



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 March 2016
EMA/246355/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: fosinopril

Procedure no.: PSUSA/00001474/201507



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
ELITEN 10 mg compresse		27735012	PHARMASWISS Ceská REPUBLIKA S.R.O.	IT
ELITEN 20 mg compresse		27735024	PHARMASWISS Ceská REPUBLIKA S.R.O.	IT
FOSINIL 20 mg tabletten		2007039228	PHARMASWISS Ceská REPUBLIKA S.R.O.	LU
FOSINIL20 mg comprimés		BE 157927	PHARMASWISS Ceská REPUBLIKA S.R.O.	BE
Fosinoprilnatrium CF 5 mg, tabletten		RVG 32269	CENTRAFARM B.V.	NL
Fosinorm 10 mg, Tabletten		33878.01.00	PHARMASWISS Ceská REPUBLIKA S.R.O.	DE
Fosinorm 20 mg, Tabletten		33878.02.00	PHARMASWISS Ceská REPUBLIKA S.R.O.	DE
Fosipres 10 mg Compresse		27747017	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
Fosipres 20 mg Compresse		27747029	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
Fositen 20 mg comprimidos		2192888	PHARMASWISS Ceská REPUBLIKA S.R.O.	PT
Fositen 20 mg comprimidos		4655189	PHARMASWISS Ceská REPUBLIKA S.R.O.	PT
Fositen 20 mg comprimidos		2208882	PHARMASWISS Ceská REPUBLIKA S.R.O.	PT
Fositen 20 mg comprimidos		2192789	PHARMASWISS Ceská REPUBLIKA S.R.O.	PT
FOSITENS 10 mg- Tabletten		1-20267	PHARMASWISS Ceská REPUBLIKA S.R.O.	AT
Fositens 20 mg comprimidos		59.716	PHARMASWISS Ceská REPUBLIKA S.R.O.	ES
FOSITENS 20 mg- Tabletten		1-20268	PHARMASWISS Ceská REPUBLIKA S.R.O.	AT
FOZITEC 10 mg, comprimé sécable		3400937200196 and 3400937200257	Merck Sante S.A.S	FR

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
FOZITEC 20 mg, comprimé		340093700318 and 3400937200486	Merck Sante S.A.S	FR
Monopril 10 mg		9900349	PHARMASWISS Ceská REPUBLIKA S.R.O.	BG
MONOPRIL 10 mg comprimate		5348/2005/01	PHARMASWISS Ceská REPUBLIKA S.R.O.	RO
Monopril 10 mg tablet?s		LT/1/97/1670/001	PHARMASWISS Ceská REPUBLIKA S.R.O.	LT
MONOPRIL 10 mg tablete		H/99/01054/001	PHARMASWISS Ceská REPUBLIKA S.R.O.	SI
Monopril 10 mg tabletēs		98-0431	PHARMASWISS Ceská REPUBLIKA S.R.O.	LV
Monopril 10 mg tabletta		OGYI-T-6122/01	PHARMASWISS Ceská REPUBLIKA S.R.O.	HU
Monopril 20 mg		9900350	PHARMASWISS Ceská REPUBLIKA S.R.O.	BG
MONOPRIL 20 mg		58/0134/99-S	PHARMASWISS Ceská REPUBLIKA S.R.O.	SK
MONOPRIL 20 mg comprimate		5349/2005/01	PHARMASWISS Ceská REPUBLIKA S.R.O.	RO
MONOPRIL 20 mg tablete		H/99/01054/002	PHARMASWISS Ceská REPUBLIKA S.R.O.	SI
Monopril 20 mg tabletēs		LT/1/97/1670/002	PHARMASWISS Ceská REPUBLIKA S.R.O.	LT
Monopril 20 mg tabletēs		98-0432	PHARMASWISS Ceská REPUBLIKA S.R.O.	LV
Monopril 20 mg tabletta		OGYI-T-6122/02	PHARMASWISS Ceská REPUBLIKA S.R.O.	HU
MONOPRIL 20 mg tablety		58/022/97-C	PHARMASWISS Ceská REPUBLIKA S.R.O.	CZ
MONOPRIL 20 mg δισκία		19547/20-11-2013	PHARMASWISS Ceská REPUBLIKA S.R.O.	GR
Monopril, 10 mg tabletid		166897	PHARMASWISS Ceská REPUBLIKA S.R.O.	EE
Monopril, 20 mg tabletid		166997	PHARMASWISS Ceská REPUBLIKA S.R.O.	EE

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TENSOGARD 10 mg compresse		27824010	PHARMASWISS Ceská REPUBLIKA S.R.O.	IT
TENSOGARD 20 mg compresse		27824022	PHARMASWISS Ceská REPUBLIKA S.R.O.	IT