



16 February 2017  
EMA/46102/2017

### Shortage of Orgalutran (ganirelix) solution for injection in a pre-filled syringe

<b>Indication</b>	Orgalutran is used to prevent premature ovulation (early release of eggs from the ovary) in women having fertility treatment and who are having ovarian stimulation (stimulation of the ovaries so that they produce more eggs).
<b>Reason for shortage</b>	Due to manufacturing capacity issues Orgalutran is currently in short supply. The company is addressing the issues, which are expected to be resolved by the end of March 2017.
<b>Member States affected<sup>1</sup></b>	Most EU Member States where Orgalutran is marketed: Belgium, Croatia, Denmark, Estonia, France, Greece, Ireland, Italy, Latvia, Lithuania, Malta, Portugal, Slovenia, Spain, Sweden, the Netherlands, as well as Norway.
<b>Information for healthcare professionals</b>	<ul style="list-style-type: none"><li>• A letter from the marketing authorisation holder has been sent to healthcare professionals in the affected countries to inform them of the supply problems.</li><li>• While the shortage is ongoing, remaining stock should only be used for patients who are already being treated with Orgalutran. No new patients should be started on Orgalutran and alternative treatment should be considered.</li><li>• Additional advice may be available from the <a href="#">national competent authority</a>.</li></ul>
<b>Information for patients</b>	<ul style="list-style-type: none"><li>• Orgalutran is currently in short supply.</li><li>• While the shortage is ongoing, remaining stocks will only be used in patients who are already being treated with Orgalutran. No new patients will be started on Orgalutran and doctors may use an alternative treatment.</li><li>• Patients who have any questions should speak to their doctor or pharmacist.</li><li>• Additional advice may be available from the <a href="#">national</a></li></ul>

<sup>1</sup> This information may change. For up-to-date information about the status of a medicine shortage in a particular Member State, contact the national competent authority.

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	<a href="#">competent authority.</a>
<b>Status</b>	Ongoing