

Annex I

List of the invented names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Austria	S.Med Handels GmbH Zachgasse1, Vienna AT-1220 Austria	Buflomed 'S.Med' 300 mg Filmtabletten	300 mg	film-coated tablet	oral use
Austria	S.Med Handels GmbH Zachgasse1, Vienna AT-1220 Austria	Buflomed 'S.Med' retard 600 mg Filmtabletten	600 mg	prolonged-release tablet	oral use
Belgium	Amdipharm Limited Temple Chambers 3 Burlington Road Dublin 4 Ireland	Loftyl	150 mg	coated tablet	oral use
Belgium	Amdipharm Limited Temple Chambers 3 Burlington Road Dublin 4 Ireland	Loftyl	50 mg/5 ml	solution for injection	intramuscular and intravenous use
Cyprus	MEDOCHEMIE LTD, 1-10 Constantinoupoleos street P.O.Box 51409 3505 Lemesos Cyprus	Ikelan solution for injection or infusion 50mg/5ml	50mg/5ml	injection	Intramuscular and intravenous use
France	BIOGARAN 15, boulevard Charles de Gaulle 92700 COLOMBES FRANCE	BUFLOMEDIL BIOGARAN 150 mg, comprimé pelliculé	150 mg	Film-coated tablet	oral use

France	QUALIMED 117, allée des Parcs 69800 SAINT-PRIEST France	BUFLOMEDIL QUALIMED 150 mg, comprimé pelliculé	150 mg	Film-coated tablet	oral use
France	TEVA SANTE Le Palatin 1, 1 cours du Triangle 92936 PARIS LA DEFENSE CEDEX France	BUFLOMEDIL TEVA 150 mg, comprimé pelliculé	150 mg	Film-coated tablet	oral use
France	ACTAVIS France La Boursidière Centre d'Affaires 92357 LE PLESSIS ROBINSON France	BUFLOMEDIL ACTAVIS 150 mg, comprimé	150 mg	Tablet	oral use
France	AMDIPHARM LTD Temple Chambers 3 Burlington Road DUBLIN 4 IRELAND	LOFTYL 50 mg/5 ml, solution injectable	50 mg/5 ml	Solution for injection	Intramuscular and intravenous use
France	AMDIPHARM LTD Temple Chambers 3, Burlington Road DUBLIN 4 IRELAND	LOFTYL 150 mg, comprimé pelliculé	150 mg	Film-coated tablet	oral use
France	ARROW GENERIQUES 26, avenue Tony Garnier 69007 LYON FRANCE	BUFLOMEDIL ARROW 150 mg, comprimé	150 mg	Tablet	oral use
France	CEPHALON FRANCE 20, rue Charles Martigny 94700 MAISONS-ALFORT FRANCE	FONZYLANE 150 mg, comprimé pelliculé	150 mg	Film-coated tablet	oral use

France	CRISTERS 22 quai Gallieni 92150 SURESNES FRANCE	BUFLOMEDIL CRISTERS 150 mg, comprimé	150 mg	Tablet	oral use
France	EG LABO - LABORATOIRES EUROGENERIC "Le Quintet" - bâtiment A 12, rue Danjou 92517 BOULOGNE BILLANCOURT Cedex FRANCE	BUFLOMEDIL EG 150 mg, comprimé pelliculé	150 mg	Film-coated tablet	oral use
France	LABORATOIRE RATIOPHARM 19, boulevard Paul Vaillant Couturier 94200 IVRY SUR SEINE France	BUFLOMEDIL RATIOPHARM 150 mg, comprimé pelliculé	150 mg	Film-coated tablet	oral use
France	MYLAN SAS 117, allée des Parcs 69800 SAINT-PRIEST France	BUFLOMEDIL MYLAN 150 mg, comprimé pelliculé	150 mg	Film-coated tablet	oral use
France	RANBAXY PHARMACIE GENERIQUES 11-15 Quai Dion Bouton 92800 PUTEAUX France	BUFLOMEDIL RPG 150 mg, comprimé pelliculé	150 mg	Film-coated tablet	oral use
France	RANBAXY PHARMACIE GENERIQUES 11-15 Quai Dion Bouton 92800 PUTEAUX France	BUFLOMEDIL RPG 150 mg, comprimé	150 mg	Tablet	oral use
France	SANDOZ 49, avenue Georges Pompidou 92300 LEVALLOIS-PERRET France	BUFLOMEDIL SANDOZ 150 mg, comprimé	150 mg	Tablet	oral use

