



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 September 2022
EMA/PRAC/800404/2022
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): lorazepam

Procedure No. PSUSA/00001909/202201



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
Ativan 1 mg Tablets	not available	PA 822/90/1	PFIZER HEALTHCARE IRELAND	IE
Ativan 1 mg Tablets	not available	MA505/06101	PFIZER HELLAS, A.E.	MT
Control 1 mg Compresse	not available	022959011	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
Control 2,5 mg compresse	not available	022959023	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
LORANS 0,5 mg tabletès	NL/H/3485/003	LT/1/20/4593/001	MEDOCHEMIE LTD.	LT
LORANS 0,5 mg tabletès	NL/H/3485/003	LT/1/20/4593/002	MEDOCHEMIE LTD.	LT
LORANS 0,5 mg tabletès	NL/H/3485/003	LT/1/20/4593/003	MEDOCHEMIE LTD.	LT
LORANS 0,5 mg tabletès	NL/H/3485/003	LT/1/20/4593/004	MEDOCHEMIE LTD.	LT
LORANS 0,5 mg tabletès	NL/H/3485/003	LT/1/20/4593/005	MEDOCHEMIE LTD.	LT
LORANS 0,5 mg tabletès	NL/H/3485/003	LT/1/20/4593/006	MEDOCHEMIE LTD.	LT
LORANS 0,5 mg tabletès	NL/H/3485/003	LT/1/20/4593/007	MEDOCHEMIE LTD.	LT
LORANS 0,5 mg tabletès	NL/H/3485/003	LT/1/20/4593/008	MEDOCHEMIE LTD.	LT
LORANS 0,5 mg tabletès	NL/H/3485/003	LT/1/20/4593/009	MEDOCHEMIE LTD.	LT
LORANS 0,5 mg tabletès	NL/H/3485/003	LT/1/20/4593/010	MEDOCHEMIE LTD.	LT
LORANS 0,5 mg tabletès	NL/H/3485/003	LT/1/20/4593/011	MEDOCHEMIE LTD.	LT
LORANS 2 mg/ml gocce orali, soluzione	not available	023001074	TEOFARMA S.R.L.	IT
Lorans, 0,5 mg tabletid	NL/H/3485/003	1006320	MEDOCHEMIE LTD.	EE
Lorazepam 0.5mg Tablets	UK/H/6930/001	PL 12762/0543	MERCURY PHARMACEUTICALS LTD.	XI
Lorazepam GenRX 0,5 mg, tabletten	NL/H/3485/003	RVG 124313	GENRX B.V.	NL
Lorazepam Medochemie Bohemia 0,5 mg compresse	NL/H/4647/001	048447015	MEDOCHEMIE BOHEMIA, SPOL. S R.O.	IT
Lorazepam Medochemie Bohemia 0,5 mg compresse	NL/H/4647/001	048447027	MEDOCHEMIE BOHEMIA, SPOL. S R.O.	IT
Lorazepam Medochemie Bohemia 0,5 mg	NL/H/4647/001	48447039	MEDOCHEMIE BOHEMIA, SPOL. S R.O.	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
comprese				
Lorazepam Medochemie Bohemia 0,5 mg compresse	NL/H/4647/001	48447041	MEDOCHÉMIE BOHEMIA, SPOL. S R.O.	IT
Lorazepam Medochemie Bohemia 0,5 mg Tabletten	NL/H/4647/001	BE556586	MEDOCHÉMIE BOHEMIA, SPOL. S R.O.	BE
Lorazepam Medochemie Bohemia 0,5 mg Tabletten	NL/H/4647/001	2203342.00.00	MEDOCHÉMIE BOHEMIA, SPOL. S R.O.	DE
Lorazepam Medochemie Bohemia 0,5 mg, tabletten	NL/H/4647/001	RVG 124010	MEDOCHÉMIE BOHEMIA, SPOL. S R.O.	NL
Lorazepam Medochemie Bohemia 1 mg compresse	NL/H/4647/002	48447054	MEDOCHÉMIE BOHEMIA, SPOL. S R.O.	IT
