



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 January 2019
EMA/31815/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: terlipressin

Procedure no.: PSUSA/00002905/201804



Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
GLYPRESSINE® 1 mg/ 5ml, poudre et solvant pour solution injectable (I.V).	not available	3400955627487	FERRING S.A.S.	FR
Glypressin 1 mg pulbere și solvent pentru soluție injectabilă	not available	7539/2006/01	FERRING GMBH	RO
Glypressin, Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung.	not available	BE150717	FERRING N.V.	BE
Glypressin, poudre et solvant pour solution injectable ou solution pour perfusion	not available	BE150717	FERRING N.V.	BE
Glypressin, poeder en oplosmiddel voor oplossing voor injectie of oplossing voor infusie	not available	BE150717	FERRING N.V.	BE
Glypressine 0,1 mg/ml solução injetável	not available	5174867	FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPessoal, LDA.	PT
РЕМЕСТИП 0,1 mg/ml инъекционный раствор	not available	9700303	FERRING GMBH	BG
Glypressin 0,85 mg oldatos injekció	not available	OGYI-T-7887/03	FERRING MAGYARORSZÁG GYÓGYSZERKERESKEDELMI KFT.	HU
Glypressin 1 mg/ 8.5 ml solution for injection	not available	PA 1009/4/2	FERRING IRELAND LTD.	IE
GLYPRESSIN 1 mg injektioneste, liuos	not available	23433	FERRING LÄÄKKEET OY	FI
Glypressin 1 mg injektionsvätska, lösning	not available	23433	FERRING LÄÄKKEET OY	FI
Glypressin, poudre et	not available	0349/09030227	FERRING N.V.	LU

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solvant pour solution injectable ou solution pour perfusion				
GLYPRESSIN 1 mg Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	not available	0349/09030227	FERRING N.V.	LU
Terlipressin acetate EVER Pharma 0.2 mg/ml solution for injection	AT/H/0629/001	PL 46654/0004	EVER VALINJECT GMBH	UK
Terlipresín EVER Pharma 0,2 mg/ml injekčný roztok	AT/H/0629/001	84/0460/16-S	EVER VALINJECT GMBH	SK
Terlipressinacetat EVER Pharma 0,2 mg/ml Injektionslösung	AT/H/0629/001	137291	EVER VALINJECT GMBH	AT
Terlipressinacetat EVER Pharma 0,2 mg/ml Injektionslösung	AT/H/0629/001	96042.00.00	EVER VALINJECT GMBH	DE
Terlipressini acetat EVER Pharma, 0,2 mg/ml, roztwór do wstrzykiwań	AT/H/0629/001	23660	EVER VALINJECT GMBH	PL
Acetat de Terlipresină EVER Pharma 0,2 mg/ml soluție injectabilă	AT/H/0629/001	9592/2017/01-04	EVER VALINJECT GMBH	RO
ACETATE DE TERLIPRESSINE EVER PHARMA 0,2 mg/ml, solution injectable	AT/H/0629/001	34009 550 312 3 9	EVER VALINJECT GMBH	FR
ACETATE DE TERLIPRESSINE EVER PHARMA 0,2 mg/ml, solution injectable	AT/H/0629/001	34009 550 312 4 6	EVER VALINJECT GMBH	FR
ACETATE DE	AT/H/0629/001	34009 550 312 6 0	EVER VALINJECT GMBH	FR

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TERLIPRESSINE EVER PHARMA 0,2 mg/ml, solution injectable				
ACETATE DE TERLIPRESSINE EVER PHARMA 0,2 mg/ml, solution injectable	AT/H/0629/001	34009 550 312 7 7	EVER VALINJECT GMBH	FR
Terlipresin acetát EVER Pharma 0,2 mg/ml injekční roztok	AT/H/0629/001	84/720/15-C	EVER VALINJECT GMBH	CZ
Terlipressina acetato EVER Pharma 0,2 mg/ml soluzione iniettabile	AT/H/0629/001	044409011	EVER VALINJECT GMBH	IT
Terlipressina acetato EVER Pharma 0,2 mg/ml soluzione iniettabile	AT/H/0629/001	044409023	EVER VALINJECT GMBH	IT
Terlipressina acetato EVER Pharma 0,2 mg/ml soluzione iniettabile	AT/H/0629/001	044409035	EVER VALINJECT GMBH	IT
Terlipressina acetato EVER Pharma 0,2 mg/ml soluzione iniettabile	AT/H/0629/001	044409047	EVER VALINJECT GMBH	IT
Terlipresina acetato EVER Pharma 1 mg solución inyectable	AT/H/0629/001	82806	EVER VALINJECT GMBH	ES
Terlipresina acetato EVER Pharma 2 mg solución inyectable	AT/H/0629/001	82807	EVER VALINJECT GMBH	ES
Remestyp, 100 mikrogramów/ml, roztwór do wstrzykiwań	not available	R/0999	FERRING LÉCIVA A.S.	PL
Glycylpressin 1 mg Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	not available	389.01.00	FERRING GMBH	DE

