

Anhang I

**Verzeichnis der Bezeichnungen, Darreichungsformen, Stärken, art der
Anwendung der Arzneimittel,
der Inhaber der Genehmigung für das Inverkehrbringen in den
Mitgliedstaaten**

Mitgliedstaat EU/EWR	Inhaber der Genehmigung für das Inverkehrbringen	Name	Stärke	Darreichungsfor m	Art der Anwendung	Inhalt (Konzentration)
Austria	GlaxoSmithKline Pharma GmbH Albert-Schweitzer-Gasse 6 1140 Wien Austria	Flolan 0,5 mg - Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	0.5 mg	Powder and solvent for solution for infusion	Intravenous use	0.5mg/50ml
Austria	GlaxoSmithKline Pharma GmbH Albert-Schweitzer-Gasse 6 1140 Wien Austria	Flolan 1,5 mg - Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	1.5 mg	Powder and solvent for solution for infusion	Intravenous use	1.5mg/100ml
Belgium	GlaxoSmithKline s.a. / n.v. Rue du Tilleul 13 1332 Genval Belgium	Flolan 0.5 mg powder and solvent for solution for infusion	0.5 mg	Powder and solvent for solution for infusion	Intravenous use	0.5mg/50ml
Belgium	GlaxoSmithKline s.a. / n.v. Rue du Tilleul 13 1332 Genval Belgium	Flolan 1.5 mg powder and solvent for solution for infusion	1.5 mg	Powder and solvent for solution for infusion	Intravenous use	1.5mg/100ml
Belgium	GlaxoSmithKline s.a. / n.v. Rue du Tilleul 13 1332 Genval Belgium	Flolan 1.5 mg powder for solution for infusion	1.5 mg	Powder for solution for infusion	Intravenous use	1.5mg /vial
Czech Republic	The Wellcome Foundation Ltd., Berkeley Avenue 21, Greenford, Middlesex, UB6 ONN United Kingdom	Flolan 0.5 mg, powder and solvent for solution for infusion	0.5 mg	Powder and solvent for solution for infusion	Intravenous use	0.5mg/50ml

Mitgliedstaat EU/EWR	Inhaber der Genehmigung für das Inverkehrbringen	Name	Stärke	Darreichungsfor m	Art der Anwendung	Inhalt (Konzentration)
Czech Republic	The Wellcome Foundation Ltd., Berkeley Avenue 21, Greenford, Middlesex, UB6 ONN United Kingdom	Flolan 1.5 mg, powder and solvent for solution for infusion	1.5 mg	Powder and solvent for solution for infusion	Intravenous use	1.5mg/50ml
Denmark	GlaxoSmithKline Pharma A/S Nykaer 68, 2605 Broendby Denmark	Epoprostenol 500 micrograms	0.5 mg	Powder and solvent for solution for infusion	Intravenous use	0.5mg/50ml
Denmark	GlaxoSmithKline Pharma A/S Nykaer 68, 2605 Broendby Denmark	Epoprostenol 1.5 mg	1.5 mg	Powder and solvent for solution for infusion	Intravenous use	1.5mg/50ml
Estonia	Glaxo Wellcome UK Limited trading as Glaxo Wellcome Operations Glaxo Wellcome House Berkeley Avenue, Greenford Middlesex UB6 ONN United Kingdom	Flolan	0.5 mg	Powder and solvent for solution for infusion	Intravenous use	0.5mg/50ml
France	Laboratoire GLAXOSMITHKLINE 100, route de Versailles 78163 Marly-le-Roi Cedex France	Flolan 0.5 mg, powder and solvent for solution for injection	0.5 mg	Powder and solvent for solution for injection	Intravenous use	0.5mg/50ml
France	Laboratoire GLAXOSMITHKLINE 100, route de Versailles 78163 Marly-le-Roi Cedex France	Flolan 1.5 mg, powder and solvent for solution for injection	1.5 mg	Powder and solvent for solution for injection	Intravenous use	1.5mg/50ml