Lorazepam Medochemie Bohemia 1 mg compresse	NL/H/4647/002	48447066	MEDOCHÉMIE BOHEMIA, SPOL. S R.O.	IT
Lorazepam Medochemie Bohemia 1 mg compresse	NL/H/4647/002	48447078	MEDOCHÉMIE BOHEMIA, SPOL. S R.O.	IT
Lorazepam Medochemie Bohemia 1 mg compresse	NL/H/4647/002	48447080	MEDOCHÉMIE BOHEMIA, SPOL. S R.O.	IT
Lorazepam Medochemie Bohemia 1 mg Tabletten	NL/H/4647/002	BE556595	MEDOCHÉMIE BOHEMIA, SPOL. S R.O.	BE
Lorazepam Medochemie Bohemia 1 mg Tabletten	NL/H/4647/002	2203343.00.00	MEDOCHÉMIE BOHEMIA, SPOL. S R.O.	DE
Lorazepam Medochemie Bohemia 1 mg, tabletten	NL/H/4647/002	RVG 124011	MEDOCHÉMIE BOHEMIA, SPOL. S R.O.	NL
Lorazepam Medochemie Bohemia 2,5 mg compresse	NL/H/4647/003	48447092	MEDOCHÉMIE BOHEMIA, SPOL. S R.O.	IT
Lorazepam Medochemie Bohemia 2,5 mg compresse	NL/H/4647/003	48447104	MEDOCHÉMIE BOHEMIA, SPOL. S R.O.	IT
Lorazepam Medochemie	NL/H/4647/003	48447116	MEDOCHÉMIE BOHEMIA,	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
Bohemia 2,5 mg compresse			SPOL. S R.O.	
Lorazepam Medochemie Bohemia 2,5 mg compresse	NL/H/4647/003	48447128	MEDOCHÉMIE BOHEMIA, SPOL. S R.O.	IT
Lorazepam Medochemie Bohemia 2,5 mg Tabletten	NL/H/4647/003	BE556604	MEDOCHÉMIE BOHEMIA, SPOL. S R.O.	BE
Lorazepam Medochemie Bohemia 2,5 mg Tabletten	NL/H/4647/003	2203344.00.00	MEDOCHÉMIE BOHEMIA, SPOL. S R.O.	DE
Lorazepam Medochemie Bohemia 2,5 mg, tabletten	NL/H/4647/003	RVG 124012	MEDOCHÉMIE BOHEMIA, SPOL. S R.O.	NL
Lorazepam Medochemie Romania 0,5 mg compresse	NL/H/4646/001	47983010	MEDOCHÉMIE ROMANIA S.R.L.	IT
Lorazepam Medochemie Romania 0,5 mg compresse	NL/H/4646/001	47983022	MEDOCHÉMIE ROMANIA S.R.L.	IT
Lorazepam Medochemie Romania 0,5 mg compresse	NL/H/4646/001	47983034	MEDOCHÉMIE ROMANIA S.R.L.	IT
Lorazepam Medochemie Romania 0,5 mg compresse	NL/H/4646/001	47983046	MEDOCHÉMIE ROMANIA S.R.L.	IT
Lorazepam Medochemie Romania 0,5 mg Tabletten	NL/H/4646/001	BE556613	MEDOCHÉMIE ROMANIA S.R.L.	BE
Lorazepam Medochemie Romania 0,5 mg, tabletten	NL/H/4646/001	RVG 124020	MEDOCHÉMIE ROMANIA S.R.L.	NL
Lorazepam Medochemie Romania 1 mg compresse	NL/H/4646/002	47983059	MEDOCHÉMIE ROMANIA S.R.L.	IT
Lorazepam Medochemie Romania 1 mg compresse	NL/H/4646/002	47983061	MEDOCHÉMIE ROMANIA S.R.L.	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
Lorazepam Medochemie Romania 1 mg compresse	NL/H/4646/002	47983073	MEDOCHÉMIE ROMANIA S.R.L.	IT
Lorazepam Medochemie Romania 1 mg compresse	NL/H/4646/002	47983085	MEDOCHÉMIE ROMANIA S.R.L.	IT
Lorazepam Medochemie Romania 1 mg Tabletten	NL/H/4646/002	BE556622	MEDOCHÉMIE ROMANIA S.R.L.	BE
Lorazepam Medochemie Romania 1 mg, tabletten	NL/H/4646/002	RVG 124021	MEDOCHÉMIE ROMANIA S.R.L.	NL
