

Anness I

**Lista tal-ismijiet, għamliet farmaċewtiċi, qawwiet tal-prodotti mediċinali,
mnejn jingħata, l-applikanti, id-detenturi tal-awtorizzazzjoni għat-tqeghid
fis-suq fl-istati membri**

Stat Membru (EEA)	Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq	INN	Isem Ivvintat	Qawwa	Għamla Farmaċewtika	Mnjen jingħata
Awstria	UCB Pharma GmbH Geiselbergstraße 17-19 1110 Wien Awstria	Hydroxyzine dihydrochloride	Atarax 25 mg – Filmtabletten	25 mg	Pillola miksija b'rita	Mill-ħalq
Belġju	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belġju	Hydroxyzine hydrochloride	Atarax	10 mg	Pillola miksija b'rita	Mill-ħalq
Belġju	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belġju	Hydroxyzine hydrochloride	Atarax	25 mg	Pillola miksija b'rita	Mill-ħalq
Belġju	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belġju	Hydroxyzine hydrochloride	Atarax	100 mg	Pillola miksija b'rita	Mill-ħalq
Bulgarija	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belġju	Hydroxyzine hydrochloride	Atarax	25 mg	Pillola miksija b'rita	Mill-ħalq
Bulgarija	Actavis EAD 29 Atanas Dukov Str. Sofia 1407 Bulgarija	Hydroxyzine hydrochloride	Neurolax	25 mg	Pillola miksija b'rita	Mill-ħalq
Ċipru	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belġju	Hydroxyzine hydrochloride	Atarax	25 mg	Pillola miksija b'rita	Mill-ħalq
Ċipru	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belġju	Hydroxyzine hydrochloride	Atarax	2 mg/ml	Mistura	Mill-ħalq
Repubblika Ċeka	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belġju	Hydroxyzine dihydrochloride	Atarax	25 mg	Pillola miksija b'rita	Mill-ħalq

Stat Membru (EEA)	Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq	INN	Isem Ivvintat	Qawwa	Għamla Farmaċewtika	Mnjen jingħata
Danimarka	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Danimarka	Hydroxyzine hydrochloride	Atarax	2 mg/ml	Soluzzjoni orali	Mill-ħalq
Danimarka	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Danimarka	Hydroxyzine hydrochloride	Atarax	10 mg	Pillola miksija b'rita	Mill-ħalq
Danimarka	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Danimarka	Hydroxyzine hydrochloride	Atarax	25 mg	Pillola miksija b'rita	Mill-ħalq
Finlandja	UCB Pharma Oy Finland Itsehallintokuja 6 02600 ESPOO Finlandja	Hydroxyzine hydrochloride	ATARAX	2 mg/ml	Mistura	Mill-ħalq
Finlandja	UCB Pharma Oy Finland Itsehallintokuja 6 02600 ESPOO Finlandja	Hydroxyzine hydrochloride	ATARAX	25 mg	Pillola miksija b'rita	Mill-ħalq
Franza	UCB Pharma S.A. 420 Avenue Estienne d'Orves Défense Ouest 92700 Colombes Franza	Hydroxyzine hydrochloride	ATARAX 100 mg, comprimé pelliculé sécable	100 mg	Pillola miksija b'rita	Mill-ħalq
Franza	UCB Pharma S.A. 420 Avenue Estienne d'Orves Défense Ouest 92700 Colombes Franza	Hydroxyzine hydrochloride	ATARAX 100 mg/2 ml, solution injectable	100 mg/2 ml	Soluzzjoni għall- injezzjoni	Użu minn ġol- vina
Franza	UCB Pharma S.A. 420 Avenue Estienne d'Orves Défense Ouest 92700 Colombes Franza	Hydroxyzine hydrochloride	ATARAX 25 mg, comprimé pelliculé sécable	25 mg	Pillola miksija b'rita	Mill-ħalq

