



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

02 December 2021  
EMA/757577/2021  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: terlipressin

Procedure no.: PSUSA/00002905/202104

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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>
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 TERLIPRESSINE EVER PHARMA 0,2 mg/ml, solution injectable	AT/H/0629/001	34009 550 312 6 0	EVER VALINJECT GMBH	FR
ACETATE DE TERLIPRESSINE EVER PHARMA 0,2 mg/ml, solution injectable	AT/H/0629/001	34009 550 312 7 7	EVER VALINJECT GMBH	FR
Glycylpressin 0,1 mg/ml - Injektionslösung	not available	1-31305	FERRING ARZNEIMITTEL GES.M.B.H.	AT
GLYCYLPRESSIN 0,1 mg/ml Injektionslösung	not available	69482.00.00	FERRING GMBH	DE
Glycylpressin 1 mg - Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	not available	16.732	FERRING ARZNEIMITTEL GES.M.B.H.	AT
Glycylpressin 1 mg Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	not available	389.01.00	FERRING GMBH	DE
GLYPRESSIN	not available	960004	FERRING LÆGEMIDLER A/S	IS
Glypressin 1 mg/ 8.5 ml solution for injection	not available	PA 1009/4/2	FERRING IRELAND LTD.	IE
Glypressin 0,85 mg oldatos injekció	not available	OGYI-T-7887/03	FERRING MAGYARORSZÁG GYÓGYSZERKERESKEDEL MI KFT.	HU
GLYPRESSIN 1 mg injektiokuiva-aine ja liuotin, liuosta varten	not available	12305	FERRING LÄÄKKEET OY	FI
GLYPRESSIN 1 mg injektioneste, liuos	not available	23433	FERRING LÄÄKKEET OY	FI
GLYPRESSIN 1 mg Injektionslösung	not available	BE440307	FERRING N.V.	BE
Glypressin 1 mg injektionsvätska, lösning	not available	23433	FERRING LÄÄKKEET OY	FI
GLYPRESSIN 1 mg oplossing voor injectie	not available	BE440307	FERRING N.V.	BE
GLYPRESSIN 1 mg poeder en oplosmiddel voor	not available	BE150717	FERRING N.V.	BE

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oplossing voor injectie of oplossing voor infusie				
GLYPRESSIN 1 mg poudre et solvant pour solution injectable ou solution pour perfusion	not available	BE150717	FERRING N.V.	BE
Glypressin 1 mg Powder and Solvent for Solution for Injection	not available	PA 1009/004/001	FERRING IRELAND LTD.	IE
Glypressin 1 mg pulver och vätska till injektionsvätska, lösning	not available	12305	FERRING LÄÄKKEET OY	FI
GLYPRESSIN 1 mg Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	not available	BE150717	FERRING N.V.	BE
GLYPRESSIN 1 mg solución inyectable	not available	72.359	FERRING S.A.U.	ES
GLYPRESSIN 1 mg solución inyectable	not available	72.359	FERRING S.A.U.	ES
GLYPRESSIN 1 mg solution injectable	not available	BE440307	FERRING N.V.	BE
GLYPRESSIN 1 mg stungulyf, lausn	not available	IS/1/10/101/01	FERRING LÆGEMIDLER A/S	IS
Glypressin 1 mg/5 ml por és oldószer oldatos injekcióhoz	not available	OGYI-T-7887/01	FERRING MAGYARORSZÁG GYÓGYSZERKERESKEDEL MI KFT.	HU
Glypressin 1 mg/5 ml por és oldószer oldatos injekcióhoz	not available	OGYI-T-7887/02	FERRING MAGYARORSZÁG GYÓGYSZERKERESKEDEL MI KFT.	HU
GLYPRESSIN 1mg polvo y disolvente para solución inyectable	not available	61.412	FERRING S.A.U.	ES
GLYPRESSINE® 1 mg/ 5ml, poudre et solvant pour solution injectable (I.V).	not available	3400955627487	FERRING S.A.S.	FR
GLYPRESSINE® 1 mg/ 8,5ml, solution injectable.	not available	34009 577 005 6 0	FERRING S.A.S.	FR
REMESTYP 0,2 Injekční roztok	not available	84/102/78-C	FERRING LÉCIVA A.S.	CZ
Remestyp 0,2 Injekčný roztok	not available	84/0102/78-CS	FERRING LÉCIVA A.S.	SK
REMESTYP 1,0 injekční roztok	not available	84/110/98-C	FERRING LÉCIVA A.S.	CZ
Remestyp 1,0 Injekčný roztok	not available	84/0102/78-CS	FERRING LÉCIVA A.S.	SK

