



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

23 February 2023  
EMA/160430/2023  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: carbetocin

Procedure no.: PSUSA/00000546/202206

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<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
PABAL 100 micrograms/ml solution for injection	DK/H/2872/001	PL 03194/0058	FERRING PHARMACEUTICALS LTD.	XI
PABAL 100 Mikrogramm/ml - Injektionslösung	DK/H/2872/001	1-26452	FERRING ARZNEIMITTEL GES.M.B.H.	AT
Pabal 100 microgrammes/ml solution injectable	DK/H/2872/001	BE 293185	FERRING N.V.	BE
PABAL 100 microgram/ml oplossing voor injectie	DK/H/2872/001	BE293185	FERRING N.V.	BE
DURATOCIN 100 mikrogramů/ml injekční roztok	DK/H/2872/001	56/144/06-C	FERRING LÉCIVA A.S.	CZ
Pabal, injektionsvæske, opløsning	DK/H/2872/001	40119	FERRING LÆGEMIDLER A/S	DK
PABAL, 100 mikrogrammi/ml, süstelähus	DK/H/2872/001	539807	FERRING GMBH	EE
Pabal 100 mikrog/ml injektioneste, liuos	DK/H/2872/001	22767	FERRING LÄÄKKEET OY	FI
PABAL 100 μικρογραμμάρια/ml ενέσιμο διάλυμα	DK/H/2872/001	23977/07/24-6-2008	FERRING HELLAS MEPE	GR

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PABAL 100 Mikrogramm/ml Injektionslösung	DK/H/2872/001	64579.00.00	FERRING ARZNEIMITTEL GMBH	DE
PABAL 100 microgrammes/ml, solution injectable	DK/H/2872/001	34009 550 109 2 0	FERRING S.A.S.	FR
PABAL 100 mÍkróg/ml stungulyf, lausn	DK/H/2872/001	IS/1/07/001/01	FERRING LÆGEMIDLER A/S	IS
PABAL 100 micrograms/ml solution for injection	DK/H/2872/001	PA 1009/21/1	FERRING IRELAND LTD.	IE
DURATOCIN 100 microgrammi/ml soluzione iniettabile	DK/H/2872/001	037567017/M	FERRING S.P.A.	IT
PABAL 100 mikrogramm/ml oldatos injekció	DK/H/2872/001	OGYI-T-20118/02	FERRING MAGYARORSZÁG GYÓGYSZERKERESKEDELMI KFT.	HU
PABAL 100 mikrogramų/ml injekcinis tirpalas	DK/H/2872/001	LT/1/07/0794/002	FERRING GMBH	LT
PABAL 100 microgrammes/ml solution injectable	DK/H/2872/001	2009040442	FERRING N.V.	LU
PABAL 100 microgram/ml oplossing voor injectie	DK/H/2872/001	RVG 33356	FERRING B.V.	NL

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PABAL 100 mikrogram/ml injeksjonsvæske, oppløsning	DK/H/2872/001	06-4460	FERRING LEGEMIDLER AS	NO
Pabal 100 mikrogram/ml injektionsvätska, lösning	DK/H/2872/001	22767	FERRING LÄÄKKEET OY	FI
PABAL, 100 mikrogramów/ml, roztwór do wstrzykiwań	DK/H/2872/001	12292	FERRING GMBH	PL
PABAL 100 microgramas/ml solução injectável	DK/H/2872/001	5794383	FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPESSOAL, LDA.	PT
DURATOBAL 100 microgramos/ ml solución inyectable	DK/H/2872/001	68.550	FERRING S.A.U.	ES
PABAL 100 mikrogramov/ml injekčný roztok	DK/H/2872/001	56/0223/06-S	FERRING LÉCIVA A.S.	SK
Pabal 100 mikrogram/ml injektionsvätska, lösning	DK/H/2872/001	24549	FERRING LÄKEMEDEL AB	SE
PABAL 100 Mikrogramm/ml Injektionslösung	DK/H/2872/001	BE293185	FERRING N.V.	BE
PABAL 100 Mikrogramm/ml Injektionslösung	DK/H/2872/001	2009040442	FERRING N.V.	LU

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Carbetocin 100 micrograms solution for injection in pre-filled syringe	ES/H/0254/001	PL 24837/0131	CONSILIENT HEALTH LTD	XI
Carbetocina GP-Pharm 100 microgramos solución inyectable en jeringa precargada.	ES/H/0254/001	79228	GP-PHARM S.A.	ES
Carbetocin Aguettant 100 Mikrogramm/ml Injektionslösung in einer Fertigspritze	ES/H/0254/001	135894	LABORATOIRE AGUETTANT	AT
Carbetocin Aguettant 100 Mikrogramm/ml, Injektionslösung in einer Fertigspritze	ES/H/0254/001	91044.00.00	LABORATOIRE AGUETTANT	DE
CARBETOCINE AGUETTANT 100 microgrammes/ml, solution injectable en seringue pré-remplie	ES/H/0254/001	34009 550 002 5 9	LABORATOIRE AGUETTANT	FR
Carbetocina Aguettant 100 microgrammi/ml, soluzione iniettabile in siringa preimpita	ES/H/0254/001	043549017	LABORATOIRE AGUETTANT	IT
Carbetocin Aguettant 100 mikrogram/ml injektionsvätska, lösning i förfylld spruta	ES/H/0254/001	61721	LABORATOIRE AGUETTANT	SE

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Carbetocin "Aguettant", injektionsvæske, opløsning i fyldt injektionssprøjte	ES/H/0254/001	65768	LABORATOIRE AGUETTANT	DK
Carbetocin Aguettant 100 mikrogram/ml injeksjonsvæske, opløsning i ferdigfylt sprøyte	ES/H/0254/001	21-13890	LABORATOIRE AGUETTANT	NO
CARBETOCINE AGUETTANT 100 microgrammes/ml solution injectable en seringue pré-remplie	ES/H/0254/001	BE590631	LABORATOIRE AGUETTANT	BE
CARBETOCINE AGUETTANT 100 microgram/ml oplossing voor injectie in voorgevulde spuit	ES/H/0254/001	BE590631	LABORATOIRE AGUETTANT	BE
CARBETOCINE AGUETTANT 100 Mikrogramm/ml Injektionslösung in einer Fertigspritze	ES/H/0254/001	BE590631	LABORATOIRE AGUETTANT	BE
Carbetocin Aguettant 100 mikrog/ml, injektioneste, liuos, esitäytetty ruisku	ES/H/0254/001	38879	LABORATOIRE AGUETTANT	FI

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Carbetocin Aguetant 100 mikrog/ml injektionsvätska, lösning i förfylld spruta	ES/H/0254/001	38879	LABORATOIRE AGUETTANT	FI