



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Human Medicines Division

## Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states for terlipressin-containing medicinal products indicated in the treatment of hepatorenal syndrome

Referral under Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

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<b>Member State in EEA</b>	<b>Marketing authorisation holder</b>	<b>Product name</b>	<b>INN/active substance + strength</b>	<b>Pharmaceutical form</b>	<b>Route of administration</b>
Austria	Ever Valinject Gmbh	Terlipressinacetat Ever Pharma	Terlipressin Acetate 1mg/5ml	Solution for injection	Intravenous use
Austria	Ferring Arzneimittel Ges.M.B.H.	Glycylpressin	Terlipressin Acetate 1mg	Powder and solvent for solution for injection	Intravenous use
Austria	Ferring Arzneimittel Ges.M.B.H.	Glycylpressin	Terlipressin 0.1mg/ml	Solution for injection	Intravenous use
Belgium	Alliance Pharma (Ireland) Limited	Variquel	Terlipressin Acetate 0.2mg/ml	Solution for injection	Intravenous use
Bulgaria	Ever Valinject Gmbh	Терлип्रेसин Ацетат Ever Pharma	Terlipressin Acetate 2mg/10ml	Solution for injection	Intravenous use
Czech Republic	Ever Valinject Gmbh	Terlipresin Acetát Ever Pharma	Terlipressin Acetate 1mg/5ml	Solution for injection	Intravenous use
Denmark	Alliance Pharma (Ireland) Limited	Variquel	Terlipressin Acetate 0.2mg/ml	Solution for injection	Intravenous use
France	Alliance Pharma (Ireland) Limited	Variquel	Terlipressin Acetate 0.2mg/ml	Solution for injection	Intravenous use
France	Altan Pharma Ltd	Terlipressine Altan	Terlipressin Acetate 1mg/8.5ml	Solution for injection	Intravenous use
France	Ever Valinject Gmbh	Acetate De Terlipressine Ever Pharma	Terlipressin Acetate 0.2mg/ml	Solution for injection	Intravenous use

France	Ferring S.A.S.	Glypressine	Terlipressin Acetate 1mg	Powder and solvent for solution for injection	Intravenous use
France	Ferring S.A.S.	Glypressine	Terlipressin Acetate 1mg	Solution for injection	Intravenous use
Germany	Alliance Pharma (Ireland) Limited	Variquel	Terlipressin Acetate 0.2mg/ml	Solution for injection	Intravenous use
Germany	Ever Valinject Gmbh	Terlipressinacetat Ever Pharma	Terlipressin Acetate 1mg/5ml	Solution for injection	Intravenous use
Germany	Ferring Gmbh	Glycylpressin	Terlipressin Acetate 0.2mg/ml	Powder And Solvent For Solution For Injection	Intravenous use
Germany	Ferring Gmbh	Glycylpressin	Terlipressin 0.1mg/ml	Solution for injection	Intravenous use
Germany	AraMed GmbH	Terlipressin Adoh	Terlipressin Acetate 0.12mg/ml	Solution for injection	Intravenous use
Ireland	Alliance Pharma (Ireland) Limited	Variquel	Terlipressin Acetate 0.2mg/ml	Solution for injection	Intravenous use
Ireland	Ever Valinject Gmbh	Terlipressin Acetate Ever Pharma	Terlipressin Acetate 2mg/10ml	Solution for injection	Intravenous use
Ireland	Ferring Ireland Ltd.	Glypressin	Terlipressin Acetate 1mg	Powder and solvent for solution for injection	Intravenous use
Ireland	Ferring Ireland Ltd.	Glypressin	Terlipressin Acetate 0.12mg/ml	Solution for injection	Intravenous use
Italy	Dr. Reddy's S.R.L.	Terlipressina Dr. Reddy's	Terlipressin Acetate 1mg/8.5ml	Solution for injection	Intravenous use