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Glypressin, 1 mg süstelahu	DK/H/0829/002	718610	FERRING GMBH	EE
Glypressin 1 mg injekční roztok	DK/H/0829/002	84/849/10-C	FERRING LÉCIVA A.S.	CZ
Glypressin, injektionsvæske, opløsning	DK/H/0829/002	41408	FERRING LÆGEMIDLER A/S	DK
Glypressin 1 mg ενέσιμο διάλυμα	DK/H/0829/002	63013/24-9-2015	FERRING HELLAS MEPE	GR
Glypressin 1 mg šķīdums injekcijām	DK/H/0829/002	10-0584	FERRING GMBH	LV
Glypressin 1 mg injekcinis tirpalas	DK/H/0829/002	LT/1/05/0470/002	FERRING GMBH	LT
Glypressin 1 mg injeksjonsvæske, oppløsning	DK/H/0829/002	10-7649	FERRING LEGEMIDLER AS	NO
Glypressin, 1 mg, roztwór do wstrzykiwań	DK/H/0829/002	17729	FERRING GMBH	PL
Glypressin 1 mg solution for injection	DK/H/0829/002	MA 832/00702	FERRING PHARMACEUTICALS LTD.	MT
Glypressin 1 mg raztopina za injiciranje	DK/H/0829/002	H/05/00711/001	FERRING GMBH	SI
Glypressin 1 mg injekčný roztok	DK/H/0829/002	84/0874/10-S	FERRING LÉCIVA A.S.	SK
Glypressin 1 mg injektionsvätska, lösning	DK/H/0829/002	44516	FERRING LÄKEMEDEL AB	SE
Glycylpressin 1 mg - Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	not available	16.732	FERRING ARZNEIMITTEL GES.M.B.H.	AT
Glycylpressin 0,1 mg/ml - Injektionslösung	not available	1-31305	FERRING ARZNEIMITTEL GES.M.B.H.	AT
REMESTYP 0,2 Injekční roztok	not available	84/102/78-C	FERRING LÉCIVA A.S.	CZ
REMESTYP 1,0 injekční	not available	84/110/98-C	FERRING LÉCIVA A.S.	CZ

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roztok				
GLYPRESSIN 1mg polvo y disolvente para solución inyectable	not available	61.412	FERRING S.A.U.	ES
Glypressin, oplossing voor injectie 0,1 mg/ml	not available	RVG 35309	FERRING B.V.	NL
GLYPRESSINE® 1 mg/ 8,5ml, solution injectable.	not available	577 005-6 OU 34009 577 005 6 0	FERRING S.A.S.	FR
Glypressin 1 mg prašak i otapalo za otopinu za injekciju	DK/H/0829/001	HR-H-413434003	FERRING GMBH	HR
Glypressin 1 mg, prášek a rozpouštědlo pro injekční roztok	DK/H/0829/001	84/393/05-C	FERRING LÉCIVA A.S.	CZ
Glypressin, pulver og solvens til injektionsvæske, opløsning	DK/H/0829/001	18059	FERRING LÆGEMIDLER A/S	DK
Glypressin, 1 mg süstelähuse pulber ja lahusti	DK/H/0829/001	493305	FERRING GMBH	EE
Glypressin 1 mg pulveris un šķīdinātājs injekciju šķīduma pagatavošanai	DK/H/0829/001	06-0025	FERRING GMBH	LV
Glypressin 1 mg milteliai ir tirpiklis injekciniam tirpalui	DK/H/0829/001	LT/1/05/0470/001	FERRING GMBH	LT
Glypressin 1 mg pulver og væske til injeksjonsvæske, oppløsning	DK/H/0829/001	05-3442	FERRING LEGEMIDLER AS	NO
Glypressin, 1 mg, proszek i rozpuszczalnik do sporządzania	DK/H/0829/001	11915	FERRING GMBH	PL

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roztworu do wstrzykiwań				
Glypressin 1 mg, powder and solvent for solution for injection	DK/H/0829/001	MA 832/00701	FERRING PHARMACEUTICALS LTD.	MT
Glypressin 1 mg prašek in vehikel za raztopino za injiciranje	DK/H/0829/001	H/05/00711/002	FERRING ARZNEIMITTEL GES.M.B.H.	SI
Glypressin 1 mg Prášok a rozpúšťadlo na injekčný roztok	DK/H/829/001	84/0314/05-S	FERRING LÉCIVA A.S.	SK
Glypressin 1 mg pulver och vätska till injektionsvätska, lösning	DK/H/0829/001	22444	FERRING LÄKEMEDEL AB	SE
GLYPRESSIN 1 mg solución inyectable	not available	72.359	FERRING S.A.U.	ES
GLYCYLPRESSIN 0,1 mg/ml Injektionslösung	not available	69482.00.00	FERRING GMBH	DE
GLYPRESSIN 1 mg Injektionslösung	not available	BE440307	FERRING N.V.	BE
GLYPRESSIN 1 mg solution injectable	not available	BE440307	FERRING N.V.	BE
GLYPRESSIN 1 mg oplossing voor injectie	not available	BE440307	FERRING N.V.	BE
GLYPRESSIN 1 mg solution injectable	not available	2014120386	FERRING N.V.	LU
GLYPRESSIN 1 mg Injektionslösung	not available	2014120386	FERRING N.V.	LU
Glypressin 1 mg/5 ml por és oldószer oldatos injekcióhoz	not available	OGYI-T-7887/01	FERRING MAGYARORSZÁG GYÓGYSZERKERESKEDELMI KFT.	HU
Glypressin 1 mg/5 ml por és oldószer oldatos injekcióhoz	not available	OGYI-T-7887/02	FERRING MAGYARORSZÁG GYÓGYSZERKERESKEDELMI KFT.	HU
GLYPRESSIN 1 mg stungulyf, lausn	not available	IS/1/10/101/01	FERRING LÆGEMIDLER A/S	IS

