



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 May 2014
EMA/281911/2014
Procedure Management and Business Support

Annex I

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

Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1400

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

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Cyprus	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Atarax	Hydroxyzine hydrochloride	2 mg/ml	Syrup	Oral use
Czech Republic	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Atarax	Hydroxyzine dihydrochloride	25 mg	Film-coated tablet	Oral use
Denmark	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Denmark	Atarax	Hydroxyzine hydrochloride	2 mg/ml	Oral solution	Oral use
Denmark	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Denmark	Atarax	Hydroxyzine hydrochloride	10 mg	Film-coated tablet	Oral use
Denmark	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Denmark	Atarax	Hydroxyzine hydrochloride	25 mg	Film-coated tablet	Oral use
Finland	UCB Pharma Oy Finland Itsehallintokuja 6 02600 ESPOO Finland	ATARAX	Hydroxyzine hydrochloride	2 mg/ml	Syrup	Oral use
Finland	UCB Pharma Oy Finland Itsehallintokuja 6 02600 ESPOO Finland	ATARAX	Hydroxyzine hydrochloride	25 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
France	UCB Pharma S.A. 420 Avenue Estienne d'Orves Défense Ouest 92700 Colombes France	ATARAX 100 mg, comprimé pelliculé sécable	Hydroxyzine hydrochloride	100 mg	Film-coated tablet	Oral Use
France	UCB Pharma S.A. 420 Avenue Estienne d'Orves Défense Ouest 92700 Colombes France	ATARAX 100 mg/2 ml, solution injectable	Hydroxyzine hydrochloride	100 mg/2 ml	Solution for injection	Intravenous use
France	UCB Pharma S.A. 420 Avenue Estienne d'Orves Défense Ouest 92700 Colombes France	ATARAX 25 mg, comprimé pelliculé sécable	Hydroxyzine hydrochloride	25 mg	Film-coated tablet	Oral Use
France	UCB Pharma S.A. 420 Avenue Estienne d'Orves Défense Ouest 92700 Colombes France	ATARAX sirop	Hydroxyzine hydrochloride	2 mg/ml	Syrup	Oral Use
France	Laboratoire Renaudin Z A. Errobi Itxassou 64250 Cambo les Bains France	HYDROXYZINE RENAUDIN 100 mg /2 ml, solution injectable	Hydroxyzine hydrochloride	100 mg/2 ml	Solution for injection	Intravenous use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
France	Inopharm limited 7 Florinis Street - Greg Tower, 6th Floor PO Box 24854 1304 Nicosia Cyprus	HYDROLAX 25 mg, comprimé pelliculé sécable	Hydroxyzine hydrochloride	25 mg	Film-coated tablet	Oral Use
France	Inopharm limited 7 Florinis Street - Greg Tower, 6th Floor PO Box 24854 1304 Nicosia Cyprus	HYDROXYZINE INOPHARM 25 mg, comprimé pelliculé sécable	Hydroxyzine hydrochloride	25 mg	Film-coated tablet	Oral Use
France	Inopharm limited 7 Florinis Street - Greg Tower, 6th Floor PO Box 24854 1304 Nicosia Cyprus	RAXTA 25 mg, comprimé pelliculé sécable	Hydroxyzine hydrochloride	25 mg	Film-coated tablet	Oral Use
France	Inopharm limited 7 Florinis Street - Greg Tower, 6th Floor PO Box 24854 1304 Nicosia Cyprus	TADRO 25 mg, comprimé pelliculé sécable	Hydroxyzine hydrochloride	25 mg	Film-coated tablet	Oral Use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
France	Inopharm limited 7 Florinis Street - Greg Tower, 6th Floor PO Box 24854 1304 Nicosia Cyprus	XYTA 25 mg, comprimé pelliculé sécable	Hydroxyzine hydrochloride	25 mg	Film-coated tablet	Oral Use
Germany	UCB Pharma GmbH Alfred-Nobel-Str. 10 40789 Monheim Germany	AH 3 N Tabletten	Hydroxyzine hydrochloride	25 mg	Film-coated tablet	Oral use
Germany	UCB Pharma GmbH Alfred-Nobel-Str. 10 40789 Monheim Germany	Atarax Tabletten	Hydroxyzine hydrochloride	25 mg	Film-coated tablet	Oral use
Greece	Olvos Science AE Eleftherias 4, 145 64, Kifisia, Greece	EFIDAC	Hydroxyzine	5%	Gel	Cutaneous use
