1 December 2016
EMA/863940/2016
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: amlodipine

Procedure no.: PSUSA/00000174/201603

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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
Accuretic 10 mg/12,5 mg Filmtabletten	not available	BE164367	PFIZER S.A. (BELGIUM)	BE
Accuretic 20 mg/12,5 mg Filmtabletten	not available	BE164376	PFIZER S.A. (BELGIUM)	BE
Accuretic 10 mg/12,5 mg Filmtabletten	not available	2004098396	PFIZER S.A. (BELGIUM)	LU
Accuretic 20 mg/12,5 mg Filmtabletten	not available	2004098397	PFIZER S.A. (BELGIUM)	LU
ACCURETIC® (Υδροχλωρική Κιναπρίλη/Υδροχλωροθειαζίδη)	not available	42503/15-10-2008	PFIZER HELLAS, A.E.	GR
ACCUZIDE 10/12,5 mg plėvele dengtos tabletės	not available	LT/1/2000/0926/002	PFIZER LIMITED	LT
ACCUZIDE 10/12,5 mg plėvele dengtos tabletės	not available	LT/1/2000/0926/001	PFIZER LIMITED	LT
ACCUZIDE 20/12,5 mg plėvele dengtos tabletės	not available	LT/1/2000/0926/005	PFIZER LIMITED	LT
ACCUZIDE 20/12,5 mg plėvele dengtos tabletės	not available	LT/1/2000/0926/003	PFIZER LIMITED	LT
ACCUZIDE 20/12,5 mg plėvele dengtos tabletės	not available	LT/1/2000/0926/004	PFIZER LIMITED	LT
Accuzide 10 potahované tablety	not available	58/1079/94-C	PFIZER, SPOL. S R.O.	CZ
Accuzide 10 mg/12,5 mg apvalkotās tabletes	not available	01-0279	PFIZER LIMITED	LV
Accuzide, comprimate filmate, 10 mg/12,5 mg	not available	6705/2006/01	PFIZER EUROPE MA EEIG	RO
ACCUZIDE, 10 mg + 12,5 mg, tabletki powlekane	not available	8673	PFIZER EUROPE MA EEIG	PL

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
Accuretic 20 mg/12.5 mg Tablets	not available	PA 0822/008/002	PFIZER HEALTHCARE IRELAND	IE
Accuretic 20 mg + 12,5 mg compresse rivestite con film	not available	028295018	PFIZER ITALIA S.R.L.	IT
Accuretic 20 mg + 12,5 mg compresse rivestite con film	not available	028295044	PFIZER ITALIA S.R.L.	IT
ACCUZIDE 20 filmom obalené tablety	not available	58/0056/02–S	PFIZER LIMITED	SK
Accuzide 20 mg/25 mg apvalkotās tabletes	not available	09-0488	PFIZER LIMITED	LV
Accupro comp 10/12,5 mg filmdragerade tabletter	not available	11859	PFIZER AB	SE
Accuzide 20 mg/12,5 mg apvalkotās tabletes	not available	01-0280	PFIZER LIMITED	LV
ACCUZIDE 10 filmom obalené tablety	not available	58/0065/98–S	PFIZER LIMITED	SK
Accupro comp 20/12,5 mg filmdragerade tabletter	not available	11860	PFIZER AB	SE
Accuretic 10/12.5 mg	not available	PL 00057/0518	PFIZER LIMITED	UK
ACCUZIDE 20, 20 mg + 12,5 mg, tabletki powlekane	not available	8674	PFIZER EUROPE MA EEIG	PL
Accuzide Forte Plus, comprimate filmate, 20 mg/25 mg	not available	6707/2006/01	PFIZER EUROPE MA EEIG	RO
Accuzide Filmtabletten	not available	1-20206	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Accuzide Forte, comprimate filmate, 20 mg/12,5 mg	not available	6706/2006/01	PFIZER EUROPE MA EEIG	RO
Accuzide 20 potahované tablety	not available	58/560/00-C	PFIZER, SPOL. S R.O.	CZ
Accuzide forte Filmtabletten	not available	1-20208	PFIZER CORPORATION AUSTRIA GESELLSCHAFT	AT

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			M.B.H.	
Accuzide 20 mg/12,5 mg filmtabletta	not available	OGYI-T-7968/04	PFIZER KFT.	HU
Аккузид 20 mg/12,5 mg филмирани таблетки	not available	2005540	PFIZER EUROPE MA EEIG	BG
Acuretic 20 mg + 12,5 mg comprimidos revestidos por película	not available	2338887	LABORATÓRIOS PFIZER, LDA.	PT
Acuretic 20 mg + 12,5 mg comprimidos revestidos por película	not available	2794485	LABORATÓRIOS PFIZER, LDA.	PT
Accuzide 10 mg/12,5 mg filmtabletta	not available	OGYI-T-7968/01	PFIZER KFT.	HU
Аккузид 10 mg/12,5 mg филмирани таблетки	not available	20050539	PFIZER EUROPE MA EEIG	BG
Acuretic 20 mg + 12,5 mg comprimidos revestidos por película	not available	2338986	LABORATÓRIOS PFIZER, LDA.	PT
ACUILIX 20 mg/12,5 mg, comprimé pelliculé sécable	not available	34009 372 439 4 0	PFIZER HOLDING FRANCE (S.C.A.)	FR
Accuzide® 20 mg/25 mg diuplus Filmtabletten	not available	26904.01.00	PFIZER PHARMA GMBH	DE
Accuzide® 10 mg/12,5 mg Filmtabletten	not available	26902.00.00	PFIZER PHARMA GMBH	DE
ACUILIX 20 mg/12,5 mg, comprimé pelliculé sécable	not available	34009 336 408 5 9	PFIZER HOLDING FRANCE (S.C.A.)	FR
ACUILIX 20 mg/12,5 mg, comprimé pelliculé sécable	not available	34009 336 407 9 8	PFIZER HOLDING FRANCE (S.C.A.)	FR
Accuzide® 20 mg/12,5 mg Filmtabletten	not available	26902.02.00	PFIZER PHARMA GMBH	DE
Acuzide 20/12,5, filmomhulde tabletten 20/12,5 mg	not available	RVG 15835	PFIZER B.V.	NL
Accupro comp 10 mg / 12,5 mg filmdragerade tabletter	not available	11619	PFIZER OY	FI
Accupro comp 20 mg / 12,5 mg	not available	11620	PFIZER OY	FI