France	ZYDUS FRANCE 25, rue des Peupliers ZAC Les Hautes Pâtures - Parc d'Activités des Peupliers 92000 NANTERRE France	BUFLOMEDIL ZYDUS 150 mg, comprimé	150 mg	Tablet	oral use
Germany	Amdipharm Limited Temple Chamcers, 3 Burlington Road IRL- DUBLIN 4 Irland	Bufedil long Retardtabletten	600 mg	Prolonged-release tablet	oral use
Germany	AbZ-Pharma GmbH Dr.Georg-Spohn-Str. 7 D-89143 Blaubeuren Germany	Buflomedil AbZ, 600 mg Retardtabletten	600 mg	Prolonged-release tablet	oral use
Germany	Actavis Deutschland GmbH & Co. KG Elisabeth-Selbert-Str. 1 D-40764 Langenfeld Germany	Buflor-Puren 300	300 mg	Film-coated tablet	oral use
Germany	Actavis Deutschland GmbH & Co. KG Elisabeth-Selbert-Str. 1 D-40764 Langenfeld Germany	BUFLO-Puren 600 retard	600mg	Prolonged-release tablet	oral use
Germany	CT Arzneimittel GmbH Lengeder Str. 42a D-13407 Berlin	Buflomedil-CT 150mg Filmtabletten	150 mg	Film-coated tablet	oral use
Germany	CT Arzneimittel GmbH Lengeder Str. 42a D-13407 Berlin	Buflomedil-CT 300mg Filmtabletten	300 mg	Film-coated tablet	oral use

Germany	CT Arzneimittel GmbH Lengeder Str. 42a D-13407 Berlin	Buflomedil-CT 50mg/5ml Ampullen	50mg / 5ml	Solution for injection, solution for infusion	Intravenous and intramuscular use
Germany	CT Arzneimittel GmbH Lengeder Str. 42a D-13407 Berlin	Buflomedil-CT 600mg Retardtabletten	600 mg	Prolonged-release tablet	oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	Buflomedil- ratiopharm 300 mg Filmtabletten	300 mg	Film-coated tablet	oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	Buflomedil- ratiopharm 600 mg Retardtabletten	600 mg	Prolonged-release tablet	oral use
Germany	Riemser Arzneimittel AG An der Wiek 7 D-17493 Greifswald - Insel Riems Germany	Complamin Buflomedil 600 mg retard	600 mg	Prolonged-release tablet	oral use
Germany	Riemser Arzneimittel AG An der Wiek 7 D-17493 Greifswald - Insel Riems Germany	Complamin Buflomedil Injekt	50mg / 5ml	Solution for injection	intravenous and intramuscular use
Germany	Sanofi-Aventis Deutschland GmbH Industriepark Höchst, Gebäude K703 D-65926 Frankfurt am Main Germany	Defluina peri	300 mg	Film-coated tablet	oral use

Germany	Sanofi-Aventis Deutschland GmbH Industriepark Höchst, Gebäude K703 D-65926 Frankfurt am Main Germany	Deflunia peri mite	150 mg	Film-coated tablet	oral use
Germany	Stadapharm GmbH Stadastr. 2 - 18 D-61118 Bad Vilbel	Buflomedil Stada 150mg Filmtabletten	150 mg	Film-coated tablet	oral use
Germany	Stadapharm GmbH Stadastr. 2 - 18 D-61118 Bad Vilbel	Buflomedil Stada 300mg Filmtabletten	300 mg	Film-coated tablet	oral use
Greece	BROS LTD AYGIS AND GALINIS 15 KIFISSIA ATHENS 14564 Greece	THIOCODIN	150MG/TAB	COATED TABLET	oral use
Greece	BROS LTD AYGIS AND GALINIS 15 KIFISSIA ATHENS 14564 Greece	THIOCODIN	300MG/TAB	COATED TABLET	oral use
Greece	AMDIPHARM LIMITED, IRELAND Temple Chambers 3 Burlington Road Dublin 4 Ireland	LOFTYL	150MG/TAB	FILM COATED TABLET	oral use
Greece	AMDIPHARM LIMITED, IRELAND Temple Chambers 3 Burlington Road Dublin 4 Ireland	LOFTYL	300MG/TAB	FILM COATED TABLET	oral use

