

Gonazon (WD)

Procedural steps taken and scientific information after the authorisation

No	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
IB/0005	1B-13-b Change in test procedure for active substance or starting material- other changes test procedure, 1B-38-c Change in test procedure of the finished product	22/07/2009	22/07/2009		The EMEA approved a type IB variation for a change in test procedure of finished product, and consequently a change in test procedure for active substance, to replace the analytical method for the quantification of the active substance and its related impurities.
R/0004	Renewal of the marketing authorisation	16/04/2008	13/06/2008	SPC, Annex II, Labelling, PL	The European Commission renewed the marketing authorisation for Gonazon.
IA/0003	1A-04 Change in name and/or address of a manufacturer of the active substance	05/09/2007	05/09/2007		The EMEA approved a type IA variation to change the name of the manufacturer of the active substance from Diosynth N.V. to N. V Organon.
X/0002	X-3-IV Change or addition of a new pharmaceutical form	08/11/2006	11/01/2007	SPC, Annex II, Labelling, PL	The European Commission approved an extension to add a new target species, pharmaceutical form and indication (implant for dogs).
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art.	03/03/2004	19/03/2004	PL	The EMEA accepted a notification for the deletion of the local representatives from the package insert

¹ Notifications are issued for type variations (unless part of a group or a worksharing application). Opinions are issued for all other procedures.

² No Commission Decision is issued for type IA and type IB variations or for type II variations and annual re-assessments that do not affect the annexes.

³ SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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	61.3 Notification)				