

ANNEX I

**LIST OF THE INVENTED NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE
MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION AND MARKETING
AUTHORISATION HOLDERS IN THE MEMBER STATES**

CLOBUTINOL CONTAINING MEDICINAL PRODUCTS WITH MARKETING AUTHORISATION IN THE EUROPEAN UNION

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration
Austria	Boehringer Ingelheim Austria GmbH Dr.Boehringer-Gasse 5-11 A-1121 Wien Austria	Silomat - Dragees	40 mg	Coated tablet	Oral use
Austria	Boehringer Ingelheim Austria GmbH Dr.Boehringer-Gasse 5-11 A-1121 Wien Austria	Silomat - Hustensaft	40 mg/10 ml	Oral solution	Oral use
Austria	Boehringer Ingelheim Austria GmbH Dr.Boehringer-Gasse 5-11 A-1121 Wien Austria	Silomat - Tropfen	60 mg/ml	Oral drops, solution	Oral use
Belgium	SCS Boehringer Ingelheim Comm.V., Avenue Ariane 16 B-1200 Brussels Belgium	Silomat	40 mg	Tablets	Oral use
Belgium	SCS Boehringer Ingelheim Comm.V., Avenue Ariane 16 B-1200 Brussels Belgium	Silomat	60mg	Oral solution	Oral use
Belgium	SCS Boehringer Ingelheim Comm.V., Avenue Ariane 16 B-1200 Brussels Belgium	Silomat	20 mg/ 5 ml	Syrup	Oral use
Czech Republic	Boehringer Ingelheim GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	Silomat	20 mg/2 ml	Solution for injection	Intramuscular or intravenous use

Czech Republic	Boehringer Ingelheim GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	Silomat	40 mg / 10 ml.	Syrup	Oral use
Czech Republic	Boehringer Ingelheim GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	Silomat	900 mg /15 ml	Oral drops, solution	Oral use
Germany	Boehringer Ingelheim Pharma GmbH & Co.KG Binger Str. 173 D-55216 Ingelheim Germany	Clobutinol Kapseln 80 mg	80 mg	Capsule, hard	Oral use
Germany	Boehringer Ingelheim Pharma GmbH & Co.KG Binger Str. 173 D-55216 Ingelheim Germany	Clobutinol - Tropfen TH	40 mg/ 0.67 ml	Oral drops, solution	Oral use
Germany	Boehringer Ingelheim Pharma GmbH & Co.KG Binger Str. 173 D-55216 Ingelheim Germany	Silomat Ampullen gegen Reizhusten	20 mg/ 2 ml	Solution for injection	Intramuscular or intravenous use
Germany	Boehringer Ingelheim Pharma GmbH & Co.KG Binger Str. 173 D-55216 Ingelheim Germany	Silomat Dragees gegen Reizhusten	40 mg	Coated tablet	Oral use
Germany	Boehringer Ingelheim Pharma GmbH & Co.KG Binger Str. 173 D-55216 Ingelheim Germany	Silomat Saft gegen Reizhusten	40 mg/ 10 ml	Solution	Oral use

Germany	Boehringer Ingelheim Pharma GmbH & Co.KG Binger Str. 173 D-55216 Ingelheim Germany	Silomat Tropfen gegen Reithusten	40 mg/ 0.67 ml	Oral drops, solution	Oral use
Germany	Chephasaar Chemisch- Pharmazeutische Fabrik GmbH Mühlstr. 50 D-66386 Sankt Ingbert Germany	Clobutinol- Chephasaar Kapsel 40 mg	40 mg	Capsule, hard	Oral use
Germany	Chephasaar Chemisch- Pharmazeutische Fabrik GmbH Mühlstr. 50 D-66386 Sankt Ingbert Germany	Clobutinol- Chephasaar Saft 4mg/ml	4 mg/1 ml	Oral solution	Oral use
Germany	Chephasaar Chemisch- Pharmazeutische Fabrik GmbH Mühlstr. 50 D-66386 Sankt Ingbert Germany	Clobutinol- MIP Kapsel 40 mg	40 mg	Capsule, hard	Oral use
Germany	Chephasaar Chemisch- Pharmazeutische Fabrik GmbH Mühlstr. 50 D-66386 Sankt Ingbert Germany	Clobutinol- MIP Tropfen 80 mg/ml	80 mg/ 1 ml	Oral solution	Oral use
Germany	Chephasaar Chemisch- Pharmazeutische Fabrik GmbH Mühlstr. 50 D-66386 Sankt Ingbert Germany	Rofatuss forte	80 mg	Capsule, hard	Oral use