Stat Membru (EEA)	Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq	INN	Isem Ivvintat	Qawwa	Għamla Farmaċewtika	Mnjen jingħata
Franza	UCB Pharma S.A. 420 Avenue Estienne d'Orves Défense Ouest 92700 Colombes Franza	Hydroxyzine hydrochloride	ATARAX sirop	2 mg/ml	Mistura	Mill-ħalq
Franza	Laboratoire Renaudin Z A. Errobi Itxassou 64250 Cambo les Bains Franza	Hydroxyzine hydrochloride	HYDROXYZINE RENAUDIN 100 mg /2 ml, solution injectable	100 mg/2 ml	Soluzzjoni għall-injezzjoni	Użu minn ġol-vina
Franza	Inopharm limited 7 Florinis Street Greg Tower, 6th Floor PO Box 24854 1304 Nicosia Ċipru	Hydroxyzine hydrochloride	HYDROLAX 25 mg, comprimé pelliculé sécable	25 mg	Pillola miksija b'rita	Mill-ħalq
Franza	Inopharm limited 7 Florinis Street Greg Tower, 6th Floor PO Box 24854 1304 Nicosia Ċipru	Hydroxyzine hydrochloride	HYDROXYZINE INOPHARM 25 mg, comprimé pelliculé sécable	25 mg	Pillola miksija b'rita	Mill-ħalq
Franza	Inopharm limited 7 Florinis Street Greg Tower, 6th Floor PO Box 24854 1304 Nicosia Ċipru	Hydroxyzine hydrochloride	RAXTA 25 mg, comprimé pelliculé sécable	25 mg	Pillola miksija b'rita	Mill-ħalq
Franza	Inopharm limited 7 Florinis Street Greg Tower, 6th Floor PO Box 24854 1304 Nicosia Ċipru	Hydroxyzine hydrochloride	TADRO 25 mg, comprimé pelliculé sécable	25 mg	Pillola miksija b'rita	Mill-ħalq

Stat Membru (EEA)	Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq	INN	Isem Ivvintat	Qawwa	Għamla Farmaċewtika	Mnjen jingħata
Franza	Arrow Generiques 26 Avenue Tony Garnier 69007 Lyon Franza	Hydroxyzine hydrochloride	HYDROXYZINE ARROW 25 mg, comprimé pelliculé sécable	25 mg	Pillola miksija b'rita	Mill-ħalq
Ġermanja	UCB Pharma GmbH Alfred-Nobel-Str. 10 40789 Monheim Ġermanja	Hydroxyzine hydrochloride	AH 3 N Tabletten	25 mg	Pillola miksija b'rita	Mill-ħalq
Ġermanja	UCB Pharma GmbH Alfred-Nobel-Str. 10 40789 Monheim Ġermanja	Hydroxyzine hydrochloride	Atarax Tabletten	25 mg	Pillola miksija b'rita	Mill-ħalq
Greċja	Olvos Science AE Eleftherias 4 145 64, Kifisia Greċja	Hydroxyzine	EFIDAC	5%	Ġel	Minn ġol-ġilda
Greċja	UCB A.E. Ag. Dimitriou 63 17456, Alimos, Athens Greċja	Hydroxyzine	ATARAX	25 mg	Pillola miksija b'rita	Mill-ħalq
Greċja	UCB A.E. Ag. Dimitriou 63 17456, Alimos, Athens Greċja	Hydroxyzine	ATARAX	100 mg/2 ml	Soluzzjoni għall-injezzjoni	Minn ġol-muskolu
Greċja	UCB A.E. Ag. Dimitriou 63 17456, Alimos, Athens Greċja	Hydroxyzine	ATARAX	10 mg/5 ml	Soluzzjoni Orali	Mill-ħalq
Greċja	UCB A.E. Ag. Dimitriou 63 17456, Alimos, Athens Greċja	Hydroxyzine	ATARAX	100 mg	Pillola miksija b'rita	Mill-ħalq

Stat Membru (EEA)	Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq	INN	Isem Ivvintat	Qawwa	Għamla Farmaċewtika	Mnjen jingħata
Greċja	Uni-Pharma Kleon Tsetis Farmakeftika Ergastria ABEE 14 Km. Nat. Road Athens-Lamia 14564, K. Kifisia Greċja	Hydroxyzine	IREMOFAR	25 mg	Pillola miksija b'rita	Mill-ħalq
Greċja	Uni-Pharma Kleon Tsetis Farmakeftika Ergastria ABEE 14 Km. Nat. Road Athens-Lamia 14564, K. Kifisia Greċja	Hydroxyzine	IREMOFAR	10 mg/5 ml	Soluzzjoni Orali	Mill-ħalq
Greċja	Uni-Pharma Kleon Tsetis Farmakeftika Ergastria ABEE 14 Km. Nat. Road Athens-Lamia 14564, K. Kifisia Greċja	Hydroxyzine	IREMOFAR	5%	Ġel	Minn ġol-ġilda
Ungerija	UCB Magyarország Kft. Árpád fejedelem útja 26-28 1023 Budapest Ungerija	Hydroxyzine hydrochloride	Atarax 25 mg filmtabletta	25 mg	Pillola miksija b'rita	Mill-ħalq
Iżlanda	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Danimarka	Hydroxyzine hydrochloride	Atarax	2 mg/ml	Soluzzjoni Orali	Mill-ħalq
Iżlanda	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Danimarka	Hydroxyzine hydrochloride	Atarax	25 mg	Pillola miksija b'rita	Mill-ħalq
Irlanda	UCB Pharma Ireland Ltd United Drug House Magna Drive, Magna Business Park Citywest Road Dublin 24 Irlanda	Hydroxyzine hydrochloride	Ucerax 10mg/5ml Syrup	2 mg/ml	Mistura	Mill-ħalq

