

PROCESS FOR REQUESTING INCLUSION OF OFF-LABEL INFORMATION IN MICROMEDEX[®] DATABASES

The Healthcare business of Thomson Reuters is recognized worldwide as a provider of unbiased information in the areas of drugs, disease, and toxicology. Our Micromedex content facilitates the practice of evidence-based medicine whereby the clinician can identify best practices and choose the most appropriate treatment plan for a specific patient.

The proprietary, unbiased information contained in Micromedex products is based on an ongoing editorial review of primary literature published in thousands of peer-reviewed journals as well as FDA-approved product labeling. Inclusion of information is determined through identification of relevant literature and through the use of validated and documented literature evaluation techniques that assess methodological rigor, appropriateness of statistical analyses, as well as clinical relevance. Micromedex surveillance of the literature is extensive and continuous.

EXTERNAL REQUESTS FOR INCLUSION OF INFORMATION

In addition to our rigorous internal processes, Thomson Reuters occasionally receives external requests for inclusion of information in our Micromedex databases. We adhere to a policy under which external requests may be submitted for consideration. If there are certain articles or studies you would like to forward to us for consideration, submit your request in writing.

This request must include the following:

- Name of requestor
- Date of submission
- Affiliation of requestor (e.g., name of pharmaceutical company, organization, institution, etc.)
- Disclosure of relevant financial relationships with a bearing on the drug or product(s) in question
- Contact information including address, phone number, and e-mail address
- Identification and brief explanation of request (should clearly indicate if request involves a patient safety issue)
- If applicable, a statement describing the proposed indication including:
 - Specific disease state
 - Specific patient population
 - Whether the treatment involves mono- or combination therapy
- If the treatment involves combination therapy, address specific components of the therapy
- Evidence base for request including all negative and/or inconclusive findings and certification of inclusion of all such findings; a complete bibliography; and two (2) reprints of original articles, abstracts, poster presentations, or other documentation. All submitted journal articles, abstracts, and conference presentations must be reprints/reproductions from the journal and/or conference proceeding. The preceding items that are not reprints/reproductions will be disregarded. For unpublished findings or findings published in abstracts, proceedings, or poster presentations, additional details about methodology (e.g., statistical tests, power determination, and randomization procedures) and results should be included (e.g., IRB Papers, original poster presentation submissions, trial protocols, detailed study results, etc.).



Evidence in the form of randomized, controlled trials published in peer-reviewed journals is preferred. Unpublished information indicating potential breakthrough therapies will be considered. Animal studies will not be considered. All submitted evidence may be referenced at the discretion of Thomson Reuters. Furthermore, Thomson Reuters will retain on file all submitted information—published and unpublished—in accordance with internal policy and as allowable under U.S. copyright law.

We are unable to provide any feedback or response regarding any literature/evidence submitted. All requests will be reviewed in accordance with established policies on content development, including the Policy on Off-Label Indications. Furthermore, if submitted information warrants inclusion in Micromedex databases, we cannot provide the requestor with a prepublication copy of text. Finally, the inclusion or exclusion of information in our databases as well as assignment of an efficacy rating or other relevant ratings is at the sole discretion of editorial staff.

Thomson Reuters reserves the right to modify its policy on requesting inclusion of information in its databases, as deemed appropriate.

SUBMISSIONS SHOULD BE MAILED TO:

Thomson Reuters
Attn: Editorial Assistant
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Greenwood Village, CO 80111

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