



Ovaleap® (Follitropin alfa)

Solution for injection with 600 IU Follitropin alfa per ml in prefilled cartridge: 300 IU/0.5 ml, 450 IU/0.75 ml, 900 IU/1.5 ml.

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Document Version: 1.0
Document Date: 18 December 2020
Based on EU RMP version 3.3 (25 September 2020)

Disclaimer: The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of Ovaleap® is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Ovaleap® in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Theramex Ireland Limited is fully responsible for the accuracy and correctness of the content of the published summary RMP of Ovaleap®.

SUMMARY OF THE EU RISK MANAGEMENT PLAN

Safety concern	Proposed pharmacovigilance activities (routine and additional)	Proposed risk minimisation activities (routine and additional)
<i>Important identified risks</i>		
None		
<i>Important potential risks</i>		
None		
<i>Important missing information</i>		
None		