



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 October 2018
EMA/270645/2015
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: lorazepam

Procedure no.: PSUSA/00001909/201801



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
Placinoral 2 mg comprimidos	not available	56.195	FERRER INTERNACIONAL, S.A.	ES
TEMESTA 1 mg, comprimé sécable	not available	34009 357 469-3 1	LABORATOIRE BIODIM	FR
TEMESTA 2,5 mg, comprimé sécable	not available	34009 314 899-6 2	LABORATOIRE BIODIM	FR
LORAZEPAM DESGEN 5 mg comprimidos	not available	55103	GENERFARMA S.L.	ES
LORSEDAL® – Comprimidos a 1,0 mg	not available	9298257	PROSPA - LABORATÓRIOS FARMACÊUTICOS, S.A.	PT
LORSEDAL® – Comprimidos a 2,5 mg	not available	4536595	PROSPA - LABORATÓRIOS FARMACÊUTICOS, S.A.	PT
LORSEDAL® – Comprimidos a 5,0 mg	not available	4536793	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	9298273	PROSPA - LABORATÓRIOS FARMACÊUTICOS, S.A.	PT
LORSEDAL® – Comprimidos a 5,0 mg	not available	9298281	PROSPA - LABORATÓRIOS FARMACÊUTICOS, S.A.	PT
ORFIDAL 1 mg comprimidos	not available	49.796	PFIZER, S.L.	ES
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 2,5 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
LORANS 2 mg/ml gocce orali, soluzione	not available	023001074	UCB PHARMA SPA (MILAN IT)	IT
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
Lorazepam-neuraxpharm 1 mg Schmelztabletten	DE/H/4558/001	95983.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE

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Lorazepam-neuraxpharm 2,5 mg Schmelztabletten	DE/H/4558/002	95984.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Temesta 1 mg tablett	not available	10299	PFIZER OY	FI
TEMESTA 4 mg/ml Injektionslösung	not available	BE106757	PFIZER S.A. (BELGIUM)	BE
Temesta Expidet 2,5 mg Lyophilisate zum Einnehmen	not available	BE134084	PFIZER S.A. (BELGIUM)	BE
Temesta Expidet 1,0 mg Lyophilisate zum Einnehmen	not available	BE134075	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 2,5 mg Tabletten	not available	BE022233	PFIZER S.A. (BELGIUM)	BE
Temesta Expidet 2,5 mg Lyophilisate zum Einnehmen	not available	2006058573	PFIZER S.A. (BELGIUM)	LU
TEMESTA 4 mg/ml Injektionslösung Lorazepam	not available	2009010133	PFIZER S.A. (BELGIUM)	LU
Temesta Expidet 1,0 mg Lyophilisate zum Einnehmen	not available	2006058572	PFIZER S.A. (BELGIUM)	LU
Temesta 2,5 mg Tabletten	not available	2006058571	PFIZER S.A. (BELGIUM)	LU
Temesta 1 mg Tabletten	not available	2006058570	PFIZER S.A. (BELGIUM)	LU
Ativan 1mg Tablets	not available	MA505/06101	PFIZER HELLAS, A.E.	MT
Ativan 1mg Tablets	not available	PA 822/90/1	PFIZER HEALTHCARE IRELAND	IE
TAVOR 2,5 mg COMPRESSE OROSOLUBILI	not available	022531127	PFIZER ITALIA S.R.L.	IT
TAVOR 1 mg COMPRESSE	not available	022531103	PFIZER ITALIA S.R.L.	IT

