

5.16 ENOXAPARIN,

Injection containing enoxaparin sodium 20 mg

(2,000 I.U. anti-Xa) in 0.2 mL pre-filled syringe;

Injection containing enoxaparin sodium 40 mg

(4,000 I.U. anti-Xa) in 0.4 mL pre-filled syringe;

Injection containing enoxaparin sodium 60 mg

(6,000 I.U. anti-Xa) in 0.6 mL pre-filled syringe;

Injection containing enoxaparin sodium 80 mg

(8,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe;

Injection containing enoxaparin sodium 100 mg

(10,000 I.U. anti-Xa) in 1 mL pre-filled syringe,

Exarane™,

Injection containing enoxaparin sodium 120 mg

(12,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe;

Injection containing enoxaparin sodium 150 mg

(15,000 I.U. anti-Xa) in 1 mL pre-filled syringe,

Exarane Forte™,

Juno Pharmaceuticals Pty Ltd

1 Purpose of Submission

- 1.1 The Category 3 submission requested the PBS listing of a new biosimilar brand of enoxaparin (Exarane™) on the General Schedule (Section 85) under the same circumstances as the PBS-listed reference biologic Clexane Safety-Lock® for the prevention of thrombo-embolic disorders.
- 1.2 The submission also requested listing of two new strengths of enoxaparin, 120 mg in 0.8 mL and 150 mg in 1 mL (Exarane Forte™) that are not currently on the PBS, under the same circumstances as the PBS-listed reference biologic Clexane Safety-Lock for the prevention of thrombo-embolic disorders.

2 Background

Registration status

- 2.1 The TGA Delegate's Overview (DO) was supportive of registering Exarane and Exarane Forte with the same indications as the reference brand, Clexane®.
- 2.2 The Delegate was satisfied of the biosimilarity of Exarane and Exarane Forte with Clexane. The TGA evaluation report uses the term Clexane to refer to both Clexane and Clexane Safety-Lock brands, therefore it can be inferred that the TGA DO was satisfied of the biosimilarity of Exarane and Exarane Forte with Clexane Safety-Lock.
- 2.3 Exarane and Exarane Forte were TGA approved on 27 June 2023.

Previous PBAC consideration

- 2.4 Exarane and Exarane Forte have not been previously considered by the PBAC.
- 2.5 Clexane 20 mg/0.2 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL and 100 mg/mL were delisted from the PBS on 1 October 2021. Clexane Safety-Lock is currently the only PBS-listed brand of enoxaparin on the PBS. It has Unrestricted Benefit and Restricted Benefit listings on the General Schedule for haemodialysis in the following strengths: 20 mg/0.2 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL and 100 mg/mL.
- 2.6 At its November 2014 meeting, the PBAC recommended that Clexane and Clexane Safety-Lock should be considered equivalent for the purposes of substitution (enoxaparin public summary document, November 2014).
- 2.7 At its July 2019 meeting, the PBAC recommended the Unrestricted Benefit listing of Clexane Safety-Lock 120 mg/0.8 mL and 150 mg/mL. At its July 2020 meeting, the PBAC recommended the Restricted Benefit and Unrestricted Benefit listings of Enoxapo® 120 mg/0.8 mL and 150 mg/1 mL. However, neither of these recommendations has proceeded to PBS listing.

3 Requested listing

- 3.1 The submission requested listing Exarane under the same circumstances as the currently PBS-listed brand Clexane Safety-Lock, and also requested two new strengths of enoxaparin (Exarane Forte): 120 mg/0.8 mL and 150 mg/mL.
- 3.2 The requested restriction is shown below. Secretariat suggested additions are in italics.

