

Miconazole Nitrate

Type of Posting: Notice of Intent to Revise

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Expert Committee: Monographs-Chemical Medicines 6

In accordance with section 7.04 (c) of the 2015–2020 Rules and Procedures of the Council of Experts, this is to provide notice that the Chemical Medicines Monographs 6 Expert Committee intends to revise the Miconazole Nitrate monograph.

Comments with supporting data were received that indicate the *Optical Rotation <781S>, Procedure, Specific Rotation* is not the appropriate procedure to determine the optical rotation of Miconazole Nitrate. Based on submitted data, the Chemical Medicines Monographs 6 Expert Committee proposes to revise the Miconazole Nitrate monograph to change the procedure to *Optical Rotation <781A>, Procedure, Angular Rotation* measured at 20°. This revision will be processed as an accelerated revision to accommodate products in the market.

The Miconazole Nitrate Revision Bulletin will supersede the currently official monograph.

Should you have any questions, please contact Richard Nguyen, Scientific Liaison to the Chemical Medicines Monograph 6 Expert Committee at (301–816–8170 or rbn@usp.org).

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