

6.13 FOLLITROPIN ALFA + LUTROPIN ALFA AND LUTROPIN ALFA follitropin alfa 150 units + lutropin alfa 75 units [1 vial] (& inert substance diluent [1 vial], 1 pack lutropin alfa 75 international units injection [1 x 75 international units vial] (& inert substance diluent [1 x 1 mL vial], 1 pack Pergoveris® and Luveris®, Merck Serono Australia Pty Ltd

1 Purpose of Application

1.1 The minor submission requested an increase to the maximum quantities of follitropin alfa + lutropin and lutropin alfa.

2 Requested listing

2.1 The submission requested an increase to the maximum quantities of the existing listings. A maximum quantity of 14 packs is proposed - currently the maximum quantity is seven (7) packs.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
FOLLITROPIN ALFA + LUTROPIN ALFA follitropin alfa 150 units + lutropin alfa 75 units [1 vial] (& inert substance diluent [1 vial], 1 pack	14	0	Pergoveris®	Merck Serono Australia

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
LUTROPIN ALFA lutropin alfa 75 international units injection [1 x 75 international units vial] (& inert substance diluent [1 x 1 mL vial], 1 pack	14	0	Luveris®	Merck Serono Australia

For more details on PBAC's view, see section 6 "PBAC outcome"

3 Background

3.1 Follitropin alfa + lutropin alfa and lutropin alfa are currently listed on the PBS under the Section 100 IVF program for stimulation of follicular development.

4 Consideration of the evidence

- 4.1 The minor submission presented the following documentation as supporting evidence for an increase to the maximum quantities of follitropin alfa + lutropin alfa and lutropin alfa:
- Clinical evidence previously presented to the PBAC, including:
 - Meta-analysis reported by Lehert et al (2014)
 - Study 2008, placebo controlled registration trial for lutropin alfa
 - Phase III observational trial, Burgues et al (2011)
 - Survey of fertility clinicians conducted for the March 2014 follitropin alfa + lutropin alfa submission
 - Data from the Merck Serono patient access program
 - Results of a survey of 83 expert fertility clinicians
 - PBS prescribing data for follitropin alfa + lutropin alfa and lutropin alfa
- 4.2 The basis of the minor submission's request was that the maximum quantity should provide for a clinically appropriate duration of treatment and for consistency with the maximum quantities for other products used for ovarian stimulation, i.e. follitropin alfa, follitropin beta, and human menopausal gonadotrophin.
- 4.3 The submission claimed that a quantity of 14 vials is considered clinically appropriate and would provide for a sufficient duration of treatment of ovarian stimulation and follicular development for the majority of patients.

For more details on PBAC's view, see section 6 "PBAC outcome"

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item as it was a minor submission.

Consumer comments

- 5.2 The PBAC noted that no consumer comments were received for this item.

6 PBAC Outcome

- 6.1 The PBAC recommended amending the maximum PBS quantities for the current Section 100 listings of follitropin alfa + lutropin alfa and lutropin alfa from seven to 14, consistent with the maximum PBS quantities available for other drugs used for ovarian stimulation.
- 6.2 The PBAC noted that the maximum PBS quantity for other Section 100 IVF drugs, including follitropin alfa, follitropin beta and human menopausal gonadotrophin, provide for at least 11 to 15 days of treatment, while the current maximum quantities (7) for follitropin alfa + lutropin alfa and lutropin alfa only provide for seven days of treatment. The PBAC considered that the requested increase in maximum quantity to 14 vials would be clinically appropriate and would provide for a sufficient duration of treatment.

Outcome:
Recommended

7 Recommended listing

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
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Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
LUTROPIN ALFA lutropin alfa 75 international units injection [1 x 75 international units vial] (&) inert substance diluent [1 x 1 mL vial], 1 pack	14	0	Luveris®	Merck Serono Australia

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

9 Sponsor's Comment

Merck Serono is pleased that the PBAC recognises that optimal quality use of medicine for Luveris and Pergoveris requires that the duration of treatment, and therefore the Maximum Quantities, needed to be extended, in accordance with consistent feedback from expert fertility clinicians in Australia.