Italy	Ever Valinject Gmbh	Terlipressina Acetato Ever Pharma	Terlipressin Acetate 1mg/5ml	Solution for injection	Intravenous use
Italy	Ferring S.P.A.	Glipressina	Terlipressin 0.85mg	Solution for injection	Intravenous use
Netherlands	Adoh B.V.	Terlipressine Adoh	Terlipressin Acetate 1mg	Solution for injection	Intravenous injection
Netherlands	Alliance Pharma (Ireland) Limited	Variquel	Terlipressin Acetate 0.2mg/ml	Solution for injection	Intravenous use
Netherlands	Altan Pharma Ltd	Terlipressine Altan	Terlipressin Acetate 1mg/8.5ml	Solution for injection	Intravenous use
Netherlands	Ferring B.V.	Glypressin	Terlipressin Acetate 0.99mg/8.5ml	Solution for injection	Intravenous use
Poland	Altan Pharma Ltd	Terlipressin Acetate Altan Pharma	Terlipressin Acetate 1mg/8.5ml	Solution for injection	Intravenous use
Poland	Ever Valinject Gmbh	Terlipressini Acetas Ever Pharma	Terlipressin Acetate 1mg/5ml	Solution for injection	Intravenous use
Portugal	Alliance Pharma (Ireland) Limited	Variquel	Terlipressin Acetate 1mg/5ml	Solution for injection	Intravenous use
Portugal	Ever Valinject Gmbh	Terlipressina Ever Pharma	Terlipressin Acetate 1mg/5ml	Solution for injection	Intravenous use
Portugal	Ever Valinject Gmbh	Terlipressina Ever Pharma	Terlipressin Acetate 2mg/10ml	Solution for injection	Intravenous use
Portugal	Ferring Portuguesa – Produtos Farmacêuticos, Sociedade Unipessoal, Lda.	Glypressine	Terlipressin 1mg	Powder and solvent for solution for injection	Intravenous use

Portugal	Ferring Portuguesa – Produtos Farmacêuticos, Sociedade Unipessoal, Lda.	Glypressine	Terlipressin Acetate 0.12mg/8.5ml	Solution For Injection	Intravenous use
Portugal	G.E.S. Genéricos Españoles Laboratorio, S.A.	Terlipressina G.E.S.	Terlipressin Acetate 0.12mg/ml	Solution for injection	Intravenous use
Romania	Ever Valinject Gmbh	Acetat De Terlipresină Ever Pharma	Terlipressin Acetate 1mg/5ml	Solution for injection	Intravenous use
Romania	Ferring Gmbh	Glypressin	Terlipressin Acetate 1mg	Powder and solvent for solution for injection	Intravenous use
Romania	Ferring Gmbh	Glypressin	Terlipressin Acetate 0.12mg/ml	Solution for injection	Intravenous use
Slovakia	Ever Valinject Gmbh	Terlipresin Ever Pharma	Terlipressin Acetate 1mg/5ml	Solution for injection	Intravenous use
Spain	Altan Pharma Ltd	Terlipresina Altan Pharma	Terlipressin Acetate 1mg/8.5ml	Solution for injection	Intravenous use
Spain	Altan Pharmaceuticals S.A.	Terlipresina Altan	Terlipressin Acetate 1mg/8.5ml	Solution for injection	Intravenous use
Spain	Ever Valinject Gmbh	Terlipresina Acetato Ever Pharma	Terlipressin Acetate 1mg/5ml	Solution for injection	Intravenous use
Spain	Ever Valinject Gmbh	Terlipresina Acetato Ever Pharma	Terlipressin Acetate 2mg/10ml	Solution for injection	Intravenous use
Spain	Ferring S.A.U.	Glypressin	Terlipressin Acetate 0.2mg/ml	Powder and solvent for solution for injection	Intravenous use

Spain	Ferring S.A.U.	Glypressin	Terlipressin Acetate 1mg	Solution for injection	Intravenous use
Sweden	Alliance Pharma (Ireland) Limited	Variquel	Terlipressin Acetate 0.2mg/ml	Solution for injection	Intravenous use
United Kingdom (Northern Ireland)	Alliance Pharmaceuticals Ltd	Variquel	Terlipressin Acetate 0.2mg/ml	Solution for injection	Intravenous injection