
Dydrogesterone

Type of Posting: Notice of Intent to Revise

Posting Date: 31– May –2019

Targeted Official Date: 01–Dec–2020, *USP 43-NF 37, Second Supplement*

Expert Committee: Chemical Medicines Monographs 5

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 5 Expert Committee intends to revise the Dydrogesterone monograph.

USP may propose to omit a monograph from the *USP-NF* if the article is no longer marketed in the United States and where the monograph is not necessary to serve a public health need. Monographs may also be proposed for omission to address safety concerns. Based on evaluation of the monograph, the USP Chemical Medicines Monographs 5 Expert Committee has determined that the Dydrogesterone monograph should be proposed for omission in the *Pharmacopeial Forum* (PF).

USP Dydrogesterone RS, associated with this monograph, is currently unavailable. USP does not intend to develop a replacement lot for USP Dydrogesterone RS in anticipation of the omission of this monograph.

It is anticipated that the proposed revision will be published in *PF* 45(5) [Sep.–Oct. 2019].

Should you have any questions, please contact Morgan Puderbaugh, Senior Scientific Liaison (301–816–8373 or mxp@usp.org).