



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

8 October 2015  
EMA/230060/2016  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance: nitrofurantoin / nifurtoinol

Procedure no.: PSUSA/00002174/201502



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
Furabid		RVG 15290	Mercury Pharmaceuticals Ltd.	Netherlands
Furadantin		14.328	Mercury Pharmaceuticals Ltd.	Austria
Furadantin		5614 7977	Meda Ab	Sweden
Furadantin		AA 077/01701	Mercury Pharmaceuticals Ltd.	Malta
Furadantin		PA 899/13/1 PA 899/13/2	Mercury Pharmaceuticals Ltd.	Ireland
Furadantin		PL 12762/0051 PL 12762/0055 PL12762/0050	Mercury Pharmaceuticals Ltd.	United Kingdom
Furadantin Retard		6338087.00.00	Mercury Pharmaceuticals Ltd.	Germany
Furadantin Rp		6338101.00.00	Mercury Pharmaceuticals Ltd.	Germany
Furadantina Mc		9281626	Mercury Pharmaceuticals Ltd.	Portugal
Furadantine		RVG 56203=05748 RVG 05749	Mercury Pharmaceuticals Ltd.	Netherlands
Furadantine Mc		47198 47203	Mercury Pharmaceuticals Ltd.	Luxembourg
Furadantine Mc		BE001583 BE001601	Mercury Pharmaceuticals Ltd.	Belgium
Furadantine Mc		RVG 05748 RVG 05749	Mercury Pharmaceuticals Ltd.	Netherlands
Furadonins		LT/1/97/3120/001	Jsc Olainfarm	Lithuania
Furadonīns		95-0198	Jsc Olainfarm	Latvia
Furantoīna		22974 34388	Laboratorios Ern, S.A.	Spain
Furedan		014152019	Antrivex S.R.L.	Italy
Furolin®		19173/22-3-2010 77725/10/11-03-2011	IASIS PHARMACEUTICALS HELLAS S.A.	Greece
Macrobid		PA 899/14/1	Mercury Pharmaceuticals Ltd.	Ireland

Macrobid		PL 12762/0052	Mercury Pharmaceuticals Ltd.	United Kingdom
Macrochantin		027321013 027321025	Geymonat S.P.A.	Italy
Macrochantin		MA 077/00401 MA 077/00402	Mercury Pharmaceuticals Ltd.	Malta
Macrochantin		PA 899/12/1 PA 899/12/2	Mercury Pharmaceuticals Ltd.	Ireland
Macrochantin		PL 12762/0048 PL 12762/0049	Mercury Pharmaceuticals Ltd.	United Kingdom
Macrochantin		S00585	Mercury Pharmaceuticals Ltd.	Cyprus
Neo Furadantin		027320011 027320023	Grünenthal Italia S.R.L.	Italy
Nifurantin		3000549.00.00	Apogepha Arzneimittel Gmbh	Germany
Nifurantin		6338035.00.00	Apogepha Arzneimittel Gmbh	Germany
Nifurettin		3000551.00.00	Apogepha Arzneimittel Gmbh	Germany
Ninur		UP/I-530-09/12-02/252	Belupo D.D.	Croatia
Nitrofurantoin		OGYI-T-3253/01	Sanofi-Aventis Private Co Ltd	Hungary
Nitrofurantoin		PL 00289/0769 PL 00289/0770	Teva Uk Limited Brampton Road, Hampden Park	United Kingdom
Nitrofurantoin "agepha" - Tabletten		1-15045	Agepha Pharma S.R.O	Austria
Nitrofurantoin Capsules		PL 20117/0226	Morningside Healthcare Ltd	United Kingdom
Nitrofurantoin Capsules		PL 20117/0227	Morningside Healthcare Ltd	United Kingdom
Nitrofurantoin Dak Takeda Pharma		07397	Takeda Pharma A/S	Denmark
Nitrofurantoin Dr. Reddy's		08553/0087 08553/0088	Dr. Reddy's Laboratories (Uk) Ltd.	United Kingdom
Nitrofurantoin Nycomed		051194	Takeda Pharma As	Estonia
Nitrofurantoin Ratiopharm		0687/86/03/0124	Ratiopharm Gmbh	Luxembourg

Nitrofurantoin Ratiopharm		6043854.00.00	Ratiopharm Gmbh	Germany
Nitrofurantoina Arena		4993/2004/01	Arena Group S.A	Romania
Nitrofurantoine Apotex Mc 100 Mg		52232	Apotex Europe Bv	Netherlands
Nitrofurantoine Apotex Mc 50 Mg		18152	Apotex Europe Bv	Netherlands
Nitrofurantoine Mc 100 Mg Teva		RVG 57386=52232	Teva Nederland B.V.	Netherlands
Nitrofurantoine Mc 50 Mg Teva		RVG 19736=18152	Teva Nederland B.V.	Netherlands
Nitrofurantoine Actavis		RVG 108889 RVG 108890	Actavis B.V.	Netherlands
Urantoin		PL 33414/0069 PL 33414/0070	Chelonia Healthcare Limited	United Kingdom
Urfadyn PI		1998034448	Zambon Nv	Luxembourg
Urfadyn PI		BE116636	Zambon Nv	Belgium
Uro Tablinen		6165534.00.00	Winthrop Arzneimittel Gmbh	Germany
Uvamin Retard		00-1183	Mepha – Investigação, Desenvolvimento E Fabricação Farmacêutica, Lda. Porto Salvo	Latvia
Uvamin Retard		LT/1/2000/1540/001	Mepha – Investigação, Desenvolvimento E Fabricação Farmacêutica, Lda. Porto Salvo	Lithuania
Furolin®		S00384/18-2-2015	IASIS PHARMACEUTICALS HELLAS S.A.	Cyprus
Furadantine		VNL 7237	Merck Santé S.A.S.	France
Furadoine		V05110	Merck Santé S.A.S.	France
Nitrofur-C		8830	Takeda Oy	Finland