

14.3 MINOR LISTINGS AND CHANGES TO LISTINGS PROCESSED BY THE SECRETARIAT

ENOXAPARIN

**20 mg/0.2 mL injection, 10 x 0.2 mL pre-filled syringes,
40 mg/0.4 mL injection, 10 x 0.4 mL pre-filled syringes,
60 mg/0.6 mL injection, 10 x 0.6 mL pre-filled syringes,
80 mg/0.8 mL injection, 10 x 0.8 mL pre-filled syringes,
100 mg/1.0 mL injection, 10 x 1.0 mL pre-filled syringes,
Clexane Safety-Lock[®], Sanofi-Aventis Australia Pty Ltd**

1 Purpose of application

- 1.1 To request listing of a new presentation of safety-lock pre-filled syringes of enoxaparin on the PBS.

2 PBAC Outcome

- 2.1 The PBAC considered enoxaparin (Clexane Safety-Lock[®]) as price equivalent to that of the currently PBS-listed enoxaparin (Clexane[®]) for all available strengths and indications.
- 2.2 The PBAC recommended enoxaparin (Clexane Safety-Lock[®]) and enoxaparin (Clexane[®]) should be considered equivalent for the purposes of substitution.
- 2.3 The PBAC recommend listing on the PBS under the conditions as outlined below.

3 Recommended listing

Unrestricted Benefit

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer	
ENOXAPARIN SODIUM					
enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes	2	20	0	Clexane Safety-Lock®	SW
enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes	2	20	0	Clexane Safety-Lock®	SW
enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes	1	10	1	Clexane Safety-Lock®	SW
enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes	1	10	1	Clexane Safety-Lock®	SW
enoxaparin sodium 100 mg/1 mL injection, 10 x 1 mL syringes	1	10	1	Clexane Safety-Lock®	SW

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners

Restricted Benefit for patients undergoing haemodialysis.

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer	
ENOXAPARIN SODIUM					
enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes	2	20	3	Clexane Safety-Lock®	SW
enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes	2	20	3	Clexane Safety-Lock®	SW
enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes	2	20	3	Clexane Safety-Lock®	SW
enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes	2	20	3	Clexane Safety-Lock®	SW
enoxaparin sodium 100 mg/1 mL injection, 10 x 1 mL syringes	2	20	3	Clexane Safety-Lock®	SW

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners

Condition:	Haemodialysis
PBS Indication:	Haemodialysis
Restriction Level / Method:	Restricted benefit

4 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.

5 Sponsor's Comment

The sponsor had no comment.