PROCEDURAL STEPS TAKEN AFTER AUTHORISATION

For procedures finalised after 1 September 2004 please refer to module 8B

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Change of storage container of the active substance	**I/01**	**I/II**	**18.11.99**	–
Additional pack size 10 x 3 ml Penfill	**II/02**	**II**	**21.10.99**	**08.02.00**
Additional pack size 10 x 3 ml Novolet	**II/03**	**II**	**21.10.99**	**08.02.00**
Additional pack size 5 x 10 ml NovoRapid	**II/04**	**II**	**21.10.99**	**08.02.00**
Update of SPC and PL with regard to post prandial administration	**II/05**	**II**	**18.11.99**	**13.04.00**
Additional presentation: FlexPen	**II/06**	**II**	**28.08.00**	**15.01.01**
Update of SPC and PL with regard to "early hypoglycaemia in general" and "safe use in children"	**II/07**	**II**	**14.12.00**	**23.04.01**
Update of SPC and PL with regard to continuous subcutaneous insulin infusion for Novorapid vials	**II/08**	**II**	**26.04.01**	**13.07.01**
Change in the test procedure of the active substance and medicinal product	**I/09**	**I**	**01.03.01**	–
Additional facility for purification of Insulin Aspart	**II/10**	**II**	**20.09.01**	–
Change in the batch size of the finished product	**I/11**	**I/II**	**13.12.01**	–
Change for the deletion of the bio identity test	**II/12**	**II**	**21.02.02**	–
Update of the SPC and PL regarding the occurrence of fewer nocturnal hypoglycaemic episodes	**II/13**	**II**	**21.03.02**	**15.07.02**
Minor change of the manufacturing process of the active substance	**I/14**	**I/II**	**21.02.02**	–
Additional pack size 1x3ml FlexPen	**I/15**	**I**	**16.01.02**	–
New route of administration (intravenous)	**X/16**	**X**	**18.12.02**	**04.06.03**
Change in batch size for Novorapid vials	**I/17**	**I/II**	**30.05.02**	–
Change in batch size	**I/18**	**I/II**	**27.06.02**	–
New route of administration (intravenous) for all presentations	**X/19**	**X**	**18.12.02**	**04.06.03**

[1] In accordance with Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended, and for variations after 1 October 2003 in accordance with Commission Regulation (EC) No 1085/2003: **I** refers to a minor variation (Type I variation); **II** refers to a major variation (Type II variation); **I/II** refers to a minor variation following the procedure set out in Article 6, 7 and 8 of the Regulation; **X** refers to an Annex II application.
T refers to a transfer of a Marketing Authorisation in accordance with Commission Regulation (EC) No 2141/96 of 7 November 1996.
N refers to a notification in accordance with Article 61(3) of Council Directive 2001/83/EC.

[2] For Notifications and Type I variations, the date of entry into force of the change is the EMEA Notification date. The Commission Decision will be amended accordingly.

Additional presentation: InnoLet	**II/21**	**II**	**18.12.02**	**04.06.03**
Update of the SPC and PL with regard to continuous subcutaneous insulin infusion for all presentations	**II/22**	**II**	**23.01.03**	**06.06.03**
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	**I/24**	**I**	**20.06.03**	**-**
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	**I/25**	**I**	**16.07.03**	**-**
Minor changes in manufacture of the medicinal product	**I/26**	**I**	**25.09.03**	**-**
Qualitative change to the active substance	**X/27**	**X**	**03.06.04**	**24.08.04**
Update of sections 4.4 and 4.8 of SPC and PL	**II/28**	**II**	**26.02.04**	**07.04.04**
General update of SPC and PL	**II/29**	**II**	**26.02.04**	**07.04.04**
Update of or change to the pharmaceutical documentation	**II/30**	**II**	**24.03.04**	**-**
Update of or change to the pharmaceutical documentation	**II/31**	**II**	**22.04.04**	**-**