

Annex I

List of the names, pharmaceutical form(s), strength(s) of the medicinal product(s), route(s) of administration, marketing authorisation holder(s) in the member states

Member State (in EEA)	Marketing Authorisation Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Austria	Defiante Farmaceutica S.A., Rua dos Ferreiros 260, 9000-082 Funchal/Madeira, Portugal	Hydergin Fas 4,5 mg Filmtabletten	4.5 mg (1:1:1)	film-coated tablet	oral use
Austria	Defiante Farmaceutica S.A., Rua dos Ferreiros 260, 9000-082 Funchal/Madeira, Portugal	Hydergin 1 mg/ml Tropfen	1 mg/ml (1:1:1)	oral drops, solution	oral use
Austria	Defiante Farmaceutica S.A., Rua dos Ferreiros 260, 9000-082 Funchal/Madeira, Portugal	Hydergin 3 mg/ml Tropfen	3 mg/ml (1:1:1)	oral drops, solution	oral use
Austria	Defiante Farmaceutica S.A., Rua dos Ferreiros 260, 9000-082 Funchal/Madeira, Portugal	Hydergin 1 mg Tabletten	1 mg (1:1:1)	tablet	oral use
Austria	Defiante Farmaceutica S.A., Rua dos Ferreiros 260, 9000-082 Funchal/Madeira, Portugal	Hydergin 2 mg Tabletten	2 mg (1:1:1)	tablet	oral use
Austria	Defiante Farmaceutica S.A., Rua dos Ferreiros 260, 9000-082 Funchal/Madeira, Portugal	Hydergin SRO 6 mg Kapseln	6 mg (1:1:1)	modified-release capsule, hard	oral use
Belgium	Defiante Farmacêutica S.A., Rua dos Ferreiros 260, 9000-082 Funchal, Portugal	Hydergine	1mg-ml	oral solution	oral use

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Belgium	Defiante Farmacêutica S.A., Rua dos Ferreiros 260, 9000-082 Funchal, Portugal	Hydergine	1,5 mg	Tablets	oral use
Belgium	Defiante Farmacêutica S.A., Rua dos Ferreiros 260, 9000-082 Funchal, Portugal	Hydergine	4,5 mg	Tablets	oral use
Belgium	Defiante Farmacêutica S.A., Rua dos Ferreiros 260, 9000-082 Funchal, Portugal	Hydergine FAS	4,5 mg	Gastro-resistant tablet	oral use
Belgium	Nycomed Belgium N.V. Gentsesteenweg 615 1080 Brussels Belgium	Ibexone	1,5 mg	Tablets	oral use
Belgium	Nycomed Belgium N.V. Gentsesteenweg 615 1080 Brussels Belgium	Ibexone	1mg-ml	oral solution	oral use
Belgium	Nycomed Belgium N.V. Gentsesteenweg 615 1080 Brussels Belgium	Ibexone	3mg-ml	oral solution	oral use
Belgium	Nycomed Belgium N.V. Gentsesteenweg 615 1080 Brussels Belgium	Ibexone	4,5 mg	Tablets	oral use
Belgium	Nycomed Belgium N.V. Gentsesteenweg 615 1080 Brussels Belgium	STOFILAN	1,5 mg	Tablets	oral use

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Belgium	Nycomed Belgium N.V. Gentsesteenweg 615 1080 Brussels Belgium	STOFILAN	1mg-ml	oral drops solution	oral use
Belgium	Nycomed Belgium N.V. Gentsesteenweg 615 1080 Brussels Belgium	STOFILAN FORTE	4,5 mg	Tablets	oral use
Czech Republic	TEVA Czech Industries s.r.o. Ostravská 29 747 70 Opava-Komárov Czech Republic	SECATOXIN FORTE	2.5MG/ML	Oral drops, solution	oral use
Finland	Defiante Farmacêutica, S.A. Rua dos Ferreiros, 260 9000-082 Funchal Portugal	Hydergin	1,5 mg	Tablets	oral use
Finland	Defiante Farmacêutica, S.A. Rua dos Ferreiros, 260 9000-082 Funchal Portugal	Hydergin	1 mg	Tablets	oral use
France	THERICA 15, avenue Henry Dunant 27400 Louviers France	CAPERGYL 4,5 mg DOSE QUOTIDIENNE UNIQUE, capsule	4.5 mg	soft capsule	oral use
France	DEFIANTE FARMACEUTICA SA (PORTUGAL) Rua dos Ferreiros, 260 9000-082 Funchal Portugal	HYDERGINE 1 mg/ml, solution buvable en gouttes	1 mg/ml	oral drops, solution	oral use