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Stemflova 0,2 mg/ml soluzione iniettabile	NL/H/2566/001	042969016	ALLIANCE PHARMA (IRELAND) LIMITED	IT
Terlipresin acetát EVER Pharma 0,2 mg/ml injekční roztok	AT/H/0629/001	84/720/15-C	EVER VALINJECT GMBH	CZ
Terlipresín EVER Pharma 0,2 mg/ml injekčný roztok	AT/H/0629/001	84/0460/16-S	EVER VALINJECT GMBH	SK
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
Terlipressin acetate EVER Pharma 0.2 mg/ml solution for injection	AT/H/0629/001	PA1774/007/001	EVER VALINJECT GMBH	IE
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
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
Variquel 0,2 mg/ml oplossing voor injectie	NL/H/2566/001	BE445654	ALLIANCE PHARMA (IRELAND) LIMITED	BE
Variquel 0,2 mg/ml solution injectable	NL/H/2566/001	BE445654	ALLIANCE PHARMA (IRELAND) LIMITED	BE
Variquel 0,2 mg/ml solution injectable	NL/H/2566/001	2013120669	ALLIANCE PHARMA (IRELAND) LIMITED	LU
Variquel 0,2 mg/ml solution injectable	NL/H/2566/001	2013120669	ALLIANCE PHARMA (IRELAND) LIMITED	LU

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Variquel 0.2 mg/ml, solution for injection	NL/H/2566/001	PL 16853/0149	ALLIANCE PHARMACEUTICALS LTD	XI
Variquel Lösung 0,2 mg/ml Injektionslösung	NL/H/2566/001	87042.00.00	ALLIANCE PHARMA (IRELAND) LIMITED	DE
Variquel Lösung 0,2 mg/ml Injektionslösung	NL/H/2566/001	87042.00.00	ALLIANCE PHARMA (IRELAND) LIMITED	DE
Variquel Oplossing 0,17 mg/ml, oplossing voor injectie	NL/H/2566/001	RVG 111278	ALLIANCE PHARMA (IRELAND) LIMITED	NL
Variquel Solution, 0.2mg/ml, solution for injection	NL/H/2566/001	PA2325/005/001	ALLIANCE PHARMA (IRELAND) LIMITED	IE
Variquel, 0,2 mg/ml, injektionsvätska, lösning	NL/H/2566/001	49388	ALLIANCE PHARMA (IRELAND) LIMITED	SE
VARIQUEL, 0,2 mg/mL, solution injectable	NL/H/2566/001	34009 586 635 9 8	ALLIANCE PHARMA (IRELAND) LIMITED	FR
Variquel, 1 mg/5 ml (0.2mg/ml), solução injetável	NL/H/2566/001	5594718	ALLIANCE PHARMA (IRELAND) LIMITED	PT
Variquel,0,2mg/ml, injektionsvæske, opløsning	NL/H/2566/001	52487	ALLIANCE PHARMA (IRELAND) LIMITED	DK
Variquel® 0,2 mg/ml Injektionslösung	NL/H/2566/001	BE445654	ALLIANCE PHARMA (IRELAND) LIMITED	BE
Терлипресин ацетат EVER Pharma 0,2 mg/ml инжекционен разтвор	AT/H/0629/001	BG/MA/MP-52968	EVER VALINJECT GMBH	BG