



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 May 2018
EMA/333504/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): dornase alpha

Procedure No.: PSUSA/00001164/201709



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
Pulmozyme 1 mg/ml (2500 E/2,5 ml), lösning för nebulisator	UK/H/0060/001	11899	ROCHE AB	SE
Pulmozyme 1 mg/ml inhalasjonsvæske til nebulisator, oppløsning	not available	8057	F. HOFFMANN-LA ROCHE AG	NO
Pulmozyme 1 mg/ml lösning för nebulisator	UK/H/0060/001	11681	ROCHE OY	FI
Pulmozyme 1 mg/ml sumutinliuos	UK/H/0060/001	11681	ROCHE OY	FI
Pulmozyme 1 mg/ml, lausn fyrir eimgjafa	not available	930291	ROCHE A/S	IS
PULMOZYME 2 500 U/2,5 ml roztok k inhalaci	not available	52/270/95-C	ROCHE S. R. O.	CZ
Pulmozyme 2 500 U/2,5 ml Rostok na rozprašovanie	not available	52/0392/97-S	ROCHE SLOVENSKO S.R.O.	SK
Pulmozyme 2,5 mg inhalacijska raztopina za nebulator	not available	H/98/01306/001	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Pulmozyme 2,5 mg oldat porlasztásra	not available	OGYI-T-4562/01	ROCHE (MAGYARORSZÁG) KFT	HU
PULMOZYME 2.500 E./2,5 ml – Lösung für einen Vernebler	UK/H/0060/001	1-20192	ROCHE AUSTRIA GMBH	AT
Pulmozyme 2.500 U/2,5 ml solución para inhalación por nebulizador	UK/H/0060/001	60.326	ROCHE FARMA, S.A.	ES
Pulmozyme 2500 E/ 2,5 ml verneveloplossing	UK/H/0060/001	BE167002	N.V. ROCHE S.A.	BE
Pulmozyme 2500 E/2,5 ml, verneveloplossing	UK/H/0060/001	RVG 16734	ROCHE NEDERLAND B.V.	NL
Pulmozyme 2500 TV/2,5 ml purškiamasis įkvepiamasis tirpalas	not available	LT/1/96/1470/001	UAB "ROCHE LIETUVA"	LT
Pulmozyme 2500 U / 2,5 ml, solu ໕໕໕໕໐ para inala ໕໕໕໕໐ por nebuliza ໕໕໕໕໐	UK/H/0060/001	2231488	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Pulmozyme 2500 U/ 2.5 ml, nebuliser solution	not available	MA 060/00901	ROCHE PRODUCTS LTD	MT

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Pulmozyme 2500 U/ 2.5 ml, nebuliser solution	UK/H/0060/001	PL 00031/0335	ROCHE PRODUCTS LTD	UK
Pulmozyme 2500 U/2,5 ml otopina za atomizator	not available	HR-H-587894223	ROCHE D.O.O.	HR
Pulmozyme 2500 U/2,5 ml soluție de inhalat prin nebulizator	not available	6524/2014/01	ROCHE ROMANIA SRL	RO
Pulmozyme 2500 U/2,5 ml solution pour inhalation par nébuliseur	UK/H/0060/001	BE167002	N.V. ROCHE S.A.	BE
Pulmozyme 2500 U/2,5 ml solution pour inhalation par nébuliseur	UK-H-60	0178/09060393	N.V. ROCHE S.A.	LU
Pulmozyme 2500 U/2,5 ml, solution pour inhalation par nébuliseur	UK/H/0060/001	3400936467545	ROCHE	FR
Pulmozyme 2500 U/2,5 ml, solution pour inhalation par nébuliseur	UK/H/0060/001	3400936467484	ROCHE	FR
Pulmozyme 2500 U/2,5 ml, soluzione per nebulizzatore	UK/H/0060/001	029352010	ROCHE S.P.A.	IT
Pulmozyme 2500 U/2.5ml, διάλυμα για εισπνοή μέσω εκνεφωτή	UK/H/0060/001	78409/16/22.06.2017	ROCHE (HELLAS) SA	GR
Pulmozyme 2500 V/2,5 ml šķīdums izsmidzināšanai	not available	99-0403	ROCHE LATVIJA SIA	LV
Pulmozyme [®] Nebulizersolution 2500 U (2.5mg)/2.5ml corresponding to 1000 U/ml	UK/H/0060/001	2231389	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Pulmozyme, 1 mg/ml, roztwór do nebulizacji	not available	R/3758	ROCHE POLSKA SP.O.O.	PL
Pulmozyme, 2500 ühikut/2,5 ml nebuliseeritav lahus	not available	142996	ROCHE EESTI OÜ	EE

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Pulmozyme, inhalationsvæske til nebulisator, opløsning	UK/H/0060/001	15462	ROCHE A/S	DK
Pulmozyme® 2.500 E./2,5 ml, Lösung für einen Vernebler	UK/H/0060/001	30289.00.00	ROCHE PHARMA AG	DE
Пулмозим 2500 U (2,5 mg)/ 2,5 ml разтвор за небулизатор	not available	9600090	ROCHE BULGARIA EOOD	BG