



Fagron

Pentravan Safety Routes of Administration

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Scope: Pentravan® by Dermal or Vaginal Routes of Administration.

Dear Valued Customer / Partner:

Pentravan® is an oil-in-water emulsion capable to establish a greater rate and extent of absorption of the API than other transdermal bases. It has been [broadly studied](#) for a variety of applications and many studies for dermal routes of administration can be found in this link. The ingredients used in the formulation of Pentravan® are Generally Recognized as Safe when used in accordance with their intended purpose by the United States FDA.

Among the various studies are published and unpublished studies with Vaginal or Vulvar routes of administration. These are summarized as follows:

Active Pharmaceutical Ingredient	Delivered Dose	Route of Administration	No. of subjects	Clinical Condition	Reference
Gestrinone 5mg/mL	5mg/day	Vaginal	47	Endometriosis	MAIA Jr.et al., 2015
Gestrinone 5mg/mL	5mg/day	Vaginal	15	Endometriosis	MAIA Jr et al., 2014a
Gestrinone 2.5mg/mL	2.5mg/day	Vaginal	20	Endometriosis	MAIA Jr et al., 2016
Danazol 100mg/mL	100mg/day	Vaginal	14	Endometriosis	MAIA Jr.et al., 2014b
Testosterone 3mg/mL	3mg/day	Vulvar	26	Vaginal Atrophy	MAIA Jr.et al., 2013
Resveratrol 100mg/mL plus (vitamin D3) 5000 IU/mL	100mg/day Resveratrol plus 50000 IU/day Vitamin D3	Vaginal	33	Endometriosis	MAIA et al., 2016 (unpublished)
Valproic acid 250mg/mL plus Gestrinone 5mg/mL	250mg/day (Valproic acid) plus 5mg (Gestrinone)	Vaginal	33	Endometriosis	33 MAIA et al., 2016

None of these studies reported irritation, adverse events, or safety considerations. Further, Pentravan® has been in active circulation in the market since before 2008, without complaints alleging safety issues. It is acknowledged that this fact is anecdotal.



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Based on a review of the published clinical studies, safety of ingredients, and product history, Fagron can state that this **evidence is consistent with safe use in topical and vaginal routes of administration.**

Date:
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This information is provided to the best of our knowledge and belief based on a review of current composition and product history. However, there have been no formal assessments to confirm these statements.