Lorazepam Medochemie Romania 2,5 mg compresse	NL/H/4646/003	47983097	MEDOCHÉMIE ROMANIA S.R.L.	IT
Lorazepam Medochemie Romania 2,5 mg compresse	NL/H/4646/003	47983109	MEDOCHÉMIE ROMANIA S.R.L.	IT
Lorazepam Medochemie Romania 2,5 mg compresse	NL/H/4646/003	47983111	MEDOCHÉMIE ROMANIA S.R.L.	IT
Lorazepam Medochemie Romania 2,5 mg compresse	NL/H/4646/003	47983123	MEDOCHÉMIE ROMANIA S.R.L.	IT
Lorazepam Medochemie Romania 2,5 mg Tabletten	NL/H/4646/003	BE556631	MEDOCHÉMIE ROMANIA S.R.L.	BE
Lorazepam Medochemie Romania 2,5 mg, tabletten	NL/H/4646/003	RVG 124022	MEDOCHÉMIE ROMANIA S.R.L.	NL
Lorazepam Prolepha 0,5 mg, tabletten	not available	RVG 123766	PROLEPHA RESEARCH B.V.	NL
Lorazepam tablets 1mg.	not available	PL 4416/0094	SANDOZ LTD	XI
Lorazepam tablets 2.5mg.	not available	PL 4416/0095	SANDOZ LTD	XI
Lorenin 1 mg comprimidos	not available	4620282	LABORATÓRIOS PFIZER, LDA.	PT
Lorenin 1 mg comprimidos	not available	8275404	LABORATÓRIOS PFIZER, LDA.	PT
Lorenin 1 mg	not available	4620183	LABORATÓRIOS PFIZER,	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
comprimidos			LDA.	
Lorenin 2,5 mg comprimidos	not available	8275420	LABORATÓRIOS PFIZER, LDA.	PT
Lorenin 2,5 mg comprimidos	not available	4620381	LABORATÓRIOS PFIZER, LDA.	PT
Lorenin 2,5 mg comprimidos	not available	4620480	LABORATÓRIOS PFIZER, LDA.	PT
Lorsedal® - comprimidos a 5,0 mg	not available	5105879	PROSPA - LABORATÓRIOS FARMACÊUTICOS, S.A.	PT
LORSEDAL® - comprimidos a 5,0 mg	not available	5105911	PROSPA - LABORATÓRIOS FARMACÊUTICOS, S.A.	PT
LORSEDAL® - Comprimidos a 5,0 mg	not available	4536793	PROSPA - LABORATÓRIOS FARMACÊUTICOS, S.A.	PT
LORSEDAL® - Comprimidos a 5,0 mg	not available	9298281	PROSPA - LABORATÓRIOS FARMACÊUTICOS, S.A.	PT
LORSEDAL® - Comprimidos a 1,0 mg	not available	9298257	PROSPA - LABORATÓRIOS FARMACÊUTICOS, S.A.	PT
LORSEDAL® - Comprimidos a 1,0 mg	not available	9298265	PROSPA - LABORATÓRIOS FARMACÊUTICOS, S.A.	PT
LORSEDAL® - Comprimidos a 2,5 mg	not available	4536595	PROSPA - LABORATÓRIOS FARMACÊUTICOS, S.A.	PT
LORSEDAL® - Comprimidos a 2,5 mg	not available	9298273	PROSPA - LABORATÓRIOS FARMACÊUTICOS, S.A.	PT
ORFIDAL 1 mg comprimidos	not available	49.796	PFIZER, S.L.	ES
Placinoral 2 mg comprimidos	not available	56.195	FERRER INTERNACIONAL, S.A.	ES
TAVOR 1 mg COMPRESSE	not available	022531053	PFIZER ITALIA S.R.L.	IT
TAVOR 1 mg COMPRESSE OROSOLUBILI	not available	022531103	PFIZER ITALIA S.R.L.	IT
Tavor 1 mg διακία	not available	42796/10/31-5-2011	PFIZER HELLAS, A.E.	GR
TAVOR 2 mg/ml gocce orali, soluzione	not available	022531091	PFIZER ITALIA S.R.L.	IT
TAVOR 2,5 mg COMPRESSE	not available	022531077	PFIZER ITALIA S.R.L.	IT
