



> Return address PO Box 320, 1110 AH Diemen

To the Minister of Medical Care  
PO Box 20350  
2500 EJ THE HAGUE

**National Health Care  
Institute**  
Care  
Medicinal Products

Willem Dudokhof 1  
1112 ZA Diemen  
PO Box 320  
1110 AH Diemen  
[www.zorginstituutnederland.nl](http://www.zorginstituutnederland.nl)  
[info@zinl.nl](mailto:info@zinl.nl)  
T +31 (0)20 797 85 55

2024020781

Date 1 July 2024  
Re: GVS advice on naldemedine (Rizmoic®)

**Our reference**  
2024020781

Dear Ms Dijkstra,

In your letter of 25 March 2024 (CIBG-24-06770), you asked the National Health Care Institute to carry out a substantive assessment of whether the medicinal product naldemedine (Rizmoic®) is interchangeable with a product in the reimbursed package. The outcome of this can be found in the enclosed GVS report.

Rizmoic® is available as a film-coated tablet with 200 micrograms of naldemedine. Naldemedine is registered for the treatment of opioid-induced constipation (OIC) in adult patients who have previously been treated with a laxative.

The recommended dosage regimen for naldemedine is 200 micrograms (1 tablet) per day.

The marketing authorisation holder is requesting inclusion in List 1A of the Health Insurance Regulation in a newly formed cluster with naloxegol.

### **Outcome of the substantive assessment**

#### *Assessment of interchangeability*

Based on the criteria for interchangeability, the National Health Care Institute concluded that naldemedine (Rizmoic®) is interchangeable with naloxegol. The defined daily dose (DDD) of naldemedine has been set by the World Health Organisation (WHO) at 0.2 mg, and that of naloxegol at 25 mg.

#### *Therapeutic value*

Naldemedine and naloxegol are both opiate antagonists. Opiate antagonists are used in the treatment of OIC after insufficient effect from regular laxatives. The National Health Care Institute previously assessed naloxegol for this indication and found that naloxegol meets the established medical science and medical practice and has an equivalent value to methylnaltrexone.

Given the difference in administration form, methylnaltrexone is not interchangeable with naldemedine, which is why the comparison is limited to naloxegol.

Due to the lack of direct comparative studies, an indirect comparison between

naldemedine and naloxegol has been made.

Based on similar beneficial effects, adverse effects, applicability and ease of use, naldemedine meets the established medical science and medical practice for patients with opioid-induced constipation (OIC) who have been previously treated with a laxative. Based on this data, the National Health Care Institute concludes that naldemedine has an equal value to naloxegol.

**Advice**

The National Health Care Institute advises you to place naldemedine (Rizmoic®) on List 1A in a newly formed cluster with naloxegol. For naldemedine, the standard dose is set at 0.2 mg and for naloxegol at 25 mg.

Yours sincerely,

Sjaak Wijma  
*Chairperson of the Executive Board*

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