

## **Annex I**

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

<b>Member State (in EEA)</b>	<b>Marketing authorisation holder</b>	<b>INN</b>	<b>Invented name</b>	<b>Strength</b>	<b>Pharmaceutical form</b>	<b>Route of administration</b>
Austria	UCB Pharma GmbH Geiselbergstraße 17-19 1110 Wien Austria	Hydroxyzine dihydrochloride	Atarax 25 mg - Filmtabletten	25 mg	Film-coated tablet	Oral use
Belgium	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Hydroxyzine hydrochloride	Atarax	10 mg	Film-coated tablet	Oral use
Belgium	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Hydroxyzine hydrochloride	Atarax	25 mg	Film-coated tablet	Oral use
Belgium	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Hydroxyzine hydrochloride	Atarax	100 mg	Film-coated tablet	Oral use
Bulgaria	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Hydroxyzine hydrochloride	Atarax	25 mg	Film-coated tablet	Oral use
Bulgaria	Actavis EAD 29 Atanas Dukov Str. Sofia 1407 Bulgaria	Hydroxyzine hydrochloride	Neurolax	25 mg	Film-coated tablet	Oral use

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Cyprus	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Hydroxyzine hydrochloride	Atarax	25 mg	Film-coated tablet	Oral use
Cyprus	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Hydroxyzine hydrochloride	Atarax	2 mg/ml	Syrup	Oral use
Czech Republic	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Hydroxyzine dihydrochloride	Atarax	25 mg	Film-coated tablet	Oral use
Denmark	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Denmark	Hydroxyzine hydrochloride	Atarax	2 mg/ml	Oral solution	Oral use
Denmark	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Denmark	Hydroxyzine hydrochloride	Atarax	10 mg	Film-coated tablet	Oral use
Denmark	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Denmark	Hydroxyzine hydrochloride	Atarax	25 mg	Film-coated tablet	Oral use
Finland	UCB Pharma Oy Finland Itsehallintokuja 6 02600 ESPOO Finland	Hydroxyzine hydrochloride	ATARAX	2 mg/ml	Syrup	Oral use

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Finland	UCB Pharma Oy Finland Itsehallintokuja 6 02600 ESPOO Finland	Hydroxyzine hydrochloride	ATARAX	25 mg	Film-coated tablet	Oral use
France	UCB Pharma S.A. 420 Avenue Estienne d'Orves Défense Ouest 92700 Colombes France	Hydroxyzine hydrochloride	ATARAX 100 mg, comprimé pelliculé sécable	100 mg	Film-coated tablet	Oral Use
France	UCB Pharma S.A. 420 Avenue Estienne d'Orves Défense Ouest 92700 Colombes France	Hydroxyzine hydrochloride	ATARAX 100 mg/2 ml, solution injectable	100 mg/2 ml	Solution for injection	Intravenous use
France	UCB Pharma S.A. 420 Avenue Estienne d'Orves Défense Ouest 92700 Colombes France	Hydroxyzine hydrochloride	ATARAX 25 mg, comprimé pelliculé sécable	25 mg	Film-coated tablet	Oral Use
France	UCB Pharma S.A. 420 Avenue Estienne d'Orves Défense Ouest 92700 Colombes France	Hydroxyzine hydrochloride	ATARAX sirop	2 mg/ml	Syrup	Oral Use

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France	Laboratoire Renaudin Z A. Errobi Itxassou 64250 Cambo les Bains France	Hydroxyzine hydrochloride	HYDROXYZINE RENAUDIN 100 mg /2 ml, solution injectable	100 mg/2 ml	Solution for injection	Intravenous use
France	Inopharm limited 7 Florinis Street Greg Tower, 6th Floor PO Box 24854 1304 Nicosia Cyprus	Hydroxyzine hydrochloride	HYDROLAX 25 mg, comprimé pelliculé sécable	25 mg	Film-coated tablet	Oral Use
France	Inopharm limited 7 Florinis Street Greg Tower, 6th Floor PO Box 24854 1304 Nicosia Cyprus	Hydroxyzine hydrochloride	HYDROXYZINE INOPHARM 25 mg, comprimé pelliculé sécable	25 mg	Film-coated tablet	Oral Use
France	Inopharm limited 7 Florinis Street Greg Tower, 6th Floor PO Box 24854 1304 Nicosia Cyprus	Hydroxyzine hydrochloride	RAXTA 25 mg, comprimé pelliculé sécable	25 mg	Film-coated tablet	Oral Use