Stat Membru (EEA)	Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq	INN	Isem Ivvintat	Qawwa	Għamla Farmaċewtika	Mnjen jingħata
Irlanda	UCB Pharma Ireland Ltd United Drug House Magna Drive, Magna Business Park Citywest Road Dublin 24 Irlanda	Hydroxyzine hydrochloride	Ucerax 25mg Film-coated Tablets	25 mg	Pillola miksija b'rita	Mill-ħalq
Italja	UCB Pharma S.p.a. Via Gadames 57 20151 Milano Italja	Hydroxyzine hydrochloride	ATARAX	2 mg/ml	Mistura	Mill-ħalq
Italja	UCB Pharma S.p.a. Via Gadames 57 20151 Milano Italja	Hydroxyzine hydrochloride	ATARAX	25 mg	Pillola miksija b'rita	Mill-ħalq
Italja	UCB Pharma S.p.a. Via Gadames 57 20151 Milano Italja	Hydroxyzine hydrochloride	ATARAX	100 mg/2 ml	Soluzzjoni għall-injezzjoni	Minn ġol-muskolu
Luxemburgu	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belġju	Hydroxyzine dihydrochloride	Atarax	10 mg	Pillola miksija	Mill-ħalq
Luxemburgu	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belġju	Hydroxyzine dihydrochloride	Atarax	25 mg	Pillola miksija	Mill-ħalq
Luxemburgu	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belġju	Hydroxyzine dihydrochloride	Atarax	100 mg	Pillola miksija	Mill-ħalq
Malta	Alliance Pharmaceuticals Limited Avonbridge House Bath Road, Chippenham Wiltshire SN15 2BB Renju Unit	Hydroxyzine dihydrochloride	Atarax 10mg tablets	10 mg	Pillola	Mill-ħalq

Stat Membru (EEA)	Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq	INN	Isem Ivvintat	Qawwa	Għamla Farmaċewtika	Mnjen jingħata
Malta	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belġju	Hydroxyzine dihydrochloride	Atarax 25mg tablets	25 mg	Pillola	Mill-ħalq
Malta	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belġju	Hydroxyzine dihydrochloride	Atarax Syrup 0.2%	2 mg/ml	Mistura	Mill-ħalq
Norveġja	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Danimarka	Hydroxyzine	Atarax	10 mg	Pillola miksija b'rita	Mill-ħalq
Norveġja	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Danimarka	Hydroxyzine	Atarax	25 mg	Pillola miksija b'rita	Mill-ħalq
Polonja	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belġju	Hydroxyzine hydrochloride	Atarax	2 mg/ml	Mistura	Mill-ħalq
Polonja	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belġju	Hydroxyzine hydrochloride	Atarax	10 mg	Pillola miksija b'rita	Mill-ħalq
Polonja	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belġju	Hydroxyzine hydrochloride	Atarax	25 mg	Pillola miksija b'rita	Mill-ħalq
Polonja	Aflofarm Farmacja Polska Sp. z o.o. ul. Partyzancka 133/151 95-200 Pabianice Polonja	Hydroxyzine hydrochloride	Hydroxyzinum Aflofarm	2 mg/ml	Mistura	Mill-ħalq
Polonja	Biogened S.A ul. Pojezierska 99 91-342 Łódź Polonja	Hydroxyzine hydrochloride	Hydroxyzinum Biogened	1,6 mg/g	Mistura	Mill-ħalq

Stat Membru (EEA)	Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq	INN	Isem Ivvintat	Qawwa	Għamla Farmaċewtika	Mnjen jingħata
Polonja	Chemiczno-Farmaceutyczna Spółdzielnia Pracy ESPEFA ul. J. Lea 208 30-133 Kraków Polonja	Hydroxyzine hydrochloride	Hydroxyzinum Espefa	2 mg/ml	Mistura	Mill-ħalq
Polonja	Chemiczno-Farmaceutyczna Spółdzielnia Pracy ESPEFA ul. J. Lea 208 30-133 Kraków Polonja	Hydroxyzine hydrochloride	Hydroxyzinum Espefa	25 mg	Pillola miksija b'rita	Mill-ħalq
Polonja	Chemiczno-Farmaceutyczna Spółdzielnia Pracy ESPEFA ul. J. Lea 208 30-133 Kraków Polonja	Hydroxyzine hydrochloride	Hydroxyzinum Espefa	10 mg	Pillola miksija b'rita	Mill-ħalq
Polonja	Teva Pharmaceuticals Polska Sp. z o.o. ul. Emilii Plater 53 00-113 Warszawa Polonja	Hydroxyzine hydrochloride	Hydroxyzinum Teva	50 mg/ml	Soluzzjoni għall-infużjoni	Minn ġol-muskolu
Polonja	PharmaSwiss Ceska Republika s.r.o. Jankovcova 1569/2c 17000 Praha 7 PSC 170 00 Holesovice Republika Ċeka	Hydroxyzine hydrochloride	Hydroxyzinum VP	2 mg/ml	Mistura	Mill-ħalq
Polonja	PharmaSwiss Ceska Republika s.r.o. Jankovcova 1569/2c 17000 Praha 7 PSC 170 00 Holesovice Republika Ċeka	Hydroxyzine hydrochloride	Hydroxyzinum VP	10 mg	Pillola miksija b'rita	Mill-ħalq

