



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 April 2017
EMA/235642/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: fosfomycin (oral formulation)

Procedure no.: PSUSA/00010326/201607



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
Fosfomicina Monuril, 2g, granulado para solução oral	330/89	2308088	ZAMBON - PRODUTOS FARMACÊUTICOS, LDA.	PT
Fosfomicina Monuril, 2g, granulado para solução oral	330/89	2261980	ZAMBON - PRODUTOS FARMACÊUTICOS, LDA.	PT
Fosfomicina Monuril, 3g, granulado para solução oral	330/89	2308187	ZAMBON - PRODUTOS FARMACÊUTICOS, LDA.	PT
Fosfomicina Monuril, 3g, granulado para solução oral	not available	2261881	ZAMBON - PRODUTOS FARMACÊUTICOS, LDA.	PT
MONURAL 2 g, granulát do sporządzania roztworu doustnego	not available	R/6992	ZAMBON S.P.A.	PL
Monural 3 g granulátum	not available	OGYI-T-4256/01	ZAMBON S.P.A.	HU
Monural 3 g perorálny granulát	not available	15/0089/04-S	ZAMBON S.P.A.	SK
MONURAL 3 g, granulát do sporządzania roztworu doustnego	not available	R/6991	ZAMBON S.P.A.	PL
MONURAL® 3 g	not available	4902/2004/01	ZAMBON S.P.A.	RO
MONURAL® PEDIATRIC 2 g	not available	4903/2004/01-02	ZAMBON S.P.A.	RO
Monuril	not available	PL 3 1654/0006	ZAMBON S.P.A.	UK
Monuril 2000, granulaat voor drank 2 g	not available	RVG 13067	ZAMBON NEDERLAND B.V.	NL
Monuril 3 g granulaat voor drank	not available	BE146167	ZAMBON NV	BE
MONURIL 3 g granulato per soluzione orale	not available	025680024	ZAMBON ITALIA S.R.L.	IT
MONURIL 3 g granulato per soluzione orale	not available	025680036	ZAMBON ITALIA S.R.L.	IT
Monuril 3 g granules for oral solution	not available	PA1441/002/002	ZAMBON S.P.A.	IE
Monuril 3 g granules for	not available	AA1116/00101	ZAMBON S.P.A.	MT

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oral solution				
Monuril 3 g granulés pour solution buvable	not available	BE146167	ZAMBON NV	BE
Monuril 3 g granulés pour solution buvable	not available	0411/05068245	ZAMBON NV	LU
MONURIL 3 g, granulés pour solution buvable en sachet	not available	3400933209230	ZAMBON FRANCE S.A.	FR
Monuril 3000 mg Granulat	not available	15355.00.00	ZAMBON GMBH	DE
Monuril 3000, granulaat voor drank 3 g	not available	RVG 13066	ZAMBON NEDERLAND B.V.	NL
Monuril 3g - Granulat	not available	1-20352	ZAMBON S.P.A.	AT
MONURIL bambini 2 g granulato per soluzione orale	not available	025680012	ZAMBON ITALIA S.R.L.	IT
MONURIL bambini 2 g granulato per soluzione orale	not available	025680048	ZAMBON ITALIA S.R.L.	IT
Monurol, granulater til oral opløsning, enkeltdosisbeholder	not available	14905	ZAMBON S.P.A.	DK
Monurol, granulater til oral opløsning, enkeltdosisbeholder	not available	14904	ZAMBON S.P.A.	DK
SOLUFOS 500 mg cápsulas	not available	54.219	LABORATORIOS Q PHARMA S.L.	ES
URIDOZ ADULTES 3 g, granulé pour solution buvable en sachet	not available	34009 332 823 8 7	THERABEL LUCIEN PHARMA S.A.	FR
Монурал 3 г гранули за перорален разтвор	not available	20060721	ANGELINI PHARMA BULGARIA EOOD	BG