertainties, the objective of the present report is to draw up recommendations, based on the best possible evidence and experience, concerning the use of MTX in PsA patients.

## Methods

For building consensus, we followed the nominal group and Delphi method. The preparation of the document involved the distribution of tasks and comments to the participants, with the aid of a systematic literature review (SLR) and of a methodologist.

First, we established a group of 12 experts, representing all of the geographic areas of Spain. They had demonstrated experience in the management of patients with PsA and in the use of MTX. For their selection, we performed a search in MEDLINE that identified Spanish rheumatologists with publications on the subject of

the present document, as well as related works submitted to the meeting of the Spanish Society of Rheumatology (SER).

### Systematic Literature Review

The 2 coordinators of the project provided 14 questions. Given their characteristics, it was seen that they could be responded to with a single SLR (Table 1). With these questions, we defined the criteria for inclusion and exclusion. We searched for articles that involved PsA patients being treated with MTX, regardless of the dose and route of administration. These studies should analyze distinct aspects of the efficacy and safety of the drug treatment. Finally, we included only studies with the following designs: meta-analyses, systematic reviews, randomized controlled trials (RCTs), nonrandomized studies with a valid comparator group and observational studies (prospective, retrospective and cross-sectional). We searched the following bibliographic databases: MEDLINE (from inception to July 2016), EMBASE (from inception to July 2016) and Cochrane Library (from inception to July 2016). We used MeSH terms and free text, and the search was performed with the help of an expert informationist. For each review, two reviewers (EL and TO) independently analyzed the articles returned in the search of the different bibliographic databases, and prepared a detailed analysis of the included articles. In the case of discrepancy, the difference was resolved by a third person (LC). We reviewed the gray literature from the EULAR and American College of Rheumatology meetings of the preceding 2 years, as well as documentation provided by the coordinator (articles and abstracts from congresses and other forums of interest).

Subsequently, we performed a secondary hand-search of the reference lists of the articles that were ultimately included. To evaluate the methodological quality of the included reports, we utilized the Jadad scale for clinical trials and that of the Oxford Center for Evidence-Based Medicine for the remaining designs. We created evidence tables and tables showing the results that describe the main characteristics and findings of the included studies.

### Nominal Group Meeting and Delphi

The group of experts held a nominal group meeting, once they were provided with the results of the SLR, together with the major

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