TAVOR 2,5 mg	not available	022531127	PFIZER ITALIA S.R.L.	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
COMPRESSE OROSOLUBILI				
Tavor 2,5 mg δισκία	not available	42798/10/31-5-2011	PFIZER HELLAS, A.E.	GR
TAVOR 4 mg/ml soluzione iniettabile	not available	022531139	PFIZER ITALIA S.R.L.	IT
Tavor® 0,5 mg Tabletten	not available	6174941.00.00	PFIZER PHARMA GMBH	DE
Tavor® 1,0 mg Expidet® Plättchen	not available	6948.00.00	PFIZER PHARMA GMBH	DE
Tavor® 1,0 mg Tabletten	not available	6174941.01.00	PFIZER PHARMA GMBH	DE
Tavor® 2,5 mg Expidet® Plättchen	not available	6948.01.00	PFIZER PHARMA GMBH	DE
Tavor® 2,5 mg Tabletten	not available	6174941.02.00	PFIZER PHARMA GMBH	DE
Tavor® pro injectione 2 mg Injektionslösung	not available	7379.00.00	PFIZER PHARMA GMBH	DE
Tavor® Tabs 2,0 mg Tabletten	not available	6175142.00.00	PFIZER PHARMA GMBH	DE
Temelor 0,5 mg tablettes	NL/H/3485/003	21-0207	MEDOCHEMIE LTD.	LV
Temelor 0.5 mg tablets	NL/H/3485/003	MA032/14503	MEDOCHEMIE LTD.	MT
Temesta 1 mg Tabletten	not available	BE158304	PFIZER S.A. (BELGIUM)	BE
Temesta 1 mg Tabletten	not available	BE022242	PFIZER S.A. (BELGIUM)	BE
Temesta 1 mg Tabletten	not available	2006058570	PFIZER S.A. (BELGIUM)	LU
Temesta 1 mg tabletter	not available	9482	PFIZER AB	SE
Temesta 1 mg tabletti	not available	10299	PFIZER OY	FI
TEMESTA 1 mg, comprimé sécable	not available	34009 550 213 6 0	NEURAXPHARM FRANCE	FR
TEMESTA 1 mg, comprimé sécable	not available	34009 357 469-3 1	NEURAXPHARM FRANCE	FR
Temesta 2,5 mg Tabletten	not available	BE022233	PFIZER S.A. (BELGIUM)	BE
Temesta 2,5 mg Tabletten	not available	2006058571	PFIZER S.A. (BELGIUM)	LU
TEMESTA 2,5 mg, comprimé sécable	not available	34009 550 213 5 3	NEURAXPHARM FRANCE	FR
TEMESTA 2,5 mg, comprimé sécable	not available	34009 314 899-6 2	NEURAXPHARM FRANCE	FR

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
TEMESTA 4 mg/ml Injektionslösung	not available	BE106757	PFIZER S.A. (BELGIUM)	BE
TEMESTA 4 mg/ml Injektionslösung	not available	2009010133	PFIZER S.A. (BELGIUM)	LU
Temesta Expidet 1,0 mg Lyophilisate zum Einnehmen	not available	BE134075	PFIZER S.A. (BELGIUM)	BE
Temesta Expidet 1,0 mg Lyophilisate zum Einnehmen	not available	2006058572	PFIZER S.A. (BELGIUM)	LU
Temesta Expidet 2,5 mg Lyophilisate zum Einnehmen	not available	BE134084	PFIZER S.A. (BELGIUM)	BE
Temesta Expidet 2,5 mg Lyophilisate zum Einnehmen	not available	2006058573	PFIZER S.A. (BELGIUM)	LU
Temesta, oplossing voor injectie 4 mg/ml	not available	RVG 08192	PFIZER B.V.	NL
Temesta, tabletter	not available	5793	PFIZER APS	DK
Xilmac 4 mg/ml Solution for injection	not available	PA 0822/090/002	PFIZER HEALTHCARE IRELAND	IE