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GLYPRESSIN	not available	960004	FERRING LÆGEMIDLER A/S	IS
Glypressin 1 mg Powder and Solvent for Solution for Injection	not available	PA 1009/4/1	FERRING IRELAND LTD.	IE
REMESTYP 0,2 Injekční roztok	not available	84/0102/78-CS	FERRING LÉCIVA A.S.	SK
REMESTYP 1,0 Injekční roztok	not available	84/0102/78-CS	FERRING LÉCIVA A.S.	SK
Glypressine 1 mg/5 ml pó e solvente para solução injectável	not available	3311487	FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPessoal, LDA.	PT
Glypressine 1 mg/5 ml pó e solvente para solução injectável	not available	4068987	FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPessoal, LDA.	PT
Glypressin® Injection	not available	PL 03194/0018	FERRING PHARMACEUTICALS LTD.	UK
Glipressina 1 mg/ 8,5 ml soluzione iniettabile per uso endovenoso	not available	026346039	FERRING S.P.A.	IT
Variquel Solution, 0.2mg/ml, solution for injection	NL/H/2566/001	PA0943/027/001	ALLIANCE PHARMACEUTICALS LTD	IE
Variquel 0.2 mg/ml, solution for injection	NL/H/2566/001	PL 16853/0149	ALLIANCE PHARMACEUTICALS LTD	UK
Variquel Oplossing 0,17 mg/ml, oplossing voor injectie	NL/H/2566/001	RVG 111278	ALLIANCE PHARMACEUTICALS LTD	NL
Variquel 0,2 mg/ml solution injectable	NL/H/2566/001	BE445654	ALLIANCE PHARMACEUTICALS LTD	BE
Variquel 0,2 mg/ml oplossing voor injectie	NL/H/2566/001	BE445654	ALLIANCE PHARMACEUTICALS LTD	BE

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Variquel® 0,2 mg/ml Injektionslösung	NL/H/2566/001	BE445654	ALLIANCE PHARMACEUTICALS LTD	BE
Variquel Lösung 0,2 mg/ml Injektionslösung	NL/H/2566/001	87042.00.00	ALLIANCE PHARMACEUTICALS LTD	DE
Variquel, 0,2mg/ml, injektionsvæske, opløsning	NL/H/2566/001	52487	ALLIANCE PHARMACEUTICALS LTD	DK
Variquel, 0,2 mg/ml, injektionsvätska, lösning	NL/H/2566/001	49388	ALLIANCE PHARMACEUTICALS LTD	SE
Variquel 1 mg, solución inyectable	NL/H/2566/001	78317	ALLIANCE PHARMACEUTICALS LTD	ES
VARIQUEL, 0,2 mg/mL, solution injectable	NL/H/2566/001	586 635-9	ALLIANCE PHARMACEUTICALS LTD	FR
VARIQUEL, 0,2 mg/mL, solution injectable	NL/H/2566/001	34009 586 635 9 8	ALLIANCE PHARMACEUTICALS LTD	FR
Variquel 0,2 mg/ml solution injectable	NL/H/2566/001	2013120669	ALLIANCE PHARMACEUTICALS LTD	LU
Variquel, 1 mg/5 ml (0.2mg/ml), solu テアテ」o injetテ。vel	NL/H/2566/001	5594718	ALLIANCE PHARMACEUTICALS LTD	PT
Stemflova 0,2 mg/ml soluzione iniettabile	NL/H/2566/001	42969016	ALLIANCE PHARMACEUTICALS LTD	IT
GLYPRESSIN 1 mg injektiokuiva-aine ja liuotin, liuosta varten	not available	12305	FERRING LÄÄKKEET OY	FI
Glypressin 1 mg pulver och vätska till injektionsvätska, lösning	not available	12305	FERRING LÄÄKKEET OY	FI
Glypressin 0.12 mg/ml solution for injection	not available	PL 03194/0101	FERRING PHARMACEUTICALS LTD.	UK