Greece	AMDIPHARM LIMITED, IRELAND Temple Chambers 3 Burlington Road Dublin 4 Ireland	LOFTYL	150MG/ML	ORAL DROPS SOLUTION	oral use
Greece	AMDIPHARM LIMITED, IRELAND Temple Chambers 3 Burlington Road Dublin 4 Ireland	LOFTYL	50MG/5ML	SOLUTION FOR INJECTION	INTRAVENOUS INFUSION, INTRAVENOUS INJECTION, INTRAMUSCULAR
Greece	AMDIPHARM LIMITED, IRELAND Temple Chambers 3 Burlington Road Dublin 4 Ireland	LOFTYL	600MG/TAB	CONTROLLED RELEASE TABLET	oral use
Greece	BIOSPRAY ABEE 18TH KM MARATHONOS AVENUE PALLINI Athens 15344 Greece	BOTAMIRAL	300MG/TAB	FILM COATED TABLET	oral use
Greece	FARAN ABEE PRODUCTION AND DISTRIBUTION OF MEDICINES ACHAIAS AND TRIZOINIAS NEA KIFISSIA Athens 14564 Greece	VANOGE	150MG/ML	ORAL DROPS SOLUTION	oral use
Greece	FARAN ABEE PRODUCTION AND DISTRIBUTION OF MEDICINES ACHAIAS AND TRIZOINIAS NEA KIFISSIA 14565 Greece	VANOGE	300MG/TAB	FILM COATED TABLET	oral use
Greece	HELP ABEE VALAORITOU 10, METAMORFOSI ATTIKIS 144 52 Greece	VARDOLIN	150MG/ML	ORAL DROPS SOLUTION	oral use

Greece	HELP ABEE VALAORITOU 10, METAMORFOSI ATTIKIS 144 53 Greece	VARDOLIN	150MG/TAB	FILM COATED TABLET	oral use
Greece	HELP ABEE VALAORITOU 10, METAMORFOSI ATTIKIS 144 54 Greece	VARDOLIN	300MG/TAB	FILM COATED TABLET	oral use
Greece	HELP ABEE VALAORITOU 10, METAMORFOSI ATTIKIS 144 55 Greece	VARDOLIN	600MG/TAB	CONTROLLED RELEASE TABLET	oral use
Greece	NORMA HELLAS S.A. MENANDROU 54 ATHENS 10431 Greece	FLUBIR	150MG/TAB	FILM COATED TABLET	oral use
Greece	NORMA HELLAS S.A. MENANDROU 54 ATHENS 10432 Greece	FLUBIR	300MG/TAB	FILM COATED TABLET	oral use
Greece	RAFARM A.E.B.E. KORINTHOU 12, NEO PSYCHIKO 15451 Greece	ZELIAN	150MG/TAB	FILM COATED TABLET	oral use
Greece	RAFARM A.E.B.E. KORINTHOU 12, NEO PSYCHIKO 15451 Greece	ZELIAN	300MG/TAB	FILM COATED TABLET	oral use

Greece	BIOSTAM KAL. MPOUGA AND CO DIAKRIAS 6 ZOGRAFOU 157 73 Athens Greece	CHLOROFARM-S	300MG/TAB	FILM COATED TABLET	oral use
Greece	ANFARM HELLAS PERIKLEOUS 53-57 ATHENS 105 60 Greece	BLADIRON	300MG/TAB	FILM COATED TABLET	oral use
Greece	ANFARM HELLAS PERIKLEOUS 53-57 ATHENS 105 60 Greece	BLADIRON	150MG/ML	ORAL DROPS SOLUTION	oral use
Greece	A. NIKOLAKOPOULOS AND CO GALATSIU AVENUE 115, ATHENS 11146 Greece	IRRODAN RETARD	600MG/TAB	SUSTAINED RELEASE TABLET	oral use
Greece	MEDICHROM S.A. 6Km MARKOPOULOU-KOROPI AVENUE MARKOPOPULO MESOGEIWN 19003 Greece	BUFLODIL	300MG/TAB	FILM COATED TABLET	oral use
Greece	ELPEN SA PHARMACEUTICAL INDUSTRY MARATHONOS AVENUE 95 PIKERMI ATTIKIS 19009 Greece	PENPURIN	150MG/TAB	FILM COATED TABLET	oral use
Greece	ELPEN SA PHARMACEUTICAL INDUSTRY MARATHONOS AVENUE 95 PIKERMI ATTIKIS 19010 Greece	PENPURIN	300MG/TAB	FILM COATED TABLET	oral use

Greece	ELPEN SA PHARMACEUTICAL INDUSTRY MARATHONOS AVENUE 95 PIKERMI ATTIKIS 19011 Greece	PENPURIN	150MG/ML	ORAL DROPS SOLUTION	oral use
Greece	ELPEN SA PHARMACEUTICAL INDUSTRY MARATHONOS AVENUE 95 PIKERMI ATTIKIS 19012 Greece	PENPURIN	600MG/TAB	CONTROLLED RELEASE TABLET	oral use
Greece	VIOFAR LTD ETHNIKIS ANTISTASEOS AND TRIFYLLIAS ACHARNES 13671 Greece	SULODIL	300MG/TAB	FILM COATED TABLET	oral use
Greece	VIOFAR LTD ETHNIKIS ANTISTASEOS AND TRIFYLLIAS ACHARNES 13672 Greece	SULODIL	600MG/TAB	CONTROLLED RELEASE TABLET	oral use
Italy	AMDIPHARM LTD Temple Chambers, 3 Burlington Road, Dublin 4 IRELAND	LOFTYL	150 mg/ml	oral drop, solution	oral use
Italy	AMDIPHARM LTD Temple Chambers, 3 Burlington Road, Dublin 4 IRELAND	LOFTYL	10 mg/ml	solution for injection	intramuscular and intravenous use
Italy	AMDIPHARM LTD Temple Chambers, 3 Burlington Road, Dublin 4 IRELAND	LOFTYL	300 mg/10 ml	oral solution	oral use

Italy	AMDIPHARM LTD Temple Chambers, 3 Burlington Road, Dublin 4 IRELAND	LOFTYL	600 mg	prolonged-release tablet	oral use
Italy	AMDIPHARM LTD Temple Chambers, 3 Burlington Road, Dublin 4 IRELAND	LOFTYL	300 mg	tablet	oral use
Italy	BIOMEDICA FOSCAMA GROUP SpA Via della Giuliana 73 00195 Roma Italy	IRRODAN	10 mg/ml	solution for injection	intramuscular and intravenous use
Italy	BIOMEDICA FOSCAMA GROUP SpA Via della Giuliana 73 00195 Roma Italy	IRRODAN	150 mg/ml	oral drop, solution	oral use
Italy	BIOMEDICA FOSCAMA GROUP SpA Via della Giuliana 73 00195 Roma Italy	IRRODAN	300 mg	tablet	oral use
Italy	LABORATORIO FARMACEUTICO C.T. S.r.l. - Strada Solaro n. 75-77 - Villa Sayonara - Sanremo - 18038 IMPERIA Italy	BUFLOCIT	300 mg	capsule, hard	oral use
Italy	LABORATORIO FARMACEUTICO C.T. S.r.l. - Strada Solaro n. 75-77 - Villa Sayonara - Sanremo - 18038 IMPERIA Italy	BUFLOCIT	150 mg	capsule, hard	oral use

Italy	LABORATORIO FARMACEUTICO C.T. S.r.l. - Strada Solaro n. 75-77 - Villa Sayonara - Sanremo - 18038 IMPERIA Italy	BUFLOCIT	600 mg	prolonged-release tablet	oral use
Luxembourg	AMDIPHARM LIMITED 3, TEMPLE CHAMBERS IRL DUBLIN	Loftyl	50mg	solution for injection	Intramuscular and intravenous use
Luxembourg	Amdipharm Limited Temple Chambers, 3 Burlington Road Dublin 4 Ireland	Loftyl	150mg	tablets	oral use
Portugal	Amdipharm Limited Temple Chambers - 3, Burlington Road Dublin 4 Ireland	Loftyl 300	300 mg	Coated tablet	oral use
Portugal	Amdipharm Limited Temple Chambers, 3 Burlington Road Dublin 4 Ireland	Loftyl Forte	600 mg	Prolonged-release tablet	oral use
Netherlands	Amdipharm Limited Temple Chambers, 3 Burlington Road Dublin 4 Ireland	Loftyl	150 mg	tablets	oral use
Spain	Amdipharm Limited Temple Chambers, 3 Burlington Road Dublin 4 Ireland	LOFTON 150 mg comprimidos recubiertos	150mg	coated tablet	oral use

Spain	Amdipharm Limited Temple Chambers, 3 Burlington Road Dublin 4 Ireland	LOFTON 150 mg/ml gotas orales en solución	150mg/ml	oral drops solution	oral use
Poland	ICN Polfa Rezsów S.A. Przemysłowa 2 35-959 Rzeszów, Poland Office in Warsaw: ul. Marynarska 15 02-674 Warszawa, Poland	Buvasodil	150 mg	film coated tablets	oral use
Poland	ICN Polfa Rezsów S.A. Przemysłowa 2 35-959 Rzeszów, Poland Office in Warsaw: ul. Marynarska 15 02-674 Warszawa, Poland	Buvasodil	300 mg	film coated tablets	oral use