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Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ENOXAPARIN					
enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes	8558K	2	20	1	Clexane Safety-Lock ^a Exarane ^a
enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes	8510X	2	20	1	Clexane Safety-Lock ^a Exarane ^a
enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes	8262W	1	10	1	Clexane Safety-Lock ^a Exarane ^a
enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes	8263X	1	10	1	Clexane Safety-Lock ^a Exarane ^a
enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes	8264Y	1	10	1	Clexane Safety-Lock ^a Exarane ^a
enoxaparin sodium 120 mg/0.8 mL injection, 10 x 0.8 mL syringes	NEW	1	10	1	Exarane Forte
enoxaparin sodium 150 mg/mL injection, 10 x 1 mL syringes	NEW	1	10	1	Exarane Forte

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
Benefit Type: <input checked="" type="checkbox"/> Unrestricted benefit
Administrative Advice: <i>Biosimilar prescribing policy</i> <i>Prescribing of the biosimilar brand Exarane and Exarane Forte is encouraged for treatment naive patients.</i> <i>Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information about Biosimilar Uptake Drivers can be found on the PBS Biosimilars webpage (www.pbs.gov.au/info/general/biosimilars).</i>

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ENOXAPARIN					
enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes	8716R	2	20	3	Clexane Safety-Lock ^a Exarane ^a
enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes	8639Q	2	20	3	Clexane Safety-Lock ^a Exarane ^a
enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes	8640R	2	20	3	Clexane Safety-Lock ^a Exarane ^a
enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes	5434B	2	20	3	Clexane Safety-Lock ^a Exarane ^a
enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes	5435C	2	20	3	Clexane Safety-Lock ^a Exarane ^a
enoxaparin sodium 120 mg/0.8 mL injection, 10 x 0.8 mL syringes	NEW	1	10	3	Exarane Forte
enoxaparin sodium 150 mg/mL injection, 10 x 1 mL syringes	NEW	1	10	3	Exarane Forte

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

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Benefit Type: <input checked="" type="checkbox"/> Restricted benefit
Indication: Haemodialysis
Administrative Advice: <i>Biosimilar prescribing policy</i> <i>Prescribing of the biosimilar brand Exarane and Exarane Forte is encouraged for treatment naive patients.</i> <i>Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information about Biosimilar Uptake Drivers can be found on the PBS Biosimilars webpage (www.pbs.gov.au/info/general/biosimilars).</i>

- 3.3 The sponsor requested that Exarane and Clexane Safety-Lock be ‘a’ flagged for the purposes of substitution. The Secretariat noted that the PBAC recommended the Enoxapo brand of enoxaparin be “a” flagged to Clexane Safety-Lock at its July 2020 meeting (enoxaparin Public Summary Document (PSD) July 2020 PBAC meeting). The PBAC advised that this was reasonable.
- 3.4 The sponsor was supportive of the addition of an administrative note to encourage the uptake of biosimilar prescribing for treatment-naïve patients. The Secretariat noted that the PBAC recommended the note be applied to the Enoxapo brand of enoxaparin at its July 2020 meeting (enoxaparin PSD July 2020 PBAC meeting).

4 Comparator

- 4.1 The submission nominated Clexane Safety-Lock as the main comparator.
- 4.2 Clexane Safety-Lock has an automatic safety-lock system which retracts and seals the needle once the dose is administered. The Pre-PBAC response noted that the lack of a safety-lock system should not impact the listing of Exarane and Exarane Forte. This has been previously considered by the PBAC at its November 2014 meeting where the addition of a safety-lock mechanism to Clexane did not constitute any change to the listing of Clexane Safety-Lock.

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item.

Consumer comments

- 5.2 The PBAC noted and welcomed the input from individuals (1) via the Consumer Comments facility on the PBS website. The comment raised general safety concerns regarding biosimilar drugs.

Clinical claim

- 5.3 The submission claimed that Exarane and Exarane Forte were non-inferior in terms of efficacy and safety to the comparator, Clexane Safety-Lock. The TGA Delegate’s

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Overview was satisfied with the biosimilarity of Exarane and Exarane Forte to the reference brand of Clexane.