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France	Inopharm limited 7 Florinis Street Greg Tower, 6th Floor PO Box 24854 1304 Nicosia Cyprus	Hydroxyzine hydrochloride	TADRO 25 mg, comprimé pelliculé sécable	25 mg	Film-coated tablet	Oral Use
France	Arrow Generiques 26 Avenue Tony Garnier 69007 Lyon France	Hydroxyzine hydrochloride	HYDROXYZINE ARROW 25 mg, comprimé pelliculé sécable	25 mg	Film-coated tablet	Oral Use
Germany	UCB Pharma GmbH Alfred-Nobel-Str. 10 40789 Monheim Germany	Hydroxyzine hydrochloride	AH 3 N Tabletten	25 mg	Film-coated tablet	Oral use
Germany	UCB Pharma GmbH Alfred-Nobel-Str. 10 40789 Monheim Germany	Hydroxyzine hydrochloride	Atarax Tabletten	25 mg	Film-coated tablet	Oral use
Greece	Olvos Science AE Eleftherias 4 145 64, Kifisia Greece	Hydroxyzine	EFIDAC	5%	Gel	Cutaneous use
Greece	UCB A.E. Ag. Dimitriou 63 17456, Alimos, Athens Greece	Hydroxyzine	ATARAX	25 mg	Film-coated tablet	Oral use

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Greece	UCB A.E. Ag. Dimitriou 63 17456, Alimos, Athens Greece	Hydroxyzine	ATARAX	100 mg/2 ml	Solution for injection	Intramuscular use
Greece	UCB A.E. Ag. Dimitriou 63 17456, Alimos, Athens Greece	Hydroxyzine	ATARAX	10 mg/5 ml	Oral solution	Oral use
Greece	UCB A.E. Ag. Dimitriou 63 17456, Alimos, Athens Greece	Hydroxyzine	ATARAX	100 mg	Film-coated tablet	Oral use
Greece	Uni-Pharma Kleon Tsetis Farmakeftika Ergastria ABEE 14 Km. Nat. Road Athens-Lamia 14564, K. Kifisia Greece	Hydroxyzine	IREMOFAR	25 mg	Film-coated tablet	Oral use
Greece	Uni-Pharma Kleon Tsetis Farmakeftika Ergastria ABEE 14 Km. Nat. Road Athens-Lamia 14564, K. Kifisia Greece	Hydroxyzine	IREMOFAR	10 mg/5 ml	Oral solution	Oral use
Greece	Uni-Pharma Kleon Tsetis Farmakeftika Ergastria ABEE 14 Km. Nat. Road Athens-Lamia 14564, K. Kifisia Greece	Hydroxyzine	IREMOFAR	5%	Gel	Cutaneous use

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Hungary	UCB Magyarország Kft. Árpád fejedelem útja 26-28 1023 Budapest Hungary	Hydroxyzine hydrochloride	Atarax 25 mg filmtabletta	25 mg	Film-coated tablet	Oral use
Iceland	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Denmark	Hydroxyzine hydrochloride	Atarax	2 mg/ml	Oral solution	Oral use
Iceland	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Denmark	Hydroxyzine hydrochloride	Atarax	25 mg	Film-coated tablet	Oral use
Ireland	UCB Pharma Ireland Ltd United Drug House Magna Drive, Magna Business Park Citywest Road Dublin 24 Ireland	Hydroxyzine hydrochloride	Ucerax 10mg/5ml Syrup	2 mg/ml	Syrup	Oral use
Ireland	UCB Pharma Ireland Ltd United Drug House Magna Drive, Magna Business Park Citywest Road Dublin 24 Ireland	Hydroxyzine hydrochloride	Ucerax 25mg Film-coated Tablets	25 mg	Film-coated tablet	Oral use
Italy	UCB Pharma S.p.a. Via Gadames 57 20151 Milano Italy	Hydroxyzine hydrochloride	ATARAX	2 mg/ml	Syrup	Oral use