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filmdragerade tabletter				
ACEQUIDE 20 mg + 12,5 mg compresse rivestite con film	not available	028317030	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
Acequide 20 mg + 6,25 mg compresse rivestite con film	not available	028317028	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
Acequide 20 mg +12,5 mg compresse rivestite con film	not available	028317016	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
Bicetil 20 mg / 12,5 mg comprimidos recubiertos con película	not available	60.455	LABORATORIOS MENARINI, S.A.	ES
QUINAZIDE 20 mg + 12,5 mg COMPRESSE RIVESTITE CON FILM	not available	028331039	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
QUINAZIDE 20 mg + 6,25 mg COMPRESSE RIVESTITE CON FILM	not available	028331027	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
QUINAZIDE 20 mg + 12,5 mg COMPRESSE RIVESTITE CON FILM	not available	028331015	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
Quinapril/Hydrochlorothiazide 20/12.5 mg film-coated tablets	UK/H/1168/002/DC	PL 16363/0257	MILPHARM LIMITED	UK
Quinapril/Hydrochlorothiazide 20/25 mg film-coated tablets	UK/H/1168/003/DC	PL 16363/0258	MILPHARM LIMITED	UK
Quinapril/Hydrochlorothiazide Aurobindo 20/25 mg plėvele dengtos tabletės	UK/H/1168/003	LT/1/10/2166/035	AUROBINDO PHARMA LIMITED	LT
Quinapril/Hydrochlorothiazide Aurobindo 20/25 mg plėvele dengtos	UK/H/1168/003	LT/1/10/2166/036	AUROBINDO PHARMA LIMITED	LT

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tabletės				
Quinapril/Hydrochlorothiazide Aurobindo 20/25 mg plėvele dengtos tabletės	UK/H/1168/003	LT/1/10/2166/037	AUROBINDO PHARMA LIMITED	LT
Quinapril/Hydrochlorothiazide Aurobindo 20/25 mg plėvele dengtos tabletės	UK/H/1168/003	LT/1/10/2166/038	AUROBINDO PHARMA LIMITED	LT
Quinapril/Hydrochlorothiazide Aurobindo 20/25 mg plėvele dengtos tabletės	UK/H/1168/003	LT/1/10/2166/039	AUROBINDO PHARMA LIMITED	LT
Quinapril/Hydrochlorothiazide Aurobindo 20/25 mg plėvele dengtos tabletės	UK/H/1168/003	LT/1/10/2166/040	AUROBINDO PHARMA LIMITED	LT
Quinapril/Hydrochlorothiazide Aurobindo 20/25 mg plėvele dengtos tabletės	UK/H/1168/003	LT/1/10/2166/041	AUROBINDO PHARMA LIMITED	LT
Quinapril/Hydrochlorothiazide Aurobindo 20/25 mg plėvele dengtos tabletės	UK/H/1168/003	LT/1/10/2166/042	AUROBINDO PHARMA LIMITED	LT
Quinapril/Hydrochlorothiazide Aurobindo 20/25 mg plėvele dengtos tabletės	UK/H/1168/003	LT/1/10/2166/043	AUROBINDO PHARMA LIMITED	LT
Quinapril/Hydrochlorothiazide Aurobindo 20/25 mg plėvele dengtos tabletės	UK/H/1168/003	LT/1/10/2166/044	AUROBINDO PHARMA LIMITED	LT
Quinapril/Hydrochlorothiazide Aurobindo 20/25 mg plėvele dengtos tabletės	UK/H/1168/003	LT/1/10/2166/045	AUROBINDO PHARMA LIMITED	LT
Quinapril/Hydrochlorothiazide Aurobindo 20/25 mg plėvele dengtos	UK/H/1168/003	LT/1/10/2166/046	AUROBINDO PHARMA LIMITED	LT

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tabletės				
Quinapril/Hydrochlorothiazide Aurobindo 20/25 mg plėvele dengtos tabletės	UK/H/1168/003	LT/1/10/2166/047	AUROBINDO PHARMA LIMITED	LT
Quinapril/Hydrochlorothiazide Aurobindo 20/25 mg plėvele dengtos tabletės	UK/H/1168/003	LT/1/10/2166/048	AUROBINDO PHARMA LIMITED	LT
Quinapril/Hydrochlorothiazide Aurobindo 20/25 mg plėvele dengtos tabletės	UK/H/1168/003	LT/1/10/2166/049	AUROBINDO PHARMA LIMITED	LT
Quinapril/Hydrochlorothiazