



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 May 2018
EMA/303456/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: bromazepam

Procedure no.: PSUSA/00000435/201708



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
BROMAZEPAM ARROW 1,5 mg, comprimé	not available	42 470	ARROW GENERIQUES	FR
Lexatin 1,5 mg cápsulas duras	not available	53.560	ROCHE FARMA, S.A.	ES
Lexatin 3 mg cápsulas duras	not available	55.751	ROCHE FARMA, S.A.	ES
Lexatin 6 mg capsulas duras	not available	53.559	ROCHE FARMA, S.A.	ES
LEXOMIL ROCHE COMPRIME-BAGUETTE, comprimé quadrisécable	not available	34009 561 953 7 4	ROCHE	FR
LEXOMIL ROCHE COMPRIME-BAGUETTE, comprimé quadrisécable	not available	34009 317 428 4 5	ROCHE	FR
LEXOMIL ROCHE COMPRIME-BAGUETTE, comprimé quadrisécable	not available	34009 553 337 9 1	ROCHE	FR
Lexotan	not available	6517	ROCHE A/S	DK
Lexotan	not available	6518	ROCHE A/S	DK
Lexotan 1,5 mg capsule rigide	not available	022905119	ROCHE S.P.A.	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
Lexotan 1,5 mg compresse	not available	022905158	ROCHE S.P.A.	IT
Lexotan 1,5 mg comprimidos	not available	5470083	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Lexotan 1,5 mg comprimidos	not available	8423764	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Lexotan 1.5 mg tablets	not available	PA 50/49/1	ROCHE PRODUCTS LTD	IE
Lexotan 2,5 mg/ml gocce orali soluzione	not available	022905057	ROCHE S.P.A.	IT
Lexotan 3 mg capsule rigide	not available	022905121	ROCHE S.P.A.	IT
Lexotan 3 mg compresse	not available	022905145	ROCHE S.P.A.	IT
Lexotan 3 mg comprimés	not available	BE054485	N.V. ROCHE S.A.	BE
Lexotan 3 mg comprimés	not available	0178/05028669	N.V. ROCHE S.A.	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
Lexotan 3 mg comprimidos	not available	4540282	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Lexotan 3 mg comprimidos	not available	5470182	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Lexotan 3 mg tablets	not available	PA 50/49/2	ROCHE PRODUCTS LTD	IE
Lexotan 3 mg Tablets	not available	MA060/00501	ROCHE PRODUCTS LTD	MT
Lexotan 3 mg tabletten	not available	BE054485	N.V. ROCHE S.A.	BE
Lexotan 3 mg Tabletten	not available	BE054485	N.V. ROCHE S.A.	BE
Lexotan 3 mg Tabletten	not available	0178/05028669	N.V. ROCHE S.A.	LU
Lexotan 3 mg töflur	not available	751867 (IS)	ROCHE A/S	IS
Lexotan 6 mg capsule rigide	not available	022905133	ROCHE S.P.A.	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
Lexotan 6 mg comprimés	not available	BE054494	N.V. ROCHE S.A.	BE
Lexotan 6 mg comprimés	not available	0178/05028670	N.V. ROCHE S.A.	LU
Lexotan 6 mg comprimidos	not available	5470281	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Lexotan 6 mg comprimidos	not available	4576880	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Lexotan 6 mg tabletten	not available	BE054494	N.V. ROCHE S.A.	BE
Lexotan 6 mg Tabletten	not available	BE054494	N.V. ROCHE S.A.	BE
Lexotan 6 mg Tabletten	not available	0178/05028670	N.V. ROCHE S.A.	LU
Lexotan 6 mg töflur	not available	843496 (IS)	ROCHE A/S	IS
Lexotan, 3 mg, tabletki	not available	R/1836	ROCHE POLSKA SP.O.O.	PL

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
Lexotan, 6 mg, tabletki	not available	R/0946	ROCHE POLSKA SP.O.O.	PL
Lexotanil	not available	16.225	ROCHE AUSTRIA GMBH	AT
Lexotanil	not available	24191/29.06.2017	ROCHE (HELLAS) SA	GR
Lexotanil	not available	49715/16/29.06.2017	ROCHE (HELLAS) SA	GR
Lexotanil	not available	24192/29.06.2017	ROCHE (HELLAS) SA	GR
Lexotanil "Roche" 3 mg - Tabletten	not available	16.224	ROCHE AUSTRIA GMBH	AT
Lexotanil 1,5 mg tabletes	not available	99-0404	ROCHE LATVIJA SIA	LV
Lexotanil 1,5 mg tabletės	not available	LT/1/94/0551/001	UAB "ROCHE LIETUVA"	LT
Lexotanil 3 mg tabletes	not available	99-0405	ROCHE LATVIJA SIA	LV

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
Lexotanil 3 mg tabletēs	not available	LT/1/94/0551/002	UAB "ROCHE LIETUVA"	LT
Lexotanil, 1,5 mg tabletid	not available	053194	ROCHE EESTI OÜ	EE
Lexotanil, 3 mg tabletid	not available	053294	ROCHE EESTI OÜ	EE
Lexotanil®	not available	S00089	G.A. STAMATIS & CO LTD	CY
Лексотан 3 mg таблетки	not available	II-25213	ROCHE BULGARIA EOOD	BG