Mitgliedstaat EU/EWR	Inhaber der Genehmigung für das Inverkehrbringen	Name	Stärke	Darreichungsfor m	Art der Anwendung	Inhalt (Konzentration)
Ireland	GlaxoSmithKline (Ireland) Limited Stonemasons Way Rathfarnham, Dublin 16 Ireland	Flolan 500 micrograms Powder and Solvent for Solution for Infusion	0.5 mg	Powder and solvent for solution for infusion	Intravenous use	0.5mg/50ml
Ireland	GlaxoSmithKline (Ireland) Limited Stonemasons Way Rathfarnham, Dublin 16 Ireland	Flolan 1.5mg Infusion, powder and solvent for solution for infusion	1.5 mg	Powder and solvent for solution for infusion	Intravenous use	1.5mg/50ml
Italy	The Wellcome Foundation Ltd. Glaxo Wellcome house Berkeley Avenue Greenford Middlesex UB6 ONN United Kingdom	Flolan	0.5 mg	Powder and solvent for solution for infusion	Intravenous use	0.5mg/50ml
Italy	The Wellcome Foundation Ltd. Glaxo Wellcome house Berkeley Avenue Greenford Middlesex UB6 ONN United Kingdom	Flolan	0.5 mg	Powder for solution for infusion	Intravenous use	0.5mg/50ml
Italy	The Wellcome Foundation Ltd. Glaxo Wellcome house Berkeley Avenue Greenford Middlesex UB6 ONN United Kingdom	Flolan	1.5 mg	Powder and solvent for solution for infusion	Intravenous use	1.5mg/50ml

Mitgliedstaat EU/EWR	Inhaber der Genehmigung für das Inverkehrbringen	Name	Stärke	Darreichungsfor m	Art der Anwendung	Inhalt (Konzentration)
Luxembourg	GlaxoSmithKline Pharmaceuticals SA 2-4-6, Avenue Pascal B-1330 Wavre Belgium	Flolan 0.5 mg powder and solvent for solution for infusion	0.5 mg	Powder and solvent for solution for infusion	Intravenous use	0.5mg/50ml
Luxembourg	GlaxoSmithKline Pharmaceuticals SA 2-4-6, Avenue Pascal B-1330 Wavre Belgium	Flolan 1.5 mg powder and solvent for solution for infusion	1.5 mg	Powder and solvent for solution for infusion	Intravenous use	1.5mg/100ml
Malta	Glaxo Wellcome UK Limited Glaxo Wellcome House Berkeley Avenue Greenford Middlesex UB6 ONN United Kingdom	Flolan 0.5mg Injection Powder and solvent for solution for Infusion 0.5mg	0.5 mg	Powder and solvent for solution for infusion	Intravenous use	0.5mg/50ml
The Netherlands	GlaxoSmithKline B.V. Huis ter Heideweg 62 3705 LZ Zeist The Netherlands	Flolan 500 microgram, powder for solution for infusion	0.5 mg	Powder for solution for infusion	Intravenous use	0.5mg/50ml
The Netherlands	GlaxoSmithKline B.V. Huis ter Heideweg 62 3705 LZ Zeist The Netherlands	Flolan 500 microgram, powder and solvent for solution for infusion	0.5 mg	Powder and solvent for solution for infusion	Intravenous use	0.5mg/100ml
The Netherlands	GlaxoSmithKline B.V. Huis ter Heideweg 62 3705 LZ Zeist The Netherlands	Flolan 1500 microgram, powder for solution for infusion	1.5 mg	Powder for solution for infusion	Intravenous use	1.5mg/vial

Mitgliedstaat EU/EWR	Inhaber der Genehmigung für das Inverkehrbringen	Name	Stärke	Darreichungsfor m	Art der Anwendung	Inhalt (Konzentration)
The Netherlands	GlaxoSmithKline B.V. Huis ter Heideweg 62 3705 LZ Zeist The Netherlands	Flolan 1500 microgram, powder and solvent for solution for infusion	1.5 mg	Powder and solvent for solution for infusion	Intravenous use	1.5mg/100ml
Norway	GlaxoSmithKline AS Forskningsveien 2 A Postboks 180 Vinderen 0319 Oslo Norway	Flolan	0.5 mg	Powder and solvent for solution for infusion	Intravenous use	0.5mg/100ml
Norway	GlaxoSmithKline AS Forskningsveien 2 A Postboks 180 Vinderen 0319 OSLO Norway	Flolan	1.5 mg	Powder and solvent for solution for infusion	Intravenous use	1.5mg/100ml
Spain	GlaxoSmithKline, S.A. P.T.M. - C/ Severo Ochoa, 2 28760 - Tres Cantos Madrid Spain	Flolan	0.5 mg	Powder and solvent for solution for infusion	Intravenous use	0.5mg/50ml
United Kingdom	Glaxo Wellcome UK Ltd Stockley Park West Uxbridge Middlesex, UB11 1BT United Kingdom	Flolan 0.5mg Injection	0.5 mg	Freeze-Dried Powder	Intravenous use	0.5mg/50ml

Mitgliedstaat EU/EWR	Inhaber der Genehmigung für das Inverkehrbringen	Name	Stärke	Darreichungsfor m	Art der Anwendung	Inhalt (Konzentration)
United Kingdom	Glaxo Wellcome UK Ltd Stockley Park West Uxbridge Middlesex, UB11 1BT United Kingdom	Flolan 1.5mg Injection	1.5 mg	Sterile freeze- dried powder for solution for infusion	Intravenous use	1.5mg/50ml