Velosulin

Procedural steps taken and scientific information after the authorisation

MAJOR CHANGES[1]

No	Scope	Opinion issued on	Commission Decision Issued/ amended on	Product Information affected[2]	Summary
R/0006	Renewal of the Marketing Authorisation.	19/07/2007	18/09/2007	SPC, Annex II, Labelling, PL	Based on the review of the available information the CHMP is of the opinion that the quality, the safety and the efficacy of this medicinal product continues to be adequately and sufficiently demonstrated and therefore considers that the benefit/risk profile continues to be favourable. The CHMP was also of the opinion that the renewal can be granted with unlimited validity.
II/0003	Update of section 4.8 of the SPC and corresponding section of the Package Leaflet. Introduction of changes to reflect the CHMP Note for Guidance on Declaration of Storage Conditions and an update to bring the SPC, labelling and Package Leaflet in accordance with the latest QRD template and to harmonise with the MAH's other insulin products.	23/06/2004	02/08/2004	SPC, Labelling, PL	Update of section 4.8 of the SPC in order to better reflect the adverse drug reactions reported in clinical trials, to list undesirable effects using the MedDRA terminology, and to list them according to frequencies. The introduction to section 4.8 of the SPCs has also been updated to state that hypoglycaemia is the most frequent undesirable effect, but no exact frequency is included, as the frequency of hypoglycaemia is highly variable among various patient populations and dose regimens. This update of section 4.8 also includes the removal of hyperglycaemia. All information on hyperglycaemia (including symptoms) has been located in section 4.4, including the warning of the risk of fatal outcome of untreated hyperglycaemic events. The terms `diabetic retinopathy' and `painful neuropathy' have been added to section 4.8. The adverse event "Fainting/loss of consciousness" is also added to the list in section 4.8. These changes have been reflected in the section 5 of the Package Leaflet.

[1] Major changes e.g. Type II variations, Annex II applications, Renewals and Annual Reassessments
[2] SPC (Summary of Product Characteristics), Labelling, PL (Package Leaflet)

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					In addition changes have been made to the Product Information to reflect the CHMP Note for Guidance on Declaration of Storage Conditions, linguistic amendments in accordance to the latest QRD template (version 6, 1/2004) and to harmonise with other insulin products from NovoNordisk.
II/0002	Change(s) to the manufacturing process for the active substance Change(s) to the test method(s) and/or specifications for the active substance Change(s) to shelf-life or storage conditions	25/09/2003	01/10/2003		

MINOR CHANGES[3]

No	Scope	Product Information affected[2]	Date[4]
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	Labelling, PL	17/03/2008
N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)		27/04/2005
I/0001	Change in pack size for a medicinal product	SPC, Labelling, PL	09/07/2003

[3] Minor changes e.g. Type I variations and Notifications
[4] Date of entry into force of the change