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OROSOLUBILI				
TAVOR 1 mg COMPRESSE	not available	022531053	PFIZER ITALIA S.R.L.	IT
TAVOR 4 mg/ml soluzione iniettabile	not available	022531139	PFIZER ITALIA S.R.L.	IT
Temesta 1 mg comprimés	not available	BE022242	PFIZER S.A. (BELGIUM)	BE
Temesta Expidet 1,0 mg lyophilisats oraux	not available	BE134075	PFIZER S.A. (BELGIUM)	BE
Temesta Expidet 2,5 mg lyophilisats oraux	not available	BE134084	PFIZER S.A. (BELGIUM)	BE
TAVOR 2,5 mg COMPRESSE	not available	022531077	PFIZER ITALIA S.R.L.	IT
Temesta 1 mg comprimés	not available	BE158304	PFIZER S.A. (BELGIUM)	BE
Temesta 2,5 mg comprimés	not available	BE022233	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 lyophilisats oraux	not available	2006058573	PFIZER S.A. (BELGIUM)	LU
Temesta, tabletter	not available	5793	PFIZER APS	DK
Temesta 2,5 mg comprimés	not available	2006058571	PFIZER S.A. (BELGIUM)	LU
Temesta 1 mg comprimés	not available	2006058570	PFIZER S.A. (BELGIUM)	LU
Temesta 1 mg tabletti	not available	10299	PFIZER OY	FI
Temesta 4 mg/ml solution injectable	not available	2009010133	PFIZER S.A. (BELGIUM)	LU
Tavor® Tabs 2,0 mg Tabletten	not available	6175142.00.00	PFIZER PHARMA PFE GMBH	DE
Tavor® 2,5 mg Tabletten	not available	6174941.02.00	PFIZER PHARMA PFE GMBH	DE
Tavor® 1,0 mg Tabletten	not available	6174941.01.00	PFIZER PHARMA PFE GMBH	DE
Tavor® 0,5 mg Tabletten	not available	6174941.00.00	PFIZER PHARMA PFE GMBH	DE

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Tavor® 2,5 mg Expidet® Plättchen	not available	6948.01.00	PFIZER PHARMA PFE GMBH	DE
Tavor® pro injectione 2 mg Injektionslösung	not available	7379.00.00	PFIZER PHARMA PFE GMBH	DE
Tavor® 1,0 mg Expidet® Plättchen	not available	6948.00.00	PFIZER PHARMA PFE GMBH	DE
Lorenin 2,5 mg comprimidos	not available	8275420	LABORATÓRIOS PFIZER, LDA.	PT
Temesta 4 mg/ml solution injectable	not available	BE106757	PFIZER S.A. (BELGIUM)	BE
Temesta, oplossing voor injectie 4 mg/ml	not available	RVG 08192	PFIZER B.V.	NL
TAVOR® Δισκία 1 mg	not available	42796/10/31-5-2011	PFIZER HELLAS, A.E.	GR
Ativan® Injection	not available	PL 00057/1279	PFIZER LIMITED	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	4620381	LABORATÓRIOS PFIZER, LDA.	PT
Lorenin 2,5 mg comprimidos	not available	4620480	LABORATÓRIOS PFIZER, LDA.	PT
TAVOR 2 mg/ ml gocce orali, soluzione	not available	022531091	PFIZER ITALIA S.R.L.	IT
Ativan 4 mg/ml Solution for injection	not available	PA 0822/090/002	PFIZER HEALTHCARE IRELAND	IE
Temesta 1 mg tabletter	not available	9482	PFIZER AB	SE
Temesta 4 mg/ml oplossing voor injectie	not available	BE106757	PFIZER S.A. (BELGIUM)	BE
Temesta 2,5 mg tabletten	not available	BE022233	PFIZER S.A. (BELGIUM)	BE
Temesta 1 mg tabletten	not available	BE158304	PFIZER S.A. (BELGIUM)	BE

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Temesta Expidet 2,5 mg lyophilisaten voor oraal gebruik	not available	BE134084	PFIZER S.A. (BELGIUM)	BE
Temesta 1 mg tabletten	not available	BE022242	PFIZER S.A. (BELGIUM)	BE
Temesta Expidet 1,0 mg lyophilisaten voor oraal gebruik	not available	BE134075	PFIZER S.A. (BELGIUM)	BE
TAVOR® Δισκία 2,5 mg	not available	42798/10/31-5-2011	PFIZER HELLAS, A.E.	GR