



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

12 March 2020  
EMA/154431/2020  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: fosfomicin (oral formulation)

Procedure no.: PSUSA/00010326/201907

---

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union



<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Monurol, granulater til oral opløsning, enkelt dosisbeholder	not available	14904	ZAMBON S.P.A.	DK
Monuril 3000 mg Granulat	not available	15355.00.00	ZAMBON GMBH	DE
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 granulés pour solution buvable	not available	2005068245	ZAMBON NV	LU
Monuril 2000, granulaat voor drank 2 g	not available	RVG 13067	ZAMBON NEDERLAND B.V.	NL
Monuril 3000, granulaat voor drank 3 g	not available	RVG 13066	ZAMBON NEDERLAND B.V.	NL
Monurol, granulater til oral opløsning, enkelt dosisbeholder	not available	14905	ZAMBON S.P.A.	DK
Monuril	not available	PL 3 1654/0006	ZAMBON S.P.A.	UK
Fosfomicina Monuril 2 g granulado para solução oral	not available	2308088	ZAMBON - PRODUTOS FARMACÊUTICOS, LDA.	PT
Fosfomicina Monuril 2 g granulado para solução oral	not available	2261980	ZAMBON - PRODUTOS FARMACÊUTICOS, LDA.	PT
Fosfomicina Monuril, 3g, granulado para solução oral	not available	2308187	ZAMBON - PRODUTOS FARMACÊUTICOS, LDA.	PT
Fosfomicina Monuril, 3g, granulado para solução oral	not available	2261881	ZAMBON - PRODUTOS FARMACÊUTICOS, LDA.	PT
Monuril 3 g granules for oral solution	not available	PA1441/002/002	ZAMBON S.P.A.	IE
SOLUFOS 500 mg cápsulas	not available	54.219	LABORATORIOS Q PHARMA S.L.	ES
MONURIL 3 g, granulés pour solution buvable en	not available	3400933209230	ZAMBON FRANCE S.A.	FR

<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
sachet				
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
MONURIL 3 g granulato per soluzione orale	not available	025680036	ZAMBON ITALIA S.R.L.	IT
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	not available	12020/2019/01	ZAMBON S.P.A.	RO
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® PEDIATRIC 2 g	not available	12021/2019/01-02	ZAMBON S.P.A.	RO
Monuril 3g - Granulat	not available	1-20352	ZAMBON S.P.A.	AT
Монурал 3 г гранули за перорален разтвор	not available	20060721	ZAMBON S.P.A.	BG
URIDOZ 3 g, granulés pour solution buvable en sachet	not available	34009 332 823 8 7	THERABEL LUCIEN PHARMA S.A.	FR