



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

29 September 2016  
EMA/382258/2015  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: lorazepam

Procedure no.: PSUSA/00001909/201601



<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Ativan 1mg Tablets	not available	PA 0822/090/001	PFIZER HEALTHCARE IRELAND	IE
Ativan 1mg Tablets	not available	MA505/06101	PFIZER HELLAS, A.E.	MT
Ativan 4 mg/ml Solution for injection	not available	PA 0822/090/002	PFIZER HEALTHCARE IRELAND	IE
Ativan® Injection	not available	PL 00057/1279	PFIZER LIMITED	UK
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 1 mg compresse	not available	023001023	UCB PHARMA SPA (MILAN IT)	IT
LORANS 1 mg compresse	not available	023001086	UCB PHARMA SPA (MILAN IT)	IT
LORANS 2 mg/ml gocce orali, soluzione	not available	023001074	UCB PHARMA SPA (MILAN IT)	IT
LORANS 2,5 mg compresse	not available	023001047	UCB PHARMA SPA (MILAN IT)	IT
LORANS 2,5 mg compresse	not available	023001098	UCB PHARMA SPA (MILAN IT)	IT
Lorazepam tablets 1mg	PL 04416/0094	PL 04416/0094	SANDOZ LTD	UK
Lorazepam tablets 2.5mg	PL 04416/0095	PL 04416/0095	SANDOZ LTD	UK
Lorazepam tablets 2.5mg	PL 04416/0094	PL 04416/0094	SANDOZ LTD	UK
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 comprimidos	not available	4620183	LABORATÓRIOS PFIZER, LDA.	PT
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

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Lorsedal '1rg		4536496 9298257 9298265	Prospa - Laboratórios Farmacêuticos, S.A.	PT
Lorsedal' 5mg (blister)		5105879 5105911 510s903	Prospa - Laboratórios Farmacêuticos, S.A.	PT
Lorsedal" 5mg (frasco)		9298281 4536793 4536892	Prospa - Laboratórios Farmacêuticos, S.A.	PT
Lorsedal'2,5mg		9298273 4536595 4536694	Prospa - Laboratórios Farmacêuticos, S.A.	PT
ORFIDAL 1 mg comprimidos	not available	49.796	PFIZER, S.L.	ES
Placinal 2 mg comprimidos	not available	56.195	BRAINPHARMA, S.L.	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 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 COMPRESSE OROSOLUBILI	not available	022531127	PFIZER ITALIA S.R.L.	IT
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

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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
TAVOR® Διακία 1 mg	not available	S00235	PFIZER HELLAS, A.E.	CY
TAVOR® Διακία 1 mg	not available	42796/10	PFIZER HELLAS, A.E.	GR
TAVOR® Διακία 2,5 mg	not available	42798/10	PFIZER HELLAS, A.E.	GR
Temesta 1 mg comprimés	not available	BE022242	PFIZER S.A. (BELGIUM)	BE
Temesta 1 mg comprimés	not available	BE158304	PFIZER S.A. (BELGIUM)	BE
Temesta 1 mg tablett	not available	10299	PFIZER OY	FI
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	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	315 335-9	LABORATOIRE BIODIM	FR
TEMESTA 1 mg, comprimé sécable	not available	34009 357 469-3 1	LABORATOIRE BIODIM	FR
Temesta 2,5 mg comprimés	not available	BE022233	PFIZER S.A. (BELGIUM)	BE
Temesta 2,5 mg Tabletten	not available	BE022233	PFIZER S.A. (BELGIUM)	BE
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 314 899-6 2	LABORATOIRE BIODIM	FR

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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 4 mg/ml oplossing voor injectie	not available	BE106757	PFIZER S.A. (BELGIUM)	BE
Temesta 4 mg/ml solution injectable	not available	BE106757	PFIZER S.A. (BELGIUM)	BE
Temesta 4 mg/ml solution injectable	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 1,0 mg lyophilisaten voor oraal gebruik	not available	BE134075	PFIZER S.A. (BELGIUM)	BE
Temesta Expidet 1,0 mg lyophilisats oraux	not available	BE134075	PFIZER S.A. (BELGIUM)	BE
Temesta Expidet 1,0 mg lyophilisats oraux	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 Expidet 2,5 mg lyophilisaten voor oraal gebruik	not available	BE134084	PFIZER S.A. (BELGIUM)	BE
Temesta Expidet 2,5 mg lyophilisats oraux	not available	BE134084	PFIZER S.A. (BELGIUM)	BE
Temesta Expidet 2,5 mg lyophilisats oraux	not available	2006058573	PFIZER S.A. (BELGIUM)	LU

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Temesta, oplossing voor injectie 4 mg/ml	not available	RVG 08192	PFIZER B.V.	NL
Temesta, tabletter	not available	5793	PFIZER APS	DK