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Italy	UCB Pharma S.p.a. Via Gadames 57 20151 Milano Italy	Hydroxyzine hydrochloride	ATARAX	25 mg	Film-coated tablet	Oral use
Italy	UCB Pharma S.p.a. Via Gadames 57 20151 Milano Italy	Hydroxyzine hydrochloride	ATARAX	100 mg/2 ml	Solution for injection	Intramuscular use
Luxembourg	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Hydroxyzine dihydrochloride	Atarax	10 mg	Coated tablet	Oral use
Luxembourg	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Hydroxyzine dihydrochloride	Atarax	25 mg	Coated tablet	Oral use
Luxembourg	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Hydroxyzine dihydrochloride	Atarax	100 mg	Coated tablet	Oral use
Malta	Alliance Pharmaceuticals Limited Avonbridge House Bath Road, Chippenham Wiltshire SN15 2BB United Kingdom	Hydroxyzine dihydrochloride	Atarax 10mg tablets	10 mg	Tablet	Oral use

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Malta	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Hydroxyzine dihydrochloride	Atarax 25mg tablets	25 mg	Tablet	Oral use
Malta	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Hydroxyzine dihydrochloride	Atarax Syrup 0.2%	2 mg/ml	Syrup	Oral use
Norway	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Denmark	Hydroxyzine	Atarax	10 mg	Film-coated tablet	Oral use
Norway	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Denmark	Hydroxyzine	Atarax	25 mg	Film-coated tablet	Oral use
Poland	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Hydroxyzine hydrochloride	Atarax	2 mg/ml	Syrup	Oral use
Poland	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Hydroxyzine hydrochloride	Atarax	10 mg	Film-coated tablet	Oral use
Poland	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Hydroxyzine hydrochloride	Atarax	25 mg	Film-coated tablet	Oral use

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Poland	Aflofarm Farmacja Polska Sp. z o.o. ul. Partyzancka 133/151 95-200 Pabianice Poland	Hydroxyzine hydrochloride	Hydroxyzinum Aflofarm	2 mg/ml	Syrup	Oral use
Poland	Biogened S.A ul. Pojezierska 99 91-342 Łódź Poland	Hydroxyzine hydrochloride	Hydroxyzinum Biogened	1,6 mg/g	Syrup	Oral use
Poland	Chemiczno-Farmaceutyczna Spółdzielnia Pracy ESPEFA ul. J. Lea 208 30-133 Kraków Poland	Hydroxyzine hydrochloride	Hydroxyzinum Espefa	2 mg/ml	Syrup	Oral use
Poland	Chemiczno-Farmaceutyczna Spółdzielnia Pracy ESPEFA ul. J. Lea 208 30-133 Kraków Poland	Hydroxyzine hydrochloride	Hydroxyzinum Espefa	25 mg	Film-coated tablet	Oral use
Poland	Chemiczno-Farmaceutyczna Spółdzielnia Pracy ESPEFA ul. J. Lea 208 30-133 Kraków Poland	Hydroxyzine hydrochloride	Hydroxyzinum Espefa	10 mg	Film-coated tablet	Oral use
Poland	Teva Pharmaceuticals Polska Sp. z o.o. ul. Emilii Plater 53 00-113 Warszawa Poland	Hydroxyzine hydrochloride	Hydroxyzinum Teva	50 mg/ml	Solution for infusion	Intramuscular use

