



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 February 2021
EMA/270645/2015
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: primidone

Procedure no.: PSUSA/00002525/202006



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
Mylepsinum® 250 mg, Tablette	not available	6328812.00.00	TEVA GMBH	DE
Mysoline - Tabletten	not available	7.676	SANOVA PHARMA GESMBH	AT
Mysoline , tabletten 250 mg	not available	RVG 00379	SERB	NL
Mysoline 250 mg compresse	not available	009340011	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
MYSOLINE 250 mg comprimés	not available	BE079037	SERB	BE
MYSOLINE 250 mg comprimés	not available	BE079037	SERB	BE
MYSOLINE 250 mg comprimés	not available	2003027478	SERB	LU
Mysoline 250 mg comprimidos	not available	18.498	SERB	ES
Mysoline 250 mg comprimidos	not available	8988816	SERB	PT
Mysoline 250 mg comprimidos	not available	5637376	SERB	PT
Mysoline 250 mg comprimidos	not available	898824	SERB	PT
Mysoline 250 mg comprimidos	not available	5637400	SERB	PT
MYSOLINE 250 mg Tablets	not available	PA 1777/001/001	SERB	IE
Mysoline 250 mg tabletten	not available	BE079037	SERB	BE
Mysoline 250 mg Tabletten	not available	BE079037	SERB	BE
Mysoline 250 mg tabletten	not available	BE079037	SERB	BE
Mysoline 250 mg tabletten	not available	BE079037	SERB	BE
MYSOLINE 250 mg	not available	2003027478	SERB	LU

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
tabletten				
MYSOLINE 250 mg, comprimé sécable	not available	34009 306 982 5 9	SERB	FR
MYSOLINE 250 mg, comprimé sécable	not available	34009 306 981 9 8	SERB	FR
Mysoline 250mg Tablets	not available	PA 1777/001/001	SERB	IE
Mysoline 250mg Tablets	not available	AA1340/00101	SERB	MT
Mysoline 250mg Tablets	not available	PL 26080/0003	SERB	UK
Mysoline 50 mg Tablets	not available	PL 26080/0002	SERB	UK
Primidone Auden 250 mg Tablets	not available	PL 00289/2329	TEVA UK LIMITED	UK
Primidone Auden 50 mg Tablets	not available	PL 00289/2328	TEVA UK LIMITED	UK
Primidone SERB 250mg Tablets	not available	PL 26080/0004	SERB	UK