



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 June 2018
EMA/423869/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: hydroxyzine chloride / hydroxyzine pamoate and all fixed combination, hydroxyzine

Procedure no.: PSUSA/00001696/201711



Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Atarax® 25 mg Filmtabletten	not available	16161	UCB PHARMA GMBH (VIENNA AT)	AT
Atarax® 25 mg Filmtabletten	not available	16161	UCB PHARMA GMBH (VIENNA AT)	AT
Atarax 100 mg, filmomhulde tabletten	not available	BE045105	UCB PHARMA S.A. (ANDERL BE)	BE
Atarax 10 mg, filmomhulde tabletten	not available	BE045087	UCB PHARMA S.A. (ANDERL BE)	BE
Atarax 25 mg, filmomhulde tabletten	not available	BE045096	UCB PHARMA S.A. (ANDERL BE)	BE
Atarax 10 mg, com primes pellicules	not available	BE045087	UCB PHARMA S.A. (ANDERL BE)	BE
Atarax 25 mg, comprimés pellicules	not available	BE045096	UCB PHARMA S.A. (ANDERL BE)	BE
Atarax 1 00 mg, com primes pellicules	not available	BE045105	UCB PHARMA S.A. (ANDERL BE)	BE
АТАРАКС 25 mg филмирани таблетки	not available	20030268	UCB PHARMA S.A. (ANDERL BE)	BG
ATARAX (Hydroxyzine dihydrochloride) 25 mg film-coated tablet	not available	313	UCB PHARMA S.A. (ANDERL BE)	CY
ATARAX (Hydroxyzine dihydrochloride) 2 mg/ml syrup	not available	315	UCB PHARMA S.A. (ANDERL BE)	CY
Atarax 25mg potahované tablety	not available	70/891/92-C	UCB PHARMA S.A. (ANDERL BE)	CZ
AH 3® N Tabletten	not available	15189.00.00	UCB PHARMA GMBH (MONHEIM DE)	DE
ATARAX® Tabletten 25 mg Filmtabletten	not available	7081.00.00	UCB PHARMA GMBH (MONHEIM DE)	DE
Atarax 25 mg comprimidos recubiertos con película	not available	926.308	UCB PHARMA S.A. (MADRID ES)	ES
Atarax 2 mg/ml jarabe	not available	926.269	UCB PHARMA S.A. (MADRID ES)	ES

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Atarax 25 mg kalvopäällysteinen tabletti	not available	5798	UCB PHARMA OY FINLAND (ESPOO FI)	FI
Atarax 2 mg/ml siirappi	not available	5794	UCB PHARMA OY FINLAND (ESPOO FI)	FI
Atarax 2 mg/ml sirap	not available	5794	UCB PHARMA OY FINLAND (ESPOO FI)	FI
Atarax 25 mg filmdragerad tablett	not available	5798	UCB PHARMA OY FINLAND (ESPOO FI)	FI
ATARAX 25 mg, comprimé pelliculé sécable	not available	34009 339 613 9 8	UCB PHARMA S.A. (COLOMBES FR)	FR
ATARAX, sirop	not available	34009 334 665 0 3	UCB PHARMA S.A. (COLOMBES FR)	FR
ATARAX, sirop	not available	34009 334 664 4 2	UCB PHARMA S.A. (COLOMBES FR)	FR
ATARAX, sirop	not available	34009 334 663 8 1	UCB PHARMA S.A. (COLOMBES FR)	FR
ATARAX, sirop	not available	34009 300 814 3 3	UCB PHARMA S.A. (COLOMBES FR)	FR
ATARAX 25 mg, comprimé pelliculé sécable	not available	34009 300 813 7 2	UCB PHARMA S.A. (COLOMBES FR)	FR
EFIDAC	not available	41921/24-9-2008	OLVOS SCIENCE S.A.	GR
ATARAX®	not available	47915/14-10-2008	UCB A.E. (ATHENS GR)	GR
ATARAX®	not available	47909/14-10-2008	UCB A.E. (ATHENS GR)	GR
Atarax 25 mg filmtabletta	not available	OGYI-T-4577/01	UCB MAGYARORSZÁG KFT (BUDAPEST HU)	HU
Atarax 25 mg filmuhúðaðar töflur	not available	940066	UCB NORDIC A/S (COPENHAGEN DK)	IS
Atarax 2 mg/ml mixtúra, lausn	not available	940129	UCB NORDIC A/S (COPENHAGEN DK)	IS
ATARAX 20 mg/10 ml sciroppo	not available	010834012	UCB PHARMA SPA (MILAN IT)	IT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
ATARAX 25 mg compresse rivestite con film	not available	010834024	UCB PHARMA SPA (MILAN IT)	IT
Atarax 10 mg, com primes pellicules	not available	0072/10010668	UCB PHARMA S.A. (ANDERL BE)	LU
Atarax 100 mg, com primes pellicules	not available	0072/10010666	UCB PHARMA S.A. (ANDERL BE)	LU
Atarax 25 mg, com primes pellicules	not available	0072/10010669	UCB PHARMA S.A. (ANDERL BE)	LU
ATARAX® (Hydroxyzine dihydrochloride)	not available	MA030/00102	UCB PHARMA S.A. (ANDERL BE)	MT
ATARAX syrup ® (Hydroxyzine dihydrochloride)	not available	MA030/00101	UCB PHARMA S.A. (ANDERL BE)	MT
ATARAX 10 mg tabletter, filmdrasjerte	not available	3491	UCB NORDIC A/S (COPENHAGEN DK)	NO
ATARAX 25 mg tabletter, filmdrasjerte	not available	3492	UCB NORDIC A/S (COPENHAGEN DK)	NO
Atarax, tabletki powlekane, 10 mg	not available	R/2940	UCB PHARMA S.A. (ANDERL BE)	PL
Atarax, tabletki powlekane, 25 mg	not available	R/2941	UCB PHARMA S.A. (ANDERL BE)	PL
Atarax, 2 mg/ml, syrop	not available	R/2939	UCB PHARMA S.A. (ANDERL BE)	PL
Atarax 25 mg comprimidos revestidos por película	not available	5475397	UCB PHARMA (PRODUTOS FARMACÊUTICOS), LDA. (PACO PT)	PT
Atarax 25 mg comprimidos revestidos por película	not available	9641621	UCB PHARMA (PRODUTOS FARMACÊUTICOS), LDA. (PACO PT)	PT
Atarax 2 mg/ml xarope	not available	9934604	UCB PHARMA (PRODUTOS FARMACÊUTICOS), LDA. (PACO PT)	PT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Atarax 25 mg comprimidos revestidos por película	not available	9641613	UCB PHARMA (PRODUTOS FARMACÊUTICOS), LDA. (PACO PT)	PT
Atarax 10 mg filmdragerade tabletter	not available	5325	UCB NORDIC A/S (COPENHAGEN DK)	SE
Atarax 25 mg filmdragerade tabletter	not available	5326	UCB NORDIC A/S (COPENHAGEN DK)	SE
Atarax 2 mg/ml oral lösning	not available	5327	UCB NORDIC A/S (COPENHAGEN DK)	SE
ATARAX 25 mg filmom obalené tablety	not available	70/0891/92-C/S	UCB S.R.O. (PRAGUE CZ)	SK
Atarax 25mg Film-coated tablets	not available	PL 16853/0095	ALLIANCE PHARMACEUTICALS LTD	UK
Atarax 10mg Film-coated tablets	not available	PL 16853/0094	ALLIANCE PHARMACEUTICALS LTD	UK