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Poland	PharmaSwiss Ceska Republika s.r.o. Jankovcova 1569/2c 17000 Praha 7 PSC 170 00 Holesovice Czech Republic	Hydroxyzine hydrochloride	Hydroxyzinum VP	2 mg/ml	Syrup	Oral use
Poland	PharmaSwiss Ceska Republika s.r.o. Jankovcova 1569/2c 17000 Praha 7 PSC 170 00 Holesovice Czech Republic	Hydroxyzine hydrochloride	Hydroxyzinum VP	10 mg	Film-coated tablet	Oral use
Poland	PharmaSwiss Ceska Republika s.r.o. Jankovcova 1569/2c 17000 Praha 7 PSC 170 00 Holesovice Czech Republic	Hydroxyzine hydrochloride	Hydroxyzinum VP	25 mg	Film-coated tablet	Oral use
Portugal	UCB Pharma (Produtos Farmacêuticos), Lda. Rua Victor Câmara, Edifício Q 60, D. Maria I, Piso 1 Fracção D, Quinta da Fonte 2770-229 Paço de Arcos Porgutal	Hydroxyzine	Atarax	25 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Portugal	UCB Pharma (Produtos Farmacêuticos), Lda. Rua Victor Câmara, Edifício Q 60, D. Maria I, Piso 1 Fracção D, Quinta da Fonte 2770-229 Paço de Arcos Portugal	Hydroxyzine	Atarax	2 mg/ml	Syrup	Oral use
Slovak Republic	UCB s.r.o Thámova 13 180 00 Praha 8 Czech Republic	Hydroxyzine	ATARAX	25 mg	Film-coated tablet	Oral use
Spain	UCB Pharma, S.A. Paseo de la Castellana 141 planta 15 Madrid 28046 Spain	Hydroxyzine dihydrochloride	ATARAX 25 mg COMPRIMIDOS	25 mg	Film-coated tablet	Oral use
Spain	UCB Pharma, S.A. Paseo de la Castellana 141 planta 15 Madrid 28046 Spain	Hydroxyzine dihydrochloride	ATARAX 2mg/ml JARABE	2 mg/ml	Syrup	Oral use
Spain	DERMOGEN PHARMA, S.A. Aragoneses, 15 28108 Alcobendas (Madrid) Spain	Hydroxyzine dihydrochloride Propyphenazone Codeine phosphate	DOLODENS GRAGEAS	15 mg 100 mg 10 mg	Tablet	Oral use

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Sweden	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Denmark	Hydroxyzine hydrochloride	Atarax	10 mg	Film-coated tablet	Oral use
Sweden	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Denmark	Hydroxyzine hydrochloride	Atarax	25 mg	Film-coated tablet	Oral use
Sweden	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Denmark	Hydroxyzine hydrochloride	Atarax	2 mg/ml	Oral solution	Oral use
The Netherlands	UCB Pharma B.V. Lage Mosten 33 4822 NK BREDA The Netherlands	Hydroxyzine dihydrochloride	Hydroxyzine-2 HCl 10	10 mg	Film-coated tablet	Oral use
The Netherlands	UCB Pharma B.V. Lage Mosten 33 4822 NK BREDA The Netherlands	Hydroxyzine dihydrochloride	Hydroxyzine-2 HCl 25	25 mg	Film-coated tablet	Oral use
United Kingdom	UCB Pharma Limited 208 Bath Road, Slough Berkshire SL1 3WE United Kingdom	Hydroxyzine hydrochloride	Ucerax 10mg/5ml Syrup	2 mg/ml	Oral solution	Oral use
United Kingdom	UCB Pharma Limited 208 Bath Road, Slough Berkshire SL1 3WE United Kingdom	Hydroxyzine hydrochloride	Ucerax 25 mg film-coated tablets	25 mg	Coated tablet	Oral use

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United Kingdom	Alliance Pharmaceuticals Limited Avonbridge House Bath Road, Chippenham Wiltshire SN15 2BB United Kingdom	Hydroxyzine hydrochloride	Atarax 10mg film-coated tablets	10 mg	Tablet	Oral use
United Kingdom	Alliance Pharmaceuticals Limited Avonbridge House Bath Road, Chippenham Wiltshire SN15 2BB United Kingdom	Hydroxyzine hydrochloride	Atarax 25mg film-coated tablets	25 mg	Coated tablet	Oral use