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1.[illegible]

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[illegible]

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1) [illegible]6

2) [illegible]9.7

[illegible]

[illegible]

[illegible]

[illegible]9.6

[illegible]

2.[illegible]

[illegible]

[illegible]

[illegible]9.5

2.[illegible]

[illegible]

[illegible]

[illegible]HMG-CoA[illegible]HMG-CoA[illegible][illegible]

[illegible]

1) [illegible]7.1

[illegible]

[illegible]

[illegible]

1) [illegible]14.2.1

2) [illegible]14.2.[illegible]

[illegible]

[illegible]

[illegible]

[illegible]EU[illegible][illegible][illegible]

• [illegible]

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Leqvio[illegible]Prescribing Information[illegible]Revised: 6/2024[illegible]U.S[illegible][illegible][illegible]

DOSAGE AND ADMINISTRATION
2.1 Recommended Dosage
• The recommended dosage of LEQVIO, in combination with statin therapy, is 284 mg

administered as a single subcutaneous injection initially, again at 3 months, and then every 6 months.
• If a planned dose is missed by less than 3 months, administer LEQVIO and maintain dosing according to the patient’s original schedule.
• If a planned dose is missed by more than 3 months, restart with a new dosing schedule - administer LEQVIO initially, again at 3 months, and then every 6 months.
• Assess LDL-C when clinically indicated. The LDL-lowering effect of LEQVIO may be measured as early as 30 days after initiation and anytime thereafter without regard to timing of the dose.

Leqvio□Product Information□Last updated: 28/11/2024□□EU□□□□[□□]□

Posology (see section 4.2 of the SmPC)
The recommended dose is 284 mg inclisiran administered as a single subcutaneous injection: initially, again at 3 months, followed by every 6 months.

Missed doses
If a planned dose is missed by less than 3 months, inclisiran should be administered and dosing continued according to the patient’s original schedule.

If a planned dose is missed by more than 3 months, a new dosing schedule should be started – inclisiran should be administered initially, again at 3 months, followed by every 6 months.

Treatment transition from monoclonal antibody PCSK9 inhibitors Inclisiran can be administered immediately after the last dose of a monoclonal antibody PCSK9 inhibitor. To maintain LDL-C lowering it is recommended that inclisiran is administered within 2 weeks after the last dose of a monoclonal antibody PCSK9 inhibitor.

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1) Leqvio□Prescribing Information□Revised: 6/2024□□□U.S□
https://www.novartis.com/us-en/sites/novartis_us/files/leqvio.pdf

2) Leqvio□Product Information□Last updated: 28/11/2024□□EU□
https://www.ema.europa.eu/en/documents/product-information/leqvio-epar-product-information_en.pdf

3) □□□□□□□6

3.[illegible]

[illegible]

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Image

11.2 その他の副作用

	5%以上	5%未満
一般・全身障害及び投与部位の状態	注射部位反応（注射部位疼痛、注射部位紅斑、注射部位発疹等）	−
肝胆道系障害	−	肝機能障害

[illegible]

1) [illegible]11.2

2) [illegible]17

3) [illegible]11

4.[illegible]

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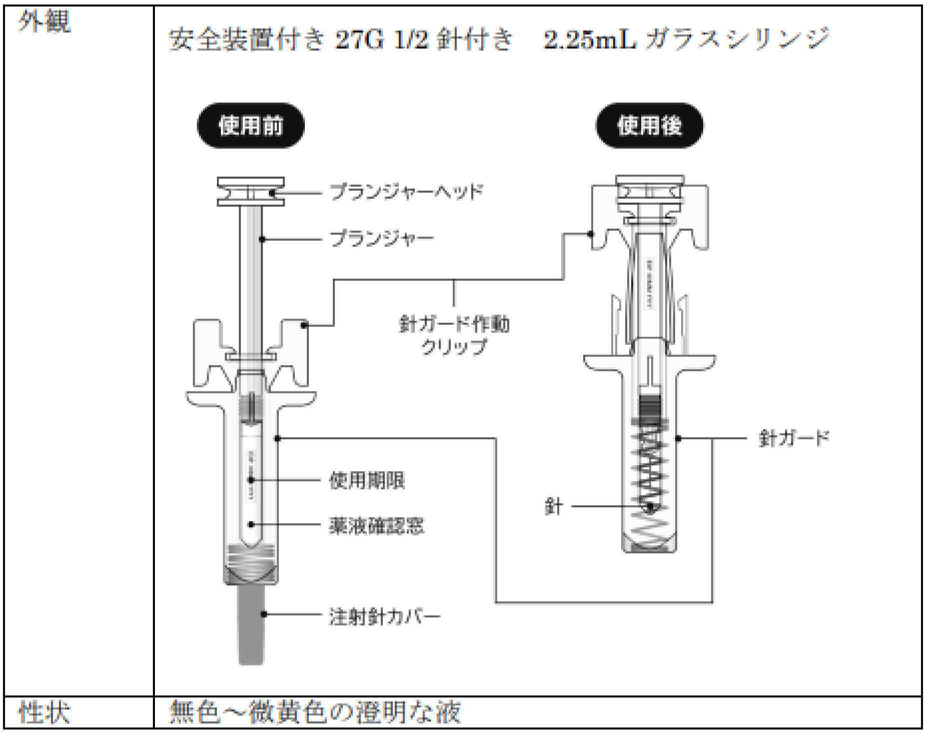
Image



外観	安全装置付き 27G 1/2 針付き　2.25mL ガラスシリンジ
性状	無色～微黄色の澄明な液

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1) □□□□□□□□14.2.3

2) □□□□□□□□□□□□□□□Ⅳ-□ (2)

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[illegible]1~30℃[illegible][illegible]
[illegible]

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1) [illegible]

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Source URL: *https://www.pro.novartis.com/jp-ja/products/leqvio/faq*