Greece	UCB A.E. Ag. Dimitriou 63 17456, Alimos Greece	ATARAX	Hydroxyzine	25 mg	Film-coated tablet	Oral use
Greece	UCB A.E. Ag. Dimitriou 63 17456, Alimos Greece	ATARAX	Hydroxyzine	100 mg/2 ml	Solution for injection	Intramuscular use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Greece	UCB A.E. Ag. Dimitriou 63 17456, Alimos Greece	ATARAX	Hydroxyzine	2 mg/ml	Oral solution	Oral use
Greece	UCB A.E. Ag. Dimitriou 63 17456, Alimos Greece	ATARAX	Hydroxyzine	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	IREMOFAR	Hydroxyzine	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	IREMOFAR	Hydroxyzine	2 mg/ml	Oral solution	Oral use
Greece	Uni-Pharma Kleon Tsetis Farmakeftika Ergastria ABEE 14 Km. Nat. Road Athens-Lamia 14564, K. Kifisia Greece	IREMOFAR	Hydroxyzine	5%	Gel	Cutaneous use
Hungary	UCB Magyarország Kft. Árpád fejedelem útja 26-28 1023 Budapest Hungary	Atarax 25 mg filmtabletta	Hydroxyzine hydrochloride	25 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Iceland	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Denmark	Atarax	Hydroxyzine	2 mg/ml	Oral solution	Oral use
Iceland	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Denmark	Atarax	Hydroxyzine	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	Ucerax 10mg/5ml Syrup	Hydroxyzine hydrochloride	2 mg/ml	Syrup	Oral use
Ireland	UCB Pharma Ireland Ltd United Drug House Magna Drive, Magna Business Park Citywest Road Dublin 24 Ireland	Ucerax 25mg Film-coated Tablets	Hydroxyzine hydrochloride	25 mg	Film-coated tablet	Oral use
Italy	UCB Pharma S.p.a. Via Gadames 57 20151 Milano Italy	ATARAX	Hydroxyzine hydrochloride	2 mg/ml	Syrup	Oral use
Italy	UCB Pharma S.p.a. Via Gadames 57 20151 Milano Italy	ATARAX	Hydroxyzine hydrochloride	25 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Italy	UCB Pharma S.p.a. Via Gadames 57 20151 Milano Italy	ATARAX	Hydroxyzine hydrochloride	100 mg/2 ml	Solution for injection	Intramuscular use
Luxembourg	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Atarax	Hydroxyzine dihydrochloride	10 mg	Coated tablet	Oral use
Luxembourg	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Atarax	Hydroxyzine dihydrochloride	25 mg	Coated tablet	Oral use
Luxembourg	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Atarax	Hydroxyzine dihydrochloride	100 mg	Coated tablet	Oral use
Malta	Alliance Pharmaceuticals Limited Avonbridge House Bath Road, Chippenham Wiltshire SN15 2BB United Kingdom	Atarax 10mg tablets	Hydroxyzine dihydrochloride	10 mg	Tablet	Oral use
Malta	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Atarax 25mg tablets	Hydroxyzine dihydrochloride	25 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Malta	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Atarax Syrup 0.2%	Hydroxyzine dihydrochloride	2 mg/ml	Syrup	Oral use
Norway	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Denmark	Atarax	Hydroxyzine	10 mg	Film-coated tablet	Oral use
Norway	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Denmark	Atarax	Hydroxyzine	25 mg	Film-coated tablet	Oral use
Poland	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Atarax	Hydroxyzine hydrochloride	2 mg/ml	Syrup	Oral use
Poland	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Atarax	Hydroxyzine hydrochloride	10 mg	Film-coated tablet	Oral use
Poland	UCB Pharma S.A. Allée de la Recherche, 60 1070 Bruxelles Belgium	Atarax	Hydroxyzine hydrochloride	25 mg	Film-coated tablet	Oral use
Poland	Aflofarm Farmacja Polska Sp. z o.o. ul. Partyzancka 133/151 95-200 Pabianice Poland	Hydroxyzinum Aflofarm	Hydroxyzine hydrochloride	2 mg/ml	Syrup	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Poland	Biogened S.A ul. Pojezierska 99 91-342 Łódź Poland	Hydroxyzinum Biogened	Hydroxyzine hydrochloride	1,6 mg/g	Syrup	Oral use
