

Anexo I

Lista das denominações, forma(s) farmacêutica(s), dosagem(ns), via(s) de administração do(s) medicamento(s), titular(es) da(s) autorização(ões) de introdução no mercado nos estados-membros

Estado-Membro UE/EEA	Requerente	Nome (de fantasia)	Dosagem	Forma Farmacêutica	Via de administração
Áustria	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale 20 mg/5 ml Suspension zum Einnehmen	20mg/5ml	suspensão oral	via oral
Áustria	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale 40 mg/5 ml Suspension zum Einnehmen	40mg/5ml	suspensão oral	via oral
Dinamarca	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	suspensão oral	via oral
Dinamarca	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	suspensão oral	via oral

Estado-Membro UE / EEA	Requerente	Nome (de fantasia)	Dosagem	Forma Farmacêutica	Via de administração
Finlândia	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale	20mg/5ml	suspensão oral	via oral
Finlândia	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale	40mg/5ml	suspensão oral	via oral
França	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	suspensão oral	via oral
França	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	suspensão oral	via oral

Estado-Membro UE / EEA	Requerente	Nome (de fantasia)	Dosagem	Forma Farmacêutica	Via de administração
Alemanha	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	suspensão oral	via oral
Alemanha	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	suspensão oral	via oral
Grécia	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	suspensão oral	via oral
Grécia	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	suspensão oral	via oral

Estado-Membro UE / EEA	Requerente	Nome (de fantasia)	Dosagem	Forma Farmacêutica	Via de administração
Irlanda	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	suspensão oral	via oral
Irlanda	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	suspensão oral	via oral
Itália	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatina Vale Pharmaceuticals	20mg/5ml	suspensão oral	via oral
Itália	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatina Vale Pharmaceuticals	40mg/5ml	suspensão oral	via oral

Estado-Membro UE / EEA	Requerente	Nome (de fantasia)	Dosagem	Forma Farmacêutica	Via de administração
Holanda	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatine Vale Pharmaceuticals 20mg/5ml suspensie voor oraal gebruik	20mg/5ml	suspensão oral	via oral
Holanda	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatine Vale Pharmaceuticals 40mg/5ml suspensie voor oraal gebruik	40mg/5ml	suspensão oral	via oral
Noruega	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	suspensão oral	via oral
Noruega	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	suspensão oral	via oral

Estado-Membro UE / EEA	Requerente	Nome (de fantasia)	Dosagem	Forma Farmacêutica	Via de administração
Portugal	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Sinvastatina Vale	20mg/5ml	suspensão oral	via oral
Portugal	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Sinvastatina Vale	40mg/5ml	suspensão oral	via oral
Espanha	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale 20 mg/5 ml suspensión oral	20mg/5ml	suspensão oral	via oral
Espanha	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale 40 mg/5 ml suspensión oral	40mg/5ml	suspensão oral	via oral

Estado-Membro UE / EEA	Requerente	Nome (de fantasia)	Dosagem	Forma Farmacêutica	Via de administração
Suécia	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	suspensão oral	via oral
Suécia	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	suspensão oral	via oral
Reino Unido	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	suspensão oral	via oral
Reino Unido	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	suspensão oral	via oral