

**6.10 DEGARELIX,  
Powder for injection 80 mg (as acetate), injection set,  
Powder for injection 120 mg (as acetate), injection set,  
Firmagon<sup>®</sup>, Ferring Pharmaceuticals Pty Ltd.**

**1 Purpose of Application**

- 1.1 The minor submission requested amending the PBS listings of degarelix for locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate from an Authority Required (STREAMLINED) to a Restricted Benefit. The submission requested this change for consistency with the PBS listed gonadotrophin releasing hormone (GnRH) agonists (goserelin, leuprorelin, and triptorelin), all of which have Restricted Benefit listings.

**2 Requested listing**

- 2.1 The submission requested the restriction level be changed from an Authority Required (STREAMLINED) to a Restriction Benefit for the following listings:
- 2784M: Firmagon<sup>®</sup> 80mg
  - 2785N: Firmagon<sup>®</sup> 120mg

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

**3 Background**

- 3.1 Degarelix, a GnHR antagonist was recommended at the July 2010 PBAC meeting for the treatment of locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate on a cost-minimisation basis to leuprorelin, a GnRH agonist. There are two other PBS-listed GnRH antagonists, certrorelix and ganirelix, but these are only listed for use in assisted reproductive technology.
- 3.2 Goserelin, a GnRH agonist also used in the treatment of carcinoma of the prostate, was changed from an Authority Required (STREAMLINED) to a Restricted Benefit on 1 May 2015 for carcinoma of the prostate. This change was subsequently applied to the other GnRH agonists, leuprorelin and triptorelin.

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

**4 Clinical place for the proposed therapy**

- 4.1 Degarelix is a selective GnRH receptor antagonist that competitively and reversibly binds to the pituitary GnRH receptors with nanomolar potency, thereby reducing the release of gonadotrophins and consequently testosterone.
- 4.2 The submission argued that although degarelix is a GnRH receptor antagonist,

ultimately both GnRH agonists and antagonists inhibit the production and release of the gonadotrophins, and subsequently reduce testosterone production. The submission argued that these products are used in the same clinical setting and noted that degarelix was listed on a cost-minimisation basis to the GnRH agonist leuprorelin.

- 4.3 The submission argued that it would be reasonable to have consistency across the GnRH analogues that are used for the treatment of carcinoma of the prostate.

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

## **5 Consideration of 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.

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

### ***Estimated PBS usage and financial implications***

- 5.3 The submission did not request a change to the existing patient population, and therefore argued that the change is expected to have nil financial impact on the PBS. The PBAC considered that changing the authority level to a Restricted Benefit should not increase uptake of degarelix.

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

## **6 PBAC Outcome**

- 6.1 The PBAC recommended amending the PBS listings of degarelix from Authority Required (STREAMLINED) to a Restricted Benefit for the treatment of locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate to be consistent with the PBS listed gonadotrophin releasing hormone (GnRH) agonists (goserelin, leuprorelin and triptorelin), which are also used in this treatment setting.
- 6.2 The PBAC noted that degarelix is used in the same clinical setting, and has the same restriction text, as the GnRH agonists. The PBAC also noted that degarelix was listed on a cost-minimisation basis to leuprorelin, and the requested change was not expected to increase utilisation. The PBAC therefore considered that it would be reasonable to make the restriction level for degarelix consistent with the restrictions for goserelin, leuprorelin, and triptorelin.

- 6.3 The PBAC noted that this submission was not eligible for an Independent Review as it received a positive recommendation.

**Outcome:**

Recommended

**7 Recommended listing**

- 7.1 Amend existing listing as follows:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
DEGARELIX degarelix 80 mg injection [1 vial] (& inert substance diluent [1 syringe], 1 pack	1	5	Firmagon 80mg	Ferring Pharmaceutical Pty Ltd
degarelix 120 mg injection [2 vials] (& insert substance diluent [2 syringes], 1 pack	1	0	Firmagon 120mg	

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>PBS Indication:</b>	Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate
<b>Restriction Level / Method:</b>	<input checked="" type="checkbox"/> Restricted benefit

**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**

Ferring welcomes the PBAC decision to recommend a change to the restriction level of degarelix from “Authority Required (STREAMLINED)” to “Restricted Benefit”.