

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, applicants / marketing authorisation holders in the Member States

Member State EU/EEA	Marketing authorisation holder company name, address	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Belgium		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Methylfenidaat Sandoz 18 mg tabletten met verlengde afgifte	18 mg	Prolonged-release tablet	Oral use
Belgium		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Methylfenidaat Sandoz 36 mg tabletten met verlengde afgifte	36 mg	Prolonged-release tablet	Oral use
Belgium		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Methylfenidaat Sandoz 54 mg tabletten met verlengde afgifte	54 mg	Prolonged-release tablet	Oral use
Cyprus	Sandoz GmbH Biochemiestrasse 10 6250 Kundl Austria		Methylphenidate Sandoz	18 mg	Prolonged-release tablet	Oral use
Cyprus	Sandoz GmbH Biochemiestrasse 10 6250 Kundl Austria		Methylphenidate Sandoz	36 mg	Prolonged-release tablet	Oral use
Cyprus	Sandoz GmbH Biochemiestrasse 10 6250 Kundl Austria		Methylphenidate Sandoz	54 mg	Prolonged-release tablet	Oral use
Denmark	Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark		Methylphenidate "Sandoz"	18 mg	Prolonged-release tablet	Oral use

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Denmark	Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark		Methylphenidate "Sandoz"	36 mg	Prolonged-release tablet	Oral use
Denmark	Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark		Methylphenidate "Sandoz"	54 mg	Prolonged-release tablet	Oral use
Finland	Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark		Methylphenidate Sandoz	18 mg	Prolonged-release tablet	Oral use
Finland	Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark		Methylphenidate Sandoz	36 mg	Prolonged-release tablet	Oral use
Finland	Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark		Methylphenidate Sandoz	54 mg	Prolonged-release tablet	Oral use
France		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Méthylphénidate Sandoz LP 18 mg, comprimé à libération prolongée	18 mg	Prolonged-release tablet	Oral use
France		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Méthylphénidate Sandoz LP 36 mg, comprimé à libération prolongée	36 mg	Prolonged-release tablet	Oral use

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France		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Méthylphénidate Sandoz LP 54 mg, comprimé à libération prolongée	54 mg	Prolonged-release tablet	Oral use
Germany		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Methylphenidathyr ochlorid - 1 A Pharma 18 mg Retardtabletten	18 mg	Prolonged-release tablet	Oral use
Germany		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Methylphenidathyr ochlorid - 1 A Pharma 36 mg Retardtabletten	36 mg	Prolonged-release tablet	Oral use
Germany		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Methylphenidathyr ochlorid - 1 A Pharma 54 mg Retardtabletten	54 mg	Prolonged-release tablet	Oral use
Iceland	Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark		Methylphenidate Sandoz, 18 mg, forðatöflur	18 mg	Prolonged-release tablet	Oral use
Iceland	Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark		Methylphenidate Sandoz, 36 mg, forðatöflur	36 mg	Prolonged-release tablet	Oral use
Iceland	Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark		Methylphenidate Sandoz, 54 mg, forðatöflur	54 mg	Prolonged-release tablet	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Luxembourg		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Methylfenidaat Sandoz 18 mg comprimé à libération prolongée	18 mg	Prolonged-release tablet	Oral use
Luxembourg		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Methylfenidaat Sandoz 36 mg comprimé à libération prolongée	36 mg	Prolonged-release tablet	Oral use
Luxembourg		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Methylfenidaat Sandoz 54 mg comprimé à libération prolongée	54 mg	Prolonged-release tablet	Oral use
Malta		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Matoride XL 18 mg Prolonged-release Tablets	18 mg	Prolonged-release tablet	Oral use
Malta		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Matoride XL 36 mg Prolonged-release Tablets	36 mg	Prolonged-release tablet	Oral use
Malta		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Matoride XL 54 mg Prolonged-release Tablets	54 mg	Prolonged-release tablet	Oral use
Norway	Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark		Methylphenidate Sandoz 18 mg depottabletter	18 mg	Prolonged-release tablet	Oral use

