



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 March 2023
EMA/36185/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): fosfomycin (oral formulation)

Procedure No. PSUSA/00010326/202207



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
Monuril 3g - Granulat	not available	1-20352	ZAMBON S.P.A.	AT
Monuril 3 g granulés pour solution buvable	not available	BE146167	ZAMBON NV	BE
Monuril 3 g granulaat voor drank	not available	BE146167	ZAMBON NV	BE
Monuril 3 g Granulat zur Herstellung einer Lösung zum Einnehmen	not available	BE146167	ZAMBON NV	BE
Монурал 3 г гранули за перорален разтвор	not available	20060721	ZAMBON S.P.A.	BG
Monuril 3000 mg Granulat	not available	15355.00.00	ZAMBON GMBH	DE
Monurol, granulater til oral opløsning, enkeltdosisbeholder	not available	14904	ZAMBON S.P.A.	DK
Monurol, granulater til oral opløsning, enkeltdosisbeholder	not available	14905	ZAMBON S.P.A.	DK
FOSFOMICINA CALCICA SOLUFOS 500 mg cápsulas	not available	54.219	LABORATORIOS Q PHARMA S.L.	ES
MONURIL 3 g, granulés pour solution buvable en sachet	not available	34009 332 092 3 0	ZAMBON FRANCE S.A.	FR
Monural 3 g granulátum	not available	OGYI-T-4256/01	ZAMBON S.P.A.	HU
Monuril 3 g granules for oral solution	not available	PA1441/002/002	ZAMBON S.P.A.	IE
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
MONURIL 3 g granulato per soluzione orale	not available	025680024	ZAMBON ITALIA S.R.L.	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
MONURIL 3 g granulato per soluzione orale	not available	025680036	ZAMBON ITALIA S.R.L.	IT
Monuril 3 g granulés pour solution buvable	not available	2005068245	ZAMBON NV	LU
Monuril 3000, granulaat voor drank 3 g	not available	RVG 13066	ZAMBON NEDERLAND B.V.	NL
MONURAL 2 g, granulato do sporządzania roztworu doustnego	not available	R/6992	ZAMBON S.P.A.	PL
MONURAL 3 g, granulato do sporządzania roztworu doustnego	not available	R/6991	ZAMBON S.P.A.	PL
Fosfomicin US Pharmacia, 3 g, granulato do sporządzania roztworu doustnego	not available	25691	US PHARMACIA SP. Z O.O.	PL
Fosfomicina Monuril, 2g, granulato para solução oral	not available	2308088	ZAMBON - PRODUTOS FARMACÊUTICOS, LDA.	PT
Fosfomicina Monuril, 2g, granulato para solução oral	not available	2261980	ZAMBON - PRODUTOS FARMACÊUTICOS, LDA.	PT
Fosfomicina Monuril, 3 g granulato para solução oral	not available	2308187	ZAMBON - PRODUTOS FARMACÊUTICOS, LDA.	PT
Fosfomicina Monuril 3 g granulato para solução oral	not available	2261881	ZAMBON - PRODUTOS FARMACÊUTICOS, LDA.	PT
MONURAL PEDIATRIC 2 g granule pentru soluție orală	not available	12021/2019/01	ZAMBON S.P.A.	RO
MONURAL PEDIATRIC 2 g granule pentru soluție orală	not available	12021/2019/02	ZAMBON S.P.A.	RO
MONURAL PEDIATRIC 2 g granule pentru soluție orală	not available	12021/2019/01	ZAMBON S.P.A.	RO
Monural 3 g perorálny	not available	15/0089/04-S	ZAMBON S.P.A.	SK

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
granulát				
Monuril 3 g granules for oral solution	not available	PL 31654/0006	ZAMBON S.P.A.	UK (NI)