

Anexa I

***Lista cu denumirile comerciale, forma farmaceutică, concentrațiile
medicamentului, calea de administrare, solicitantul în statele membre***

Stat membru UE/SEE	Candidat	Denumire (inventată)	Concentrația	Formă farmaceutică	Calea de administrare
Austria	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale 20 mg/5 ml Suspension zum Einnehmen	20mg/5ml	suspensie orală	Administrare orală
Austria	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale 40 mg/5 ml Suspension zum Einnehmen	40mg/5ml	suspensie orală	Administrare orală
Danemarca	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	suspensie orală	Administrare orală
Danemarca	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	suspensie orală	Administrare orală

Stat membru UE / SEE	Candidat	Denumire (inventată)	Concentrația	Formă farmaceutică	Calea de administrare
Finlanda	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale	20mg/5ml	suspensie orală	Administrare orală
Finlanda	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale	40mg/5ml	suspensie orală	Administrare orală
Franța	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	suspensie orală	Administrare orală
Franța	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	suspensie orală	Administrare orală

Stat membru UE / SEE	Candidat	Denumire (inventată)	Concentrația	Formă farmaceutică	Calea de administrare
Germania	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	suspensie orală	Administrare orală
Germania	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	suspensie orală	Administrare orală
Grecia	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	suspensie orală	Administrare orală
Grecia	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	suspensie orală	Administrare orală

Stat membru UE / SEE	Candidat	Denumire (inventată)	Concentrația	Formă farmaceutică	Calea de administrare
Irlanda	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	suspensie orală	Administrare orală
Irlanda	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	suspensie orală	Administrare orală
Italia	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatina Vale Pharmaceuticals	20mg/5ml	suspensie orală	Administrare orală
Italia	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatina Vale Pharmaceuticals	40mg/5ml	suspensie orală	Administrare orală

Stat membru UE / SEE	Candidat	Denumire (inventată)	Concentrația	Formă farmaceutică	Calea de administrare
Olanda	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatine Vale Pharmaceuticals 20mg/5ml suspensie voor oraal gebruik	20mg/5ml	suspensie orală	Administrare orală
Olanda	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatine Vale Pharmaceuticals 40mg/5ml suspensie voor oraal gebruik	40mg/5ml	suspensie orală	Administrare orală
Norvegia	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	suspensie orală	Administrare orală
Norvegia	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	suspensie orală	Administrare orală

Stat membru UE / SEE	Candidat	Denumire (inventată)	Concentrația	Formă farmaceutică	Calea de administrare
Portugalia	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Sinvastatina Vale	20mg/5ml	suspensie orală	Administrare orală
Portugalia	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Sinvastatina Vale	40mg/5ml	suspensie orală	Administrare orală
Spania	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale 20 mg/5 ml suspensión oral	20mg/5ml	suspensie orală	Administrare orală
Spania	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale 40 mg/5 ml suspensión oral	40mg/5ml	suspensie orală	Administrare orală

Stat membru UE / SEE	Candidat	Denumire (inventată)	Concentrația	Formă farmaceutică	Calea de administrare
Suedia	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	suspensie orală	Administrare orală
Suedia	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	suspensie orală	Administrare orală
Regatul Unit	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	suspensie orală	Administrare orală
Regatul Unit	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	suspensie orală	Administrare orală