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Norway	Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark		Methylphenidate Sandoz 36 mg depottabletter	36 mg	Prolonged-release tablet	Oral use
Norway	Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark		Methylphenidate Sandoz 54 mg depottabletter	54 mg	Prolonged-release tablet	Oral use
Poland	Sandoz GmbH Biochemiestrasse 10 6250 Kundl Austria		Difumenil	18 mg	Prolonged-release tablet	Oral use
Poland	Sandoz GmbH Biochemiestrasse 10 6250 Kundl Austria		Difumenil	36 mg	Prolonged-release tablet	Oral use
Poland	Sandoz GmbH Biochemiestrasse 10 6250 Kundl Austria		Difumenil	54 mg	Prolonged-release tablet	Oral use
Portugal	Sandoz Farmacêutica Lda. Alameda da Beloura, Edifício 1 – 2º Andar - Esc. 15 2710-693 Sintra Portugal		Metilfenidato Sandoz	18 mg	Prolonged-release tablet	Oral use

Member State EU/EEA	Marketing authorisation holder company name, address	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Portugal	Sandoz Farmacêutica Lda. Alameda da Beloura, Edifício 1 – 2º Andar - Esc. 15 2710-693 Sintra Portugal		Metilfenidato Sandoz	36 mg	Prolonged-release tablet	Oral use
Portugal	Sandoz Farmacêutica Lda. Alameda da Beloura, Edifício 1 – 2º Andar - Esc. 15 2710-693 Sintra Portugal		Metilfenidato Sandoz	54 mg	Prolonged-release tablet	Oral use
Spain	Sandoz Farmacéutica, S.A. Centro Empresarial Osa Mayor Avda Osa Mayor nº 4 28023 – Aravaca, Madrid Spain		Metilfenidato Sandoz 18 mg comprimidos de liberación prolongada EFG	18 mg	Prolonged-release tablet	Oral use
Spain	Sandoz Farmacéutica, S.A. Centro Empresarial Osa Mayor Avda Osa Mayor nº 4 28023 – Aravaca, Madrid Spain		Metilfenidato Sandoz 36 mg comprimidos de liberación prolongada EFG	36 mg	Prolonged-release tablet	Oral use

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Spain	Sandoz Farmacéutica, S.A. Centro Empresarial Osa Mayor Avda Osa Mayor nº 4 28023 – Aravaca, Madrid Spain		Metilfenidato Sandoz 54 mg comprimidos de liberación prolongada EFG	54 mg	Prolonged-release tablet	Oral use
Sweden		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Methylphenidate Sandoz	18 mg	Prolonged-release tablet	Oral use
Sweden		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Methylphenidate Sandoz	36 mg	Prolonged-release tablet	Oral use
Sweden		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Methylphenidate Sandoz	54 mg	Prolonged-release tablet	Oral use
The Netherlands		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Methylfenidaat HCl Sandoz retard 18 mg, tabletten met verlengde afgifte	18 mg	Prolonged-release tablet	Oral use
The Netherlands		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Methylfenidaat HCl Sandoz retard 36 mg, tabletten met verlengde afgifte	36 mg	Prolonged-release tablet	Oral use
The Netherlands		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Methylfenidaat HCl Sandoz retard 54 mg, tabletten met verlengde afgifte	54 mg	Prolonged-release tablet	Oral use

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United Kingdom		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Matoride XL 18 mg Prolonged-release Tablets	18 mg	Prolonged-release tablet	Oral use
United Kingdom		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Matoride XL 36 mg Prolonged-release Tablets	36 mg	Prolonged-release tablet	Oral use
United Kingdom		Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Matoride XL 54 mg Prolonged-release Tablets	54 mg	Prolonged-release tablet	Oral use