Economic analysis

- 5.4 The Sponsor requested that the ex-manufacturer prices for Exarane 20 mg/0.2 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL and 100 mg/mL be equivalent to the price of the corresponding PBS-listed formulation of Clexane Safety-Lock.
- 5.5 This is based on the equi-effective dose of 1 mg Exarane = 1 mg of Clexane Safety-Lock.
- 5.6 For the 120 mg/0.8 mL and 150 mg/mL strengths of Exarane Forte, the submission proposed that the price be calculated on a cost-minimisation basis against the 80 mg/0.8 mL formulation, as the 80 mg/0.8 mL therapy was the least expensive item on a cost per milligram basis, using the AEMP prices at \$0.86/mg.
- 5.7 At its July 2019 and July 2020 meetings, the PBAC recommended that the listing of the 120 mg and 150 mg strengths for the enoxaparin brands Clexane Forte®, Enoxaparin Winthrop®, Clexane Forte Safety-Lock® and Enoxapo should be cost minimised against the 100 mg price (para 6.4, enoxaparin PSD, July 2019 PBAC meeting, and para 6.3 enoxaparin PSD, July 2020 PBAC meeting). However, due to a price increase on 1 October 2021, the 80 mg strength now has the lowest price per milligram AEMP among the enoxaparin strengths.
- 5.8 The calculation of these prices is shown in Table 1 and Table 2 below.

Table 1: Cost per mg of currently PBS listed strengths (AEMP of Clexane Safety-Lock)

Strength	AEMP	Cost per mg
Clexane safety-lock 20 mg/0.2 mL	\$33.58	\$1.68
Clexane safety-lock 40 mg/0.4 mL	\$37.53	\$0.94
Clexane safety-lock 60 mg/0.6 mL	\$64.97	\$1.08
Clexane safety-lock 80 mg/0.8 mL	\$69.08	\$0.86
Clexane safety-lock 100 mg/mL	\$91.60	\$0.92

Source: Table 3-2, p 23 of the submission.

Table 2: Proposed AEMP for Exarane Forte 120 mg and 150 mg strengths

Product	Cost per mg	Mg of product	AEMP	Note
Clexane Safety-Lock, 80 mg/mL	\$0.8635	80	\$69.08	Currently listed price
Exarane Forte 120 mg/0.8 mL	\$0.8635	120	\$ 103.62	Priced at same cost per mg as 80 mg
Exarane Forte 150 mg/mL	\$0.8635	150	\$ 129.53	Priced at same cost per mg as 80 mg

Source: Table 3-3, p 23 of the submission, with additions by Secretariat.

Requested AEMP = cost per mg of Clexane Safety-Lock 80 mg x mg of Exarane Forte product

- 5.9 As a Category 3 submission, the economic analysis has not been independently evaluated.

Estimated PBS usage and financial implications

- 5.10 The submission claimed that the 20 mg/0.2 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL and 100 mg/mL formulations of Exarane would replace corresponding PBS-listed formulations of Clexane Safety-Lock, with no expected market growth. The submission noted that the extent of the switch is uncertain.
- 5.11 The submission stated that the financial impact would be a minor save because listing of the Exarane Forte 120 mg/0.8 mL and 150 mg/mL may replace additive therapies of lower strengths with a higher cost per milligram to reach the required dose. Examples of these potential cost-saving are presented in Table 3.

Table 3: Cost savings of the new strengths at individual patient level

New presentation	AEMP	Additive therapies replaced	AEMP	Difference (Savings)
Exarane Forte 120 mg	\$ 103.62	100 mg + 20 mg	\$ 125.18	\$ 21.56
		60 mg + 60 mg	\$ 129.94	\$ 26.32
		80 mg + 40 mg	\$ 106.61	\$ 2.99
Exarane Forte 150 mg	\$ 129.53	80 mg + 80 mg	\$ 138.16	\$ 8.64
		100 mg + 60 mg	\$ 156.57	\$ 27.05

Source: Table 3-4, p 24 of the submission.
Costs are calculated using AEMP.

