

Neupopeg

Procedural steps taken and scientific information after the authorisation Changes made after 01/02/2004

For procedures finalised before 01/02/2004, please refer to module 8A

MAJOR CHANGES¹

No	Scope	Opinion issued on	Commission Decision Issued/ amended on	Product Information affected ²	Summary
II/0037	Update of Summary of Product Characteristics The MAH has applied to amend section 4.8 of the SPC to included information about the potential for elevated Liver Function Tests (LFTs) in patients treated with pegfilgrastim.	19/03/2008	18/04/2008	SPC	The MAH has applied to amend section 4.8 of the SPC to included information about the potential for elevated Liver Function Tests (LFTs) in patients treated with pegfilgrastim.
II/0036	Change(s) to the manufacturing process for the active substance	21/02/2008	26/02/2008		
II/0035	Update of Summary of Product Characteristics and Package Leaflet	13/12/2007	17/01/2008	SPC, PL	Amendment to section 4.8 of the SPC with regard to the frequency of Sweet's syndrome. The Package Leaflet has also been amended accordingly.
II/0034	Change(s) to the manufacturing process for the active substance	15/11/2007	21/11/2007		
II/0033	Update of Summary of Product Characteristics and Package Leaflet	18/10/2007	20/11/2007	SPC, PL	Update of section 4.8 of the Summary of Product Characteristics to include: injection-site reactions, erythema and flushing. The package leaflet is updated accordingly. This variation fulfils a commitment made by the MAH which resulted from the recent renewal procedure.
II/0032	Update of Summary of Product Characteristics	18/10/2007	20/11/2007	SPC	Update of Summary of Product Characteristics to amend sections 4.2 and 5.2 with data from a study investigating the effects of renal impairment on the pharmacokinetics of pegfilgrastim. This variation fulfils a commitment made by the MAH which resulted from the recent renewal procedure.
R/0031	Renewal of the marketing authorisation	24/05/2007	16/07/2007		

¹ Major changes e.g. Type II variations, Annex II applications, Renewals and Annual Reassessments

² SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet)

No	Scope	Opinion issued on	Commission Decision Issued/ amended on	Product Information affected ²	Summary
II/0030	Change(s) to the manufacturing process for the finished product	22/03/2007	27/03/2007		
II/0029	Change to the test procedure and/or specification of a raw material	22/03/2007	27/03/2007		
II/0028	Change(s) to the manufacturing process for the active substance	24/01/2007	29/01/2007		
II/0027	Update of Summary of Product Characteristics and Package Leaflet	16/11/2006	03/01/2007	SPC, Annex II, Labelling, PL	Update to sections 4.4 and 4.8 of the SPC following a review of the Company Core Data Sheet and a recent assessment of the 7th PSUR. Update to sections 2 and 4 of the Package Leaflet with regards to information on allergy to latex and very rare events of cutaneous vasculitis. Update to section 6 of the Package Leaflet on how to administer the medicinal product.
II/0026	Change(s) to the manufacturing process for the active substance	27/07/2006	18/08/2006		
II/0024	Change(s) to the manufacturing process for the active substance	27/04/2006	03/05/2006		
II/0021	New presentation(s) The Marketing Authorisation Holder applied to add a new prefilled pen presentation to the product range.	15/09/2005	28/10/2005	SPC, Labelling, PL	
II/0020	Update of Summary of Product Characteristics and Package Leaflet	23/06/2005	01/08/2005	SPC, PL	Sections 4.4 and 4.8 of the SPC were amended to update the safety information in relation to pulmonary effects and to add "leucocytosis" further to the assessment of the 5th PSUR. The Patient Leaflet was amended accordingly.
II/0019	Change(s) to the manufacturing process for the active substance	27/07/2005	31/08/2005	Annex II	
II/0018	Update of Summary of Product Characteristics	16/03/2005	27/04/2005	SPC	Sections 4.8 and 5.1 of the SPC were amended to reflect the results from a phase 3 study showing that the addition of pegfilgrastim to docetaxel in patients with breast cancer had a beneficial effect on the primary endpoint of the incidence of febrile neutropenia.
II/0017	Quality changes The Marketing Authorisation Holder applied to update the manufacturing process for the active substance.	16/03/2005	21/03/2005		
II/0016	Update of Summary of Product	15/09/2005	28/10/2005	SPC	Sections 4.8 and 5.1 of the SPC were updated to reflect new data on the

No	Scope	Opinion issued on	Commission Decision Issued/ amended on	Product Information affected ²	Summary
	Characteristics				use of Neupopeg in patients with de novo acute myeloid leukaemia.
II/0015	Quality changes The Marketing Authorisation Holder applied to change the active substance and product specifications.	16/03/2005	21/03/2005		
II/0014	Update of Summary of Product Characteristics and Package Leaflet	15/12/2004	25/01/2005	SPC, PL	
II/0010	Change(s) to the manufacturing process for the active substance	23/06/2004	29/06/2004		
II/0008	Change(s) to the manufacturing process for the active substance	29/07/2004	02/08/2004		
II/0005	Change(s) to the manufacturing process for the active substance	22/04/2004	27/04/2004		

MINOR CHANGES³

No	Scope	Product Information affected ²	Date ⁴
IA/0025	38_a_Change in test procedure of finished product - minor change to approved test procedure		17/01/2006
IB/0023	37_a_Change in the specification of the finished product - tightening of specification limits		10/01/2006
IA/0022	28_Change in any part of primary packaging material not in contact with finished product		29/06/2005
IB/0013	12_b_02_Change in spec. of active subst./agent in manuf. of active subst. - test parameter		09/08/2004
IA/0012	28_Change in any part of primary packaging material not in contact with finished product 41_a_01_Change in pack size - change in no. of units within range of appr. pack size	SPC, Labelling, PL	18/06/2004
IB/0011	42_a_01_Change in shelf-life of finished product - as packaged for sale	SPC	01/07/2004

³ Minor changes e.g. Type I variations and Notifications

⁴ Date of entry into force of the change