IVF Media G5 Series

Procedural steps and scientific information after initial consultation

Application number	Scope	Opinion/ Notification [1] issued on	Summary
II/0008	Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II	25/01/2024	- to add the following IVF media: HSA solution, SpermFreeze, G-TL, FreezeKit Cleave, Thaw Kit Cleave, RapidWarm Cleave, RapidVit Cleave, RapidVit Blast, RapidWarm Blast, RapidVit Oocyte, RapidWarm Oocyte, RapidVit Omni, RapidWarm Omni; - to remove the following IVF media: : G-1 v5, G-2 v5, G-IVF, G-Sperm, G-Sperm PLUS, G-FreezeKit Blast, G-ThawKit Blast, G-Oocyte, IVF, Freeze-Kit 1, Thaw-Kit 1 and CCM
IB/0007	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	04/04/2023	To add Gx-IVF, Gx-TL and Gx-MOPS PLUS as new variants of the existing IVF media G-IVF PLUS, G-TL and G-MOPS PLUS, due to the addition of new excipients as antioxidants .
II/0005	Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II	17/01/2013	To add Human Serum Albumin Solution 25% manufactured by Octapharma as alternative to the currently approved Human Serum Albumin Solution 25% manufactured by Grifols

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.

			(previously Talecris) as ancillary medicinal substance.
IA/0006	A.4 - Administrative change - Change in the name and/or address of a manufacturer or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS	08/10/2012	To change the name of the Human Serum Albumin incorporated in the medical device from Talecris Biotherapeutics, Albumin (Human) 25% to Grifols Deutschland, Albumin (Human) 25%.
N/0004	Notification for ancillary medicinal substance in medical device	15/10/2008	
N/0003	Notification for ancillary medicinal substance in medical device	15/10/2008	
N/0002	Notification for ancillary medicinal substance in medical device	15/10/2008	
MF/0001	2PMF (2nd step of PMF certification procedure)	30/04/2008	