Germany	Chephasaar Chemisch- Pharmazeutische Fabrik GmbH Mühlstr. 50 D-66386 Sankt Ingbert Germany	Rofatuss N	40 mg	Capsule, hard	Oral use
Germany	Chephasaar Chemisch- Pharmazeutische Fabrik GmbH Mühlstr. 50 D-66386 Sankt Ingbert Germany	Rofatuss Saft	400 mg/ 100 ml	Oral solution	Oral use
Germany	Chephasaar Chemisch- Pharmazeutische Fabrik GmbH Mühlstr. 50 D-66386 Sankt Ingbert Germany	Rofatuss Tropfen	80 mg/ 1 ml	Oral drops, solution	Oral use
Germany	EMRA-MED Arzneimittel GmbH Otto-Hahn-Str. 11 D-22946 Trittau Germany	Silomat Dragees gegen Reizhusten	40 mg	Coated tablet	Oral use
Germany	EMRA-MED Arzneimittel GmbH Otto-Hahn-Str. 11 D-22946 Trittau Germany	Silomat Saft	40 mg/ 10 ml	Oral solution	Oral use
Germany	HEXAL AG Industriestr. 25 D-83607 Holzkirchen Germany	Clobutinol Tropfen	40 mg/ 0.67 ml	Oral drops, solution	Oral use
Germany	HEXAL AG Industriestr. 25 D-83607 Holzkirchen Germany	Tussed Hustenstillter Dragees	40 mg	Coated tablet	Oral use

Germany	HEXAL AG Industriestr. 25 D-83607 Holzkirchen Germany	Tussed Hustenstiller Saft	40 mg/ 10 ml	Oral solution	Oral use
Germany	HEXAL AG Industriestr. 25 D-83607 Holzkirchen Germany	Tussed Hustenstiller Tropfen	40 mg/ 0.67 ml	Solution	Oral use
Germany	Hofmann & Sommer GmbH & Co.KG Chemisch-pharmazeutische Fabrik Lindenstr. 11 D-07426 Königsee Germany	Nullatuss Clobutinol Hustentropfen	6 g/ 100 g	Oral drops, solution	Oral use
Germany	kohlpharma GmbH Im Holzhau 8 d-66663 Merzig Germany	Silomat Tropfen gegen Reithusten	40 mg/ 0.67 ml	Oral solution	Oral use
Germany	Pharma Westen GmbH Fixheider Str. 4 D-51381 Leverkusen Germany	Silomat Dragees gegen Reizhusten	40 mg	Coated tablet	Oral use
Germany	Pharma Westen GmbH Fixheider Str. 4 D-51381 Leverkusen Germany	Silomat Saft gegen Reizhusten	40 mg/ 10 ml	Oral solution	Oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	Hustenstiller- ratiopharm Clobutinol	20 mg/ 5 ml	Oral solution	Oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	Hustenstiller- ratiopharm Clobutinol Kapseln	80 mg	Capsule, hard	Oral use

Germany	ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	Hustenstill- ratiopharm Clobutinol Tropfen	80 mg/ 1 ml	Oral solution	Oral use
Greece	Boehringer Ingelheim Hellas S.A. 2 Ellinikou str. Athens 167 77 Greece	Silomat Compositum (Clobutinol HCl + Orciprenaline Sulfate)	20+5 mg /5ml	Syrup	Oral use
Greece	Boehringer Ingelheim Hellas S.A. 2 Ellinikou str. Athens 167 77 Greece	Silomat	60 mg/ml	Oral Solution, Drops	Oral use
Greece	Boehringer Ingelheim Hellas S.A. 2 Ellinikou str. Athens 167 77 Greece	Silomat	20mg/5ml	Syrup	Oral use
Finland	Boehringer Ingelheim Finland Ky, Tammasaarekatu 5, 00180 Helsinki, Finland	Silomat	4 mg/ml	Oral solution	Oral use
Finland	Boehringer Ingelheim Finland Ky, Tammasaarekatu 5, 00180 Helsinki, Finland	Silomat	40 mg	Coated tablets	Oral use
Finland	Orion Corporation, ORION PHARMA, Tengströminkatu 8, P.O.Box 425, 20101 Turku, Finland	Mixtus	4 mg/ml	Oral solution	Oral use
France	BOEHRINGER INGELHEIM FRANCE 37-39, rue Boissière 75116 PARIS France	Silomat	0.40%	Syrup	Oral use

France	BOEHRINGER INGELHEIM FRANCE 37-39, rue Boissière 75116 PARIS France	Silomat	20 mg / 2 mL	Solution for injection	Intramuscular or intravenous use
France	BOEHRINGER INGELHEIM FRANCE 37-39, rue Boissière 75116 PARIS France	Silomat	40 mg	Coated-tablet	Oral use
France	BOEHRINGER INGELHEIM FRANCE 37-39, rue Boissière 75116 PARIS France	Silomat	6%	Oral drops, solution	Oral use