



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 February 2022
EMA/100375/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: fosinopril, fosinopril / hydrochlorothiazide

Procedure no.: PSUSA/00010463/202107

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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
Monozide 20 mg/12,5 mg tabletès	not available	LT/1/02/2659/001	PHARMASWISS ĀESKÁ REPUBLIKA S.R.O.	LT
Monozide 20 mg/12,5 mg tabletès	not available	LT/1/02/2659/002	PHARMASWISS ĀESKÁ REPUBLIKA S.R.O.	LT
MONOZIDE 20 mg/12,5 mg, tablety	not available	58/0370/03-S	PHARMASWISS ĀESKÁ REPUBLIKA S.R.O.	SK
Monopril, 10 mg tabletid	not available	166897	PHARMASWISS ĀESKÁ REPUBLIKA S.R.O.	EE
Eliten 20 mg compresse	not available	027735024	PHARMASWISS ĀESKÁ REPUBLIKA S.R.O.	IT
Tensogard 20 mg compresse	not available	027824022	PHARMASWISS ĀESKÁ REPUBLIKA S.R.O.	IT
Fositen Plus 20 mg + 12,5 mg comprimidos	not available	4655288	BAUSCH HEALTH IRELAND LIMITED	PT
Fositen Plus 20 mg + 12,5 mg comprimidos	not available	2318681	BAUSCH HEALTH IRELAND LIMITED	PT
Fositen Plus 20 mg + 12,5 mg comprimidos	not available	2318780	BAUSCH HEALTH IRELAND LIMITED	PT

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
Fositen Plus 20 mg + 12,5 mg comprimidos	not available	2318889	BAUSCH HEALTH IRELAND LIMITED	PT
Monopril 10 mg tableta	not available	OGYI-T-6122/01	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	HU
Monopril 20 mg tabletes	not available	98-0432	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LV
MONOPRIL 20 mg tablety	not available	58/0134/99-S	BAUSCH HEALTH IRELAND LIMITED	SK
МОНОПРИЛ 10 mg таблетки	not available	9900349	BAUSCH HEALTH IRELAND LIMITED	BG
Монозид 20 mg/12,5 mg таблетки	not available	20030355	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	BG
Fositens 20 mg comprimidos	not available	59.716	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	ES
FOSIPRES 10 mg compresse	not available	027747017	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
FOSIPRES 20 mg compresse	not available	027747029	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - 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
Monozide, 20 mg/12,5 mg tabletid	not available	409703	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	EE
Fosinorm 20 mg, Tabletten	not available	33878.02.00	BAUSCH HEALTH IRELAND LIMITED	DE
FOSINIL 20 mg comprimés	not available	2007039228	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LU
Fosinorm 10 mg, Tabletten	not available	33878.01.00	BAUSCH HEALTH IRELAND LIMITED	DE
MONOPRIL 20 mg comprimate	not available	9761/2017/01	BAUSCH HEALTH IRELAND LIMITED	RO
MONOPRIL 20 mg δισκία	not available	2001503	BAUSCH HEALTH IRELAND LIMITED	GR
MONOPRIL 10 mg comprimate	not available	9760/2017/01	BAUSCH HEALTH IRELAND LIMITED	RO
FOSICOMBI 20 mg+12,5 mg compresse	not available	029020017	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
DUOPRIL 20 mg/12,5 mg tabletta	not available	OGYI-T-8565/01	BAUSCH HEALTH IRELAND LIMITED	HU

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DUOPRIL 20 mg/12,5 mg tableta	not available	OGYI-T-8565/02	BAUSCH HEALTH IRELAND LIMITED	HU
Tensozide 20 mg + 12,5 mg compresse	not available	029004013	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	IT
Monopril, 20 mg tabletid	not available	166997	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	EE
Monopril 10 mg tabletés	not available	98-0431	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LV
Monopril 20 mg tabletės	not available	LT/1/97/1670/002	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LT
Monopril Plus 20 mg/12,5 mg tablete	not available	H/02/01055/001	BAUSCH HEALTH IRELAND LIMITED	SI
FOSITENS 10 mg - Tabletten	not available	1-20267	BAUSCH HEALTH IRELAND LIMITED	AT
MONOPRIL 20 mg tablety	not available	58/022/97-C	BAUSCH HEALTH IRELAND LIMITED	CZ
Fositen 20 mg comprimidos	not available	4655189	BAUSCH HEALTH IRELAND LIMITED	PT

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
Fositen 20 mg comprimidos	not available	2192789	BAUSCH HEALTH IRELAND LIMITED	PT
Fositen 20 mg comprimidos	not available	2208882	BAUSCH HEALTH IRELAND LIMITED	PT
Fositen 20 mg comprimidos	not available	2192888	BAUSCH HEALTH IRELAND LIMITED	PT
Fositens Plus 20 mg/12,5 mg comprimidos	not available	61.529	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	ES
Monozide 20 mg/ 12,5 mg tabletes	not available	03-0033	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LV
FOSITENS 20 mg - Tabletten	not available	1-20268	BAUSCH HEALTH IRELAND LIMITED	AT
МОНОПРИЛ 20 mg таблетки	not available	9900350	BAUSCH HEALTH IRELAND LIMITED	BG
Monopril 10 mg tabletės	not available	LT/1/97/1670/001	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LT
Monopril 20 mg tableta	not available	OGYI-T-6122/02	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	HU

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
Fosicomb - Tabletten	not available	1-21946	BAUSCH HEALTH IRELAND LIMITED	AT
FOSINIL 20 mg tabletten	not available	BE 157927	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	BE
Fosinil 20 mg Tabletten	not available	BE 157927	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	BE
FOSINIL 20 mg comprimés	not available	BE 157927	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	BE
Monopril 20 mg tablete	not available	H/99/01054/002	BAUSCH HEALTH IRELAND LIMITED	SI