



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 November 2016
EMA/398898/2015
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: granisetron

Procedure no.: PSUSA/00001568/201602



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
Kytril 3 mg - Injektionslösung	IT/H/300/003	1-19775	ROCHE AUSTRIA GMBH	AT
Kytril 2 mg - Filmtabletten	IT/H/300/002	1-22001	ROCHE AUSTRIA GMBH	AT
Kytril 1 mg comprimé pelliculé	IT/H/300/001	BE173634	N.V. ROCHE S.A.	BE
Kytril 3 mg/3 ml oplossing voor injectie	IT/H/300/003	BE159512	N.V. ROCHE S.A.	BE
Kytril inj/inf Injekční roztok	IT/H/300/003	20/203/01-C	ROCHE S.R.O.	CZ
Kytril 2 mg potahované tablety	IT/H/300/002	20/202/01-C	ROCHE S.R.O.	CZ
Granisetron B. Braun 1 mg/ml Konzentrat zur Herstellung einer Injektions- oder Infusionslösung	NL/H/1094/001	69239.00.00	B. BRAUN MELSUNGEN AG	DE
Kevatril® 1 mg/1 ml Injektionslösung	IT/H/300/003	35059.00.02	ROCHE PHARMA AG	DE
Kevatril® Filmtabletten 2 mg	IT/H/300/002	35059.01.00	ROCHE PHARMA AG	DE
Kevatril® 3 mg/3 ml Injektionslösung	IT/H/300/003	35059.01.02	ROCHE PHARMA AG	DE
Kytril, 1 mg õhukese polümeerikattega tabletid	IT/H/300/001	137696	ROCHE EESTI OÜ	EE
Kytril, 1 mg/1 ml süste- või infusioonilahuse kontsentraat	IT/H/0300/003	137596	ROCHE EESTI OÜ	EE
Kytril 1 mg/1 ml solución inyectable	IT/H/300/003	61.803	ROCHE FARMA, S.A.	ES
Kytril 3 mg/3 ml solución inyectable	IT/H/300/003	59.867	ROCHE FARMA, S.A.	ES
Kytril 1 mg comprimidos recubiertos con película	IT/H/300/001	60.204	ROCHE FARMA, S.A.	ES
Kytril 1 mg kalvopäällysteinen tablettit	IT/H/300/001	12304	ROCHE OY	FI

Kytril 2 mg kalvopäällysteinen tablettit	IT/H/300/002	13836	ROCHE OY	FI
KYTRIL 2 mg, comprimé pelliculé	IT/H/0300/002	3400934301612	ROCHE	FR
KYTRIL 2 mg, comprimé pelliculé	IT/H/0300/002	3400934301551	ROCHE	FR
Kytril 1 mg/1 ml Solution for Injection	IT/H/300/003	PA 50/149/2	ROCHE PRODUCTS LTD	IE
Kytril 3 mg/3 ml Solution for Injection	IT/H/300/003	PA 50/149/3	ROCHE PRODUCTS LTD	IE
Kytril 2 mg Film-Coated Tablets	IT/H/300/002	PA 50/149/5	ROCHE PRODUCTS LTD	IE
Kytril 1 mg Film-Coated Tablets	IT/H/300/001	PA 50/149/4	ROCHE PRODUCTS LTD	IE
Kytril compresse rivestite con film da 1 mg	IT/H/300/001	028093197	ROCHE S.P.A.	IT
Kytril 1 mg/1 ml soluzione iniettabile	IT/H/300/003	028093185	ROCHE S.P.A.	IT
Kytril compresse rivestite con film da 2 mg	IT/H/300/002	028093209	ROCHE S.P.A.	IT
Kytril 3 mg/3 ml soluzione iniettabile	IT/H/300/003	028093173	ROCHE S.P.A.	IT
Kytril 1 mg/1 ml soluzione iniettabile	IT/H/300/003	028093060	ROCHE S.P.A.	IT
Kytril compresse rivestite con film da 1 mg	IT/H/0300/001	028093021	ROCHE S.P.A.	IT
Kytril 3 mg/3 ml soluzione iniettabile	IT/H/0300/003	028093019	ROCHE S.P.A.	IT
Kytril compresse rivestite con film da 2 mg	IT/H/0300/002	028093084	ROCHE S.P.A.	IT
Kytril compresse rivestite con film da 2 mg	IT/H/0300/002	028093072	ROCHE S.P.A.	IT
Granisetron B. Braun 1 mg/ml Konzentrat zur Herstellung einer Injektions- oder Infusionslösung	NL/H/1094/001	0667/09050047	B. BRAUN MELSUNGEN AG	LU
Kytril 1 mg comprimés pelliculés	IT/H/300/001	0178/96/06/0357 - 2008089874	N.V. ROCHE S.A.	LU

Kytril 3 mg/3 ml Injektionslösung	IT/H/300/003	2003107855	N.V. ROCHE S.A.	LU
Kytril 2 mg tabletten, omhulde tabletten	IT/H/300/002	RVG 19203	ROCHE NEDERLAND B.V.	NL
Kytril 1 mg tabletten, omhulde tabletten	IT/H/300/001	RVG 16285	ROCHE NEDERLAND B.V.	NL
Granisetrom Generis 3 mg/50 ml Solução para perfusão	not available	5034467	GENERIS FARMACÊUTICA, S.A.	PT
Granisetrom Generis 3 mg/50 ml Solução para perfusão	not available	5034459	GENERIS FARMACÊUTICA, S.A.	PT
Granisetrom Generis 3 mg/50 ml Solução para perfusão	not available	5034442	GENERIS FARMACÊUTICA, S.A.	PT
Granisetrom Generis 3 mg/50 ml Solução para perfusão	not available	5034434	GENERIS FARMACÊUTICA, S.A.	PT
Kytril 1 mg comprimidos revestidos por película	IT/H/300/001	2530582	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Kytril 1 mg comprimidos revestidos por película	IT/H/0300/001	2530483	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Kytril 2 mg comprimidos revestidos por película	IT/H/300/002	2520989	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Kytril 2 mg comprimidos revestidos por película	IT/H/300/002	2520880	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Kytril 1 mg/1 ml solução injectável	IT/H/0300/003	2964583	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Kytril 1 mg/1 ml solução injectável	IT/H/0300/003	2964682	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT

Kytril 2 mg filmsko obložene tablete	IT/H/300/002	H/02/00864/001	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Granisetron 1 mg Film-coated tablets	not available	PL 20416/0379	CRESCENT PHARMA LIMITED	UK
Granisetron 2 mg Film-coated tablets	not available	PL 20416/0380	CRESCENT PHARMA LIMITED	UK
Kytril 1 mg film-coated tablets	IT/H/300/001	PL 00031/0591	ROCHE PRODUCTS LTD	UK
Kytril 2 mg film-coated tablets	IT/H/300/002	PL 00031/0592	ROCHE PRODUCTS LTD	UK