Poland	Chemiczno-Farmaceutyczna Spółdzielnia Pracy ESPEFA ul. J. Lea 208 30-133 Kraków Polska	Hydroxyzinum Espefa	Hydroxyzine hydrochloride	2 mg/ml	Syrup	Oral use
Poland	Chemiczno-Farmaceutyczna Spółdzielnia Pracy ESPEFA ul. J. Lea 208 30-133 Kraków Polska	Hydroxyzinum Espefa	Hydroxyzine hydrochloride	25 mg	Film-coated tablet	Oral use
Poland	Chemiczno-Farmaceutyczna Spółdzielnia Pracy ESPEFA ul. J. Lea 208 30-133 Kraków Polska	Hydroxyzinum Espefa	Hydroxyzine hydrochloride	10 mg	Film-coated tablet	Oral use
Poland	Teva Pharmaceuticals Polska Sp. z o.o. ul. Emilii Plater 53 00-113 Warszawa Poland	Hydroxyzinum Teva	Hydroxyzine hydrochloride	50 mg/ml	Solution for infusion	Intramuscular use
Poland	PharmaSwiss Ceska Republika s.r.o. Jankovcova 1569/2c 17000 Praha 7 PSC 170 00 Holesovice Czech Republic	Hydroxyzinum VP	Hydroxyzine hydrochloride	2 mg/ml	Syrup	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Poland	PharmaSwiss Ceska Republika s.r.o. Jankovcova 1569/2c 17000 Praha 7 PSC 170 00 Holesovice Czech Republic	Hydroxyzinum VP	Hydroxyzine hydrochloride	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	Hydroxyzinum VP	Hydroxyzine hydrochloride	25 mg	Film-coated tablet	Oral use
Portugal	UCB Pharma (Produtos Farmacêuticos), Lda. Rua Victor Câmara, Edifício D. Amélia Piso 0, Sala A2, Quinta da Fonte 2770-229 Paço de Arcos Portugal	Atarax	Hydroxyzine	25 mg	Film-coated tablet	Oral use
Portugal	UCB Pharma (Produtos Farmacêuticos), Lda. Rua Victor Câmara, Edifício D. Amélia Piso 0, Sala A2, Quinta da Fonte 2770-229 Paço de Arcos Portugal	Atarax	Hydroxyzine	2 mg/ml	Syrup	Oral use
Slovak Republic	UCB s.r.o Thámová 13 180 00 Praha 8 Czech Republic	ATARAX	Hydroxyzine	25 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Spain	UCB Pharma, S.A. Paseo de la Castellana 141 planta 15. Madrid (28046) Spain	ATARAX 25 mg COMPRIMIDOS	Hydroxyzine dihydrochloride	25 mg	Film-coated tablet	Oral use
Spain	UCB Pharma, S.A. Paseo de la Castellana 141 planta 15. Madrid (28046) Spain	ATARAX 2mg/ml JARABE	Hydroxyzine dihydrochloride	2 mg/ml	Syrup	Oral use
Spain	Laboratorios Asociados Nupel S.L. Rua carpinteiros, 25. pol Ind Ceao. Lugo (27003) Spain	DOLODENS GRAGEAS	Hydroxyzine dihydrochloride Propyphenazone Codeine phosphate	15 mg 100 mg 10 mg	Coated tablet	Oral use
Sweden	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Denmark	Atarax	Hydroxyzine hydrochloride	10 mg	Film-coated tablet	Oral use
Sweden	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Denmark	Atarax	Hydroxyzine hydrochloride	25 mg	Film-coated tablet	Oral use
Sweden	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Copenhagen S Denmark	Atarax	Hydroxyzine hydrochloride	2 mg/ml	Oral solution	Oral use
The Netherlands	UCB Pharma B.V. Lage Mosten 33 4822 NK BREDA The Netherlands	Hydroxyzine-2 HCl 10	Hydroxyzine dihydrochloride	10 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands	UCB Pharma B.V. Lage Mosten 33 4822 NK BREDA The Netherlands	Hydroxyzine-2 HCl 25	Hydroxyzine dihydrochloride	25 mg	Film-coated tablet	Oral use
United Kingdom	UCB Pharma Limited 208 Bath Road Slough Berkshire SL1 3WE United Kingdom	Ucerax 10mg/5ml Syrup	Hydroxyzine hydrochloride	2 mg/ml	Oral solution	Oral use
United Kingdom	UCB Pharma Limited 208 Bath Road Slough Berkshire SL1 3WE United Kingdom	Ucerax 25 mg film- coated tablets	Hydroxyzine hydrochloride	25 mg	Coated tablet	Oral use
United Kingdom	Alliance Pharmaceuticals Limited Avonbridge House Bath Road, Chippenham Wiltshire SN15 2BB United Kingdom	Atarax 10mg film- coated tablets	Hydroxyzine hydrochloride	10 mg	Tablet	Oral use
United Kingdom	Alliance Pharmaceuticals Limited Avonbridge House Bath Road, Chippenham Wiltshire SN15 2BB United Kingdom	Atarax 25mg film- coated tablets	Hydroxyzine hydrochloride	25 mg	Coated tablet	Oral use