Stat Membru (EEA)	Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq	INN	Isem Ivvintat	Qawwa	Għamla Farmaċewtika	Mnjen jingħata
Polonja	PharmaSwiss Ceska Republika s.r.o. Jankovcova 1569/2c 17000 Praha 7 PSC 170 00 Holesovice Republika Ċeka	Hydroxyzine hydrochloride	Hydroxyzinum VP	25 mg	Pillola miksija b'rita	Mill-ħalq
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	25 mg	Pillola miksija b'rita	Mill-ħalq
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	Mistura	Mill-ħalq
Republika Slovakkja	UCB s.r.o Thámová 13 180 00 Praha 8 Republika Slovakkja	Hydroxyzine	ATARAX	25 mg	Pillola miksija b'rita	Mill-ħalq
Spanja	UCB Pharma, S.A. Paseo de la Castellana 141 planta 15 Madrid 28046 Spanja	Hydroxyzine dihydrochloride	ATARAX 25 mg COMPRIMIDOS	25 mg	Pillola miksija b'rita	Mill-ħalq
Spanja	UCB Pharma, S.A. Paseo de la Castellana 141 planta 15 Madrid 28046 Spanja	Hydroxyzine dihydrochloride	ATARAX 2mg/ml JARABE	2 mg/ml	Mistura	Mill-ħalq

Stat Membru (EEA)	Id-Detentur tal-Awtorizzazzjoni għat-tqeghid fis-suq	INN	Isem Ivvintat	Qawwa	Għamla Farmaċewtika	Mnjen jingħata
Spanja	DERMOGEN PHARMA, S.A. Aragoneses, 15 28108 Alcobendas (Madrid) Spanja	Hydroxyzine dihydrochloride Propyphenazone Codeine phosphate	DOLODENS GRAGEAS	15 mg 100 mg 10 mg	Pillola	Mill-ħalq
Svezja	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Danimarka	Hydroxyzine hydrochloride	Atarax	10 mg	Pillola miksija b'rita	Mill-ħalq
Svezja	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Danimarka	Hydroxyzine hydrochloride	Atarax	25 mg	Pillola miksija b'rita	Mill-ħalq
Svezja	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Danimarka	Hydroxyzine hydrochloride	Atarax	2 mg/ml	Soluzzjoni orali	Mill-ħalq
Olanda	UCB Pharma B.V. Lage Mosten 33 4822 NK BREDA Olanda	Hydroxyzine dihydrochloride	Hydroxyzine-2 HCl 10	10 mg	Pillola miksija b'rita	Mill-ħalq
Olanda	UCB Pharma B.V. Lage Mosten 33 4822 NK BREDA Olanda	Hydroxyzine dihydrochloride	Hydroxyzine-2 HCl 25	25 mg	Pillola miksija b'rita	Mill-ħalq
Renju Unit	UCB Pharma Limited 208 Bath Road, Slough Berkshire SL1 3WE Renju Unit	Hydroxyzine hydrochloride	Ucerax 10mg/5ml Syrup	2 mg/ml	Soluzzjoni orali	Mill-ħalq
Renju Unit	UCB Pharma Limited 208 Bath Road, Slough Berkshire SL1 3WE Renju Unit	Hydroxyzine hydrochloride	Ucerax 25 mg film-coated tablets	25 mg	Pillola miksija	Mill-ħalq

Stat Membru (EEA)	Id-Detentur tal-Awtorizzazzjoni għat-tqegħid fis-suq	INN	Isem Ivvintat	Qawwa	Għamla Farmaċewtika	Mnjen jingħata
Renju Unit	Alliance Pharmaceuticals Limited Avonbridge House Bath Road, Chippenham Wiltshire SN15 2BB Renju Unit	Hydroxyzine hydrochloride	Atarax 10mg film-coated tablets	10 mg	Pillola	Mill-ħalq
Renju Unit	Alliance Pharmaceuticals Limited Avonbridge House Bath Road, Chippenham Wiltshire SN15 2BB Renju Unit	Hydroxyzine hydrochloride	Atarax 25mg film-coated tablets	25 mg	Pillola miksija	Mill-ħalq