- 5.12 The submission estimated that 10% of the total scripts of 80 mg may be affected by listing of 120 mg and 150 mg strengths, and 2% of the total scripts of 40 mg will be affected by the listing of 120 mg strength. The submission noted that any scenarios in Table 3 may occur, however, due to the uncertainty, they have chosen the lowest costing dosing scenarios to be replaced with the new presentations that is the 80 mg + 40 mg for the 120 mg strength and 80 mg + 80 mg for the 150 mg strength.
- 5.13 The submission estimated that the listing of Exarane and Exarane Forte would be cost-saving over the first six years of listing. This is summarised in Table 4.

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Table 4: Estimated use and financial implications

	2023	2024	2025	2026	2027	2028
Estimated extent of use						
Number of scripts dispensed ^a	¹	¹	¹	¹	²	²
Estimated financial implications of Exarane and Exarane Forte						
Cost to PBS/RPBS less co-payment ^b (\$)	³	³	³	³	³	³
Estimated financial implications of Clexane Safety-Lock						
Cost to PBS/RPBS less co-payment ^b	⁴	⁴	⁴	⁴	⁴	⁴
Net financial implications						
Net cost to PBS/RPBS ^b	⁴	⁴	⁴	⁴	⁴	⁴

^a Applying the Sponsor's internal uptake rate estimates.

^b These costs were amended to reflect the current co-payment of \$30.00 for non-concession scripts and \$7.00 for all concessional and RPBS scripts.

Abbreviations: MBS = Medical Benefits Scheme; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

Source: Financial table workbook; Section 4 (Exarane and Exarane Forte).xlsx; provided as part of the submission.

The redacted values correspond to the following ranges:

¹ 100,000 to < 200,000

² 90,000 to < 100,000

³ \$0 to < \$10 million

⁴ Net cost saving

- 5.14 The submission estimated that 600,000 to < 700,000 scripts would be dispensed for Exarane and Exarane Forte over the first six years of listing (100,000 to < 200,000 in Year 1 to 90,000 to < 100,000 in Year 6).
- 5.15 The submission estimated that the net financial impact to the PBS/RPBS for the listing of Exarane and Exarane Forte would be a net saving of \$0 to < \$10 million over six years (Year 1 \$0 to < \$10 million to Year 6 \$0 to < \$10 million).
- 5.16 As a Category 3 submission, the financial analysis has not been independently evaluated.

Quality Use of Medicines

- 5.17 The submission claimed that the listing of Exarane and Exarane Forte would provide a therapeutically equivalent alternative to Clexane Safety-Lock, which would ensure ongoing patient access to treatment in the event of disruption to the supply of medicines.
- 5.18 The submission claimed that the listing of Exarane Forte 120 mg/0.8 mL and 150 mg/mL injections would reduce treatment burden on patients in need of higher doses of enoxaparin, while increasing patient compliance, clinical outcomes and cost savings for patients.

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of the biosimilar brand of enoxaparin, Exarane™, on the General Schedule (Section 85) on a cost-minimisation basis under the same

circumstances as the PBS-listed reference biologic Clexane Safety-Lock®. The PBAC also recommended the listing of two new strengths of enoxaparin, 120 mg in 0.8 mL and 150 mg in 1 mL (Exarane Forte™) on a cost-minimisation basis with the least costly alternative enoxaparin presentation on a per milligram basis.

