



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## NovoRapid

### Procedural steps taken and scientific information after the authorisation\*

\*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, please also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
Article 61(3) /	- Notification acc. Article 61(3) -	28/05/2025		Labelling	

<sup>1</sup> Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.

<sup>2</sup> A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



EMA/N/0000272759	Update Annex IIIA of the product information to grey-shade the text "Read the package leaflet before use" in Section 2, "Method of Administration," for the small immediate packaging units of the PumpCart cartridge label, to align with the currently approved mock-up/specimen layout				
Variation type IA / EMA/VR/0000267525	<p>B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted</p> <p>B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted</p>	21/05/2025	N/A		