



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

1 October 2020  
EMA/PRAC/535566/2020  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: lorazepam

Procedure no.: PSUSA/00001909/202001

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**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

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<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 822/90/1	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 4mg/ml Solution for 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 2 mg/ml gocce orali, soluzione	not available	023001074	TEOFARMA S.R.L.	IT
Lorazepam 0.5mg Tablets	UK/H/6930/001	PL 12762/0543	MERCURY PHARMACEUTICALS LTD.	UK
LORAZEPAM DESGEN 5 mg comprimidos	not available	55103	GENERFARMA S.L.	ES

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Lorazepam tablets 1mg.	not available	PL 4416/0094	SANDOZ LTD	UK
Lorazepam tablets 2.5mg.	not available	PL 4416/0095	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
LORSEDAL ®- Comprimidos a 5,0 mg	not available	4536793	PROSPA - LABORATÓRIOS FARMACÊUTICOS, S.A.	PT

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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
Placinal 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

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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 PFE GMBH	DE
Tavor® 1,0 mg Expidet® Plättchen	not available	6948.00.00	PFIZER PHARMA PFE GMBH	DE
Tavor® 1,0 mg Tabletten	not available	6174941.01.00	PFIZER PHARMA PFE GMBH	DE
Tavor® 2,5 mg Expidet® Plättchen	not available	6948.01.00	PFIZER PHARMA PFE GMBH	DE
Tavor® 2,5 mg Tabletten	not available	6174941.02.00	PFIZER PHARMA PFE GMBH	DE

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Tavor® pro injectione 2 mg Injektionslösung	not available	7379.00.00	PFIZER PHARMA PFE GMBH	DE
Tavor® Tabs 2,0 mg Tabletten	not available	6175142.00.00	PFIZER PHARMA PFE GMBH	DE
TAVOR® Δισκία 1 mg	not available	42796/10/31-5-2011	PFIZER HELLAS, A.E.	GR
TAVOR® Δισκία 2,5 mg	not available	42798/10/31-5-2011	PFIZER HELLAS, A.E.	GR
Temesta 1 mg comprimés	not available	2006058570	PFIZER S.A. (BELGIUM)	LU
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 tabletter	not available	9482	PFIZER AB	SE

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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 comprimés	not available	2006058571	PFIZER S.A. (BELGIUM)	LU
Temesta 2,5 mg tabletten	not available	BE022233	PFIZER S.A. (BELGIUM)	BE
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
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 lyophilisaten voor oraal gebruik	not available	BE134075	PFIZER S.A. (BELGIUM)	BE

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Temesta Expidet 1,0 mg lyophilisats oraux	not available	2006058572	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	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