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France	DEFIANTE FARMACEUTICA SA (PORTUGAL) Rua dos Ferreiros, 260 9000-082 Funchal Portugal	HYDERGINE 4,5 mg DOSE QUOTIDIENNE UNIQUE, comprimé	4.5 mg	tablet	oral use
Germany	Defiante Farmacêutica, S.A. Rua dos Ferreiros, 260 9000-082 Funchal Portugal	Hydergin	2 mg	Tablets	oral use
Germany	Defiante Farmacêutica, S.A. Rua dos Ferreiros, 260 9000-082 Funchal Portugal	Hydergin	1 mg/ml	Oral drops	oral use
Germany	Defiante Farmacêutica, S.A. Rua dos Ferreiros, 260 9000-082 Funchal Portugal	Hydergin	2 mg/ml	Oral drops	oral use
Greece	Defiante Farmacêutica, S.A. Rua dos Ferreiros, 260 9000-082 Funchal Portugal	Hydergine	1mg/ml	Oral drops	oral use
Italy	Defiante Farmaceutica sa Rua dos Ferreiros, 260 Funchal Madeira - Portugal	HYDERGINA	1,5 mg	tablet	oral use

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Italy	Defiante Farmaceutica sa Rua dos Ferreiros, 260 Funchal Madeira - Portugal	HYDERGINA	1 mg/ml	oral solution	oral use
Luxembourg	Defiante Farmacêutica, S.A. Rua dos Ferreiros, 260 9000-082 Funchal Portugal	Hydergin	1 mg/ml	Oral drops	oral use
Luxembourg	Defiante Farmacêutica, S.A. Rua dos Ferreiros, 260 9000-082 Funchal Portugal	Hydergin	2 mg/ml	Oral drops	oral use
Poland	Farmaceutyczna Spółdzielnia Pracy FILOFARM ul. Pułaskiego 39 85-619 Bydgoszcz Poland	Dihydroergotoxinum Filofarm	1 mg/ml	oral solution	oral use
Portugal	Defiante Farmacêutica, S.A. PRT Rua dos Ferreiros, 260 9000-082 Funchal - Madeira Portugal	Hydergine	1.5 mg	tablet	oral use
Portugal	Defiante Farmacêutica, S.A. PRT Rua dos Ferreiros, 260 9000-082 Funchal - Madeira Portugal	Hydergine	4.5 mg	tablet	oral use

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Portugal	Defiante Farmacêutica, S.A. PRT Rua dos Ferreiros, 260 9000-082 Funchal - Madeira Portugal	Hydergine	1 mg/ml	Oral drops, solution	oral use
Portugal	Defiante Farmacêutica, S.A. PRT Rua dos Ferreiros, 260 9000-082 Funchal - Madeira Portugal	Hydergine	3 mg/ml	Oral drops, solution	oral use
Romania	LEK PHARMACEUTICALS d.d. Verovskova 57, 1526 Ljubljana, Slovenia	REDERGIN	1 mg/ml	Oral drops, solution	oral use
Slovak Republic	Teva Czech Industries s.r.o. Ostravská 29, č. p. 305 747 70 Opava-Komárov Czech republic	SECATOXIN FORTE	2,5 mg / 1 ml	Oral drops, solution	oral use
Slovenia	LEK farmacevtska družba d.d., Verovskova 57, SI-1526 Ljubljana, Slovenia	Redergin 1,5 mg tablete	1,5 mg	tablet	oral use
Slovenia	LEK farmacevtska družba d.d., Verovskova 57, SI-1526 Ljubljana, Slovenia	Redergin 4,5 mg tablete	4,5 mg	tablet	oral use
Slovenia	LEK farmacevtska družba d.d., Verovskova 57, SI-1526 Ljubljana, Slovenia	Redergin 1 mg/ ml peroralna raztopina	1 mg/ml	oral solution	oral use

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Spain	DEFIANTE FARMACEUTICA, S.A. Rua dos Ferreiros, 260 9000-082 Funchal PORTUGAL	HYDERGINA SOLUCIÓN GOTAS	1 mg/ml	oral drops, solution	oral use
Spain	DEFIANTE FARMACEUTICA, S.A. Rua dos Ferreiros, 260 9000-082 Funchal PORTUGAL	HYDERGINA 4,5 mg COMPRIMIDOS	4.5 mg	tablet	oral use
Sweden	Defiante Farmacêutica, S.A. Rua dos Ferreiros, 260 9000-082 Funchal Portugal	Hydergin	1 mg	Tablets	oral use