

Procedural steps taken and scientific information after the authorisation

Changes made after 01/11/2002

Monotard

MAJOR CHANGES¹

No	Scope	Opinion issued on	Commission Decision Issued/ amended on	Product Information affected ²	Summary
II/0002	Change(s) to container	25/09/2003	01/10/2003		
II/0001	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 CHANGES³

There have been no minor changes.

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)

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