- 6.2 The PBAC considered that the nomination of Clexane-Safety Lock as the comparator was appropriate. The PBAC noted and considered that the submission's claim that Exarane and Exarane Forte are non-inferior in terms of efficacy and safety to the comparator, Clexane Safety-Lock, to be reasonable and consistent with the TGA Delegate's Overview.
- 6.3 The PBAC advised that the listing of the 20 mg/0.2 mL, 40 mg/0.4 mL, 60 mg/0.6 mL 80 mg/0.8 mL and 100 mg/mL of Exarane be based on equi-effective doses of each corresponding PBS listed formulation of Clexane Safety-Lock:
 - 1 mg Exarane/Exarane Forte = 1 mg Clexane Safety-Lock.
- 6.4 In making its recommendation about the listing of the two new strengths (120 mg/0.8 mL and 150 mg/mL), the PBAC acknowledged the clinical need for higher-strength enoxaparin that will reduce injection burden and may improve patient compliance.
- 6.5 The PBAC considered that Exarane Forte should be cost-minimised to the least costly alternative on a mg/mL basis.
- 6.6 The PBAC agreed that Exarane would replace use within the existing enoxaparin market and not grow the current utilisation. Further, the PBAC noted that the listing of Exarane Forte would result in a minor save if these new strengths replace combinations of lower strength presentations with a higher cost per milligram to reach the required dose. The PBAC therefore considered the financial impact to the PBS/RPBS for listing of Exarane and Exarane Forte to be reasonable.
- 6.7 The PBAC advised that the addition of an administrative note to encourage the uptake of biosimilar prescribing for treatment naïve patients would be appropriate, in accordance with the Government's policy to encourage the use of biosimilar medicines. The PBAC noted that it is not possible to implement the other biosimilar uptake driver of a less restrictive Authority Required type listing in this instance, as enoxaparin has Restricted Benefit and Unrestricted listings.
- 6.8 The PBAC advised, under Section 101 (4AACD) of the *National Health Act 1953*, that in the Schedule of Pharmaceutical Benefits, Exarane, Exarane Forte and Clexane Safety-Lock should be considered equivalent for the purposes of substitution (i.e. 'a' flagged in the Schedule with a NOTE stating PBS brand of one form and PBS brand of another form are equivalent for the purposes of substitution).
- 6.9 The PBAC advised no change to current arrangements for nurse practitioner prescribing or the Early Supply Rule for enoxaparin.

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- 6.10 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because enoxaparin is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over the comparator, and is not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.
- 6.11 The PBAC noted that this submission is not eligible for an Independent Review. Independent Review is not available where the PBAC makes a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Add new item and note as follows:

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enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes	8262W	1	10	1	Clexane Safety-Lock ^a Exarane ^a
enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes	8263X	1	10	1	Clexane Safety-Lock ^a Exarane ^a
enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes	8264Y	1	10	1	Clexane Safety-Lock ^a Exarane ^a
enoxaparin sodium 120 mg/0.8 mL injection, 10 x 0.8 mL syringes	NEW	1	10	1	Exarane Forte
enoxaparin sodium 150 mg/mL injection, 10 x 1 mL syringes	NEW	1	10	1	Exarane Forte

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
Benefit Type: <input checked="" type="checkbox"/> Unrestricted benefit
Administrative Advice: Biosimilar prescribing policy Prescribing of the biosimilar brand Exarane and Exarane Forte is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information about Biosimilar Uptake Drivers can be found on the can be found on the PBS Biosimilars webpage (www.pbs.gov.au/info/general/biosimilars).

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Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
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enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes	8639Q	2	20	3	Clexane Safety-Lock ^a Exarane ^a
enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes	8640R	2	20	3	Clexane Safety-Lock ^a Exarane ^a
enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes	5434B	2	20	3	Clexane Safety-Lock ^a Exarane ^a
enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes	5435C	2	20	3	Clexane Safety-Lock ^a Exarane ^a
enoxaparin sodium 120 mg/0.8 mL injection, 10 x 0.8 mL syringes	NEW	1	10	3	Exarane Forte
enoxaparin sodium 150 mg/mL injection, 10 x 1 mL syringes	NEW	1	10	3	Exarane Forte

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
Benefit Type: <input checked="" type="checkbox"/> Restricted benefit
Indication: Haemodialysis
Administrative Advice: Biosimilar prescribing policy Prescribing of the biosimilar brand Exarane and Exarane Forte is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. . Further information about Biosimilar Uptake Drivers can be found on the can be found on the PBS Biosimilars webpage (www.pbs.gov.au/info/general/biosimilars).

This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

The sponsor had no comment.