

ANNEX I

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

Member State / EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Belgium	Eurogenerics NV Heizel Esplanade b22 1020 Brussel Belgium	Orlistat EG	60 mg	capsule, hard	oral use
Belgium	Eurogenerics NV Heizel Esplanade b22 1020 Brussel Belgium	Orlistat EG	120 mg	capsule, hard	oral use
Belgium	Pharmaceuticals Works Pharma SA 19, Pelplinska street 83-200 Starogard Gdanski Poland	Orlistat Polpharma	60 mg	capsule, hard	oral use
Belgium	Pharmaceuticals Works Pharma SA 19, Pelplinska street 83-200 Starogard Gdanski Poland	Orlistat Polpharma	120 mg	capsule, hard	oral use
Belgium	Sandoz NV/SA Telecom Gardens Medialaan 40 B-Vilvoorde Belgium	Orlistat Sandoz	60 mg	capsule, hard	oral use
Belgium	Sandoz NV/SA Telecom Gardens Medialaan 40 B-Vilvoorde Belgium	Orlistat Sandoz	120 mg	capsule, hard	oral use

Member State / EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Bulgaria	Pharmaceutical Works Polpharma S.A 19, Peplinska Street Starogar Gdanski 83-200 Poland	Orlistat Polpharma	60 mg	capsule, hard	oral use
Bulgaria	Pharmaceutical Works Polpharma S.A 19, Peplinska Street Starogar Gdanski 83-200 Poland	Orlistat Polpharma	120 mg	capsule, hard	oral use
Bulgaria	Teva Pharmaceuticals Bulgaria EOOD 15 N.V Gogol Str. Sofia 1124 Bulgaria	Orlistat Teva	60 mg	capsule, hard	oral use
Bulgaria	Teva Pharmaceuticals Bulgaria EOOD 15 N.V Gogol Str. Sofia 1124 Bulgaria	Orlistat Teva	120 mg	capsule, hard	oral use
Czech Republic	Sandoz s.r.o U Nákladového nádraží 10 CZ-130 00, Praha 3, Czech Republic	Orlistat Sandoz 60 mg	60 mg	capsule, hard	oral use
Czech Republic	Sandoz s.r.o U Nákladového nádraží 10 CZ-130 00, Praha 3, Czech Republic	Orlistat Sandoz 120 mg	120 mg	capsule, hard	oral use

Member State / EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Czech Republic	Teva Pharmaceuticals CR s.r.o. Radlická 3185/1c 150 00 Prague Czech Republic	Orlistat Teva 60 mg	60 mg	capsule, hard	oral use
Czech Republic	Teva Pharmaceuticals CR s.r.o. Radlická 3185/1c 150 00 Prague Czech Republic	Orlistat Teva 120 mg	120 mg	capsule, hard	oral use
Denmark	Sandoz A/S, Edvard Thomsens Vej 14, DK-2300 Copenhagen S, Denmark	Orlistat "Sandoz"	60 mg	capsule, hard	oral use
Denmark	Teva Denmark A/S, Parallelvej 10-12, DK-2800 Kongens Lyngby, Denmark	Orlistat "Teva"	60 mg	capsule, hard	oral use
Denmark	Teva Denmark A/S, Parallelvej 10-12, DK-2800 Kongens Lyngby, Denmark	Orlistat "Teva"	120 mg	capsule, hard	oral use
Estonia	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	ORLISTAT TEVA 60MG	60 mg	capsule, hard	oral use
Estonia	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	ORLISTAT TEVA 120MG	120 mg	capsule, hard	oral use

Member State / EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Estonia	Pharmaceutical Works Polpharma S.A. 19 Pelplinska Str. 83-200 Starogard Gdanski Poland	ORLISTAT POLPHARMA 60MG	60 mg	capsule, hard	oral use
Estonia	Pharmaceutical Works Polpharma S.A. 19 Pelplinska Str. 83-200 Starogard Gdanski Poland	ORLISTAT POLPHARMA 120 MG	120 mg	capsule, hard	oral use
Estonia	Sandoz d.d. Verovskova 57 SI-1000 Ljubljana Slovenia	ORLISTAT SANDOZ 60MG	60 mg	capsule, hard	oral use
Estonia	Sandoz d.d. Verovskova 57 SI-1000 Ljubljana Slovenia	ORLISTAT SANDOZ 120 MG	120 mg	capsule, hard	oral use
Finland	ratiopharm GmbH Graf-Arco-Strasse 3 Ulm 89079 Germany	Orlistat ratiopharm	120 mg	capsule, hard	oral use
Finland	ratiopharm GmbH Graf-Arco-Strasse 3 Ulm 89079 Germany	Orlistat ratiopharm	60 mg	capsule, hard	oral use
Finland	Sandoz A/S Edvard Thomsens Vej 14 Copenhagen S 2300 Denmark	Orlistat Sandoz	60 mg	capsule, hard	oral use

Member State / EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Finland	Stada Arzneimittel AG Stadastrasse 2 - 18 Bad Vilbel 61118 Germany	Orlistat Stada	120 mg	capsule, hard	oral use
Finland	Stada Arzneimittel AG Stadastrasse 2 - 18 Bad Vilbel 61118 Germany	Orlistat Stada	60 mg	capsule, hard	oral use
France	SANDOZ 49, avenue Georges Pompidou 92300 Levallois-Perret France	ORLISTAT SANDOZ 120 mg, gélule	120 mg	capsule, hard	oral use
France	SANDOZ 49, avenue Georges Pompidou 92300 Levallois-Perret France	ORLISTAT SANDOZ 60 mg, gélule	60 mg	capsule, hard	oral use
France	EG LABO - Laboratoires EuroGenerics "Le Quintet" - bâtiment A 12, rue Danjou 92517 Boulogne Billancourt Cedex France	ORLISTAT EG 120 mg, gélule	120 mg	capsule, hard	oral use
France	EG LABO - Laboratoires EuroGenerics "Le Quintet" - bâtiment A 12, rue Danjou 92517 Boulogne Billancourt Cedex France	ORLISTAT EG 60 mg, gélule	60 mg	capsule, hard	oral use

Member State / EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
France	TEVA SANTE Le Palatin 1 1 cours du Triangle 92936 Paris la Défense Cedex France	ORLISTAT TEVA 120 mg, gélule	120 mg	capsule, hard	oral use
France	TEVA SANTE Le Palatin 1 1 cours du Triangle 92936 Paris la Défense Cedex France	ORLISTAT TEVA 60 mg, gélule	60 mg	capsule, hard	oral use
Germany	Aliud Pharma GmbH Gottlieb-Daimler-Str. 19 D-89150 Laichingen Germany	Orlistat AL 60 mg Hartkapseln	60 mg	capsule, hard	oral use
Germany	HEXAL Aktiengesellschaft Industriestr. 25 D-83607 Holzkirchen Germany	Orlistat HEXAL 120 mg Hartkapseln	120 mg	capsule, hard	oral use
Germany	HEXAL Aktiengesellschaft Industriestr. 25 D-83607 Holzkirchen Germany	Orlistat HEXAL 60 mg Hartkapseln	60 mg	capsule, hard	oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	Orlistat-ratiopharm 120 mg Hartkapseln	120 mg	capsule, hard	oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	Orlistat-ratiopharm 60 mg Hartkapseln	60 mg	capsule, hard	oral use

Member State / EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Italy	EG S.P.A. Via Scarlatti, 31 Milano 20124 Italy	ORLSTAT EUROGENERICI	60 mg	capsule, hard	oral use
Italy	EG S.P.A. Via Scarlatti, 31 Milano 20124 Italy	ORLISTAT EG	120 mg	capsule, hard	oral use
Latvia	Sandoz d.d., Verovškova 57, SI-1000 Ljubljana, Slovenia	Orlistat Sandoz	60 mg	capsule, hard	oral use
Latvia	Sandoz d.d., Verovškova 57, SI-1000 Ljubljana, Slovenia	Orlistat Sandoz	120 mg	capsule, hard	oral use
Latvia	Pharmaceutical Works POLPHARMA SA, 19 Pelplińska Street, 83-200 Starogard Gdański, Poland	Orlistat Polpharma	60 mg	capsule, hard	oral use
Latvia	Pharmaceutical Works POLPHARMA SA, 19 Pelplińska Street, 83-200 Starogard Gdański, Poland	Orlistat Polpharma	120 mg	capsule, hard	oral use
Latvia	Teva Pharma B.V., Computerweg 10, 3542DR Utrecht, The Netherlands	Orlistat Teva	60 mg	capsule, hard	oral use

Member State / EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Latvia	Teva Pharma B.V., Computerweg 10, 3542DR Utrecht, The Netherlands	Orlistat Teva	120 mg	capsule, hard	oral use
Lithuania	Teva Pharma B.V., Computerweg 10, 3542DR Utrecht, the Netherlands	Orlistat Teva	60 mg	capsule, hard	oral use
Lithuania	Teva Pharma B.V., Computerweg 10, 3542DR Utrecht, The Netherlands	Orlistat Teva	120 mg	capsule, hard	oral use
Lithuania	Sandoz d.d. Verovškova 57 SI- 1000 Ljubljana Slovènia	Orlistat Sandoz	120 mg	capsule, hard	oral use
Lithuania	Sandoz d.d. Verovškova 57 SI- 1000 Ljubljana Slovènia	Orlistat Sandoz	60 mg	capsule, hard	oral use
Lithuania	Pharmaceutical Works POLPHARMA S.A., 19 Pelplinska Street, Starogard Gdanski 83-200 Poland	Orlistat Polpharma	60 mg	capsule, hard	oral use
Lithuania	Pharmaceutical Works POLPHARMA S.A., 19 Pelplinska Street, Starogard Gdanski 83-200 Poland	Orlistat Polpharma	120 mg	capsule, hard	oral use

Member State / EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Norway	Teva Sweden AB Järnvägsgatan 11, Box 1070, 251 10 Helsingborg Sweden	Orlistat Teva	60 mg	capsule, hard	oral use
Norway	Teva Sweden AB Järnvägsgatan 11, Box 1070, 251 10 Helsingborg Sweden	Orlistat Teva	120 mg	capsule, hard	oral use
Norway	Sandoz A/S, Edvard Thomsens Vej 14, 2300 København S, Denmark	Orlistat Sandoz	60 mg	capsule, hard	oral use
Poland	Pharmaceutical Works POLPHARMA SA 19, Pelplińska Street 83-200 Starogard Gdański Poland	Orlistat Polpharma 120 mg	120 mg	capsule, hard	oral use
Poland	Sandoz GmbH Biochemiestrasse 10 Kundl, A-6250 Austria	Orlistat Sandoz 120 mg	120 mg	capsule, hard	oral use
Poland	STADA Arzneimittel AG Stadastrasse 2-18 Bad Vilbel D-61118 Germany	Orlistat STADA 120 mg	120 mg	capsule, hard	oral use
Poland	Teva Pharmaceuticals Polska Sp. z o.o. ul. Emilii Plater 53 00-113 Warszawa Poland	Orlistat Teva 120 mg	120 mg	capsule, hard	oral use

Member State / EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Poland	Pharmaceutical Works POLPHARMA SA 19, Pelplińska Street 83-200 Starogard Gdański Poland	Orlistat Polpharma 60 mg	60 mg	capsule, hard	oral use
Poland	Sandoz GmbH Biochemiestrasse 10 Kundl, A-6250 Austria	Orlistat Sandoz 60 mg	60 mg	capsule, hard	oral use
Poland	STADA Arzneimittel AG Stadastrasse 2-18 Bad Vilbel D-61118 Germany	Orlistat STADA 60 mg	60 mg	capsule, hard	oral use
Portugal	Cicum Farma Unipessoal, Lda. Quinta da Fonte, Rua Vitor Câmara, 2 - Edifício D. Amélia, Piso 1, Ala B 2770-229 Paço de Arcos Portugal	Orlistato Cicum	60 mg	capsule, hard	oral use
Portugal	Cicum Farma Unipessoal, Lda. Quinta da Fonte, Rua Vitor Câmara, 2 - Edifício D. Amélia, Piso 1, Ala B 2770-229 Paço de Arcos Portugal	Orlistato Cicum	120 mg	capsule, hard	oral use
Portugal	Pharmaceutical Works Polpharma S.A. 19, Pelplinska street 83-200 Starogard Gdanski Poland	Orlistato Ratiopharm	60 mg	capsule, hard	oral use

Member State / EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Pharmaceutical Works Polpharma S.A. 19, Pelplinska street 83-200 Starogard Gdanski Poland	Orlistato Ratiopharm	120 mg	capsule, hard	oral use
Romania	Pharmaceutical Works Polpharma SA, Address: 19, Pelplińska Street, 83-200 Starogard Gdański, Poland	Sulixa	60 mg	capsule, hard	oral use
Romania	Pharmaceutical Works Polpharma SA, Address: 19, Pelplińska Street, 83-200 Starogard Gdański, Poland	Orlistat Polpharma	120 mg	capsule, hard	oral use
Slovak Republic	TEVA Pharmaceuticals Slovakia s.r.o. Teslova 26 Bratislava 821 02 Slovak Republic	Orlistat Teva 60 mg	60 mg	capsule, hard	oral use
Slovak Republic	TEVA Pharmaceuticals Slovakia s.r.o. Teslova 26 Bratislava 821 02 Slovak Republic	Orlistat Teva 120 mg	120 mg	capsule, hard	oral use

Member State / EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Slovak Republic	Pharmaceutical Works POLPHARMA SA 19, Pelplińska Str. 83-200 Starogard Gdański Poland	Orlistat Polpharma 60 mg	60 mg	capsule, hard	oral use
Slovak Republic	Pharmaceutical Works POLPHARMA SA 19, Pelplińska Str. 83-200 Starogard Gdański poland	Orlistat Polpharma 120 mg	120 mg	capsule, hard	oral use
Sweden	Sandoz A/S, , Edvard Thomsens Vej 14 DK-2300 Köpenhamn S, Denmark	Orlistat Sandoz	60mg	capsule, hard	oral use
The Netherlands	Sandoz B.V. Veluwezoom 22 1327 AH ALMERE The Netherlands	Orlistat Sandoz 60 mg	60 mg	capsule, hard	oral use
The Netherlands	Sandoz B.V. Veluwezoom 22 1327 AH ALMERE The Netherlands	Orlistat Sandoz 120 mg	120 mg	capsule, hard	oral use

Member State / EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Teva UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex BN22 9AG United Kingdom	TEVA UK Orlistat capsules 60mg	60mg	capsule, hard	oral use
United Kingdom	Teva UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex BN22 9AG United Kingdom	TEVA UK Orlistat capsules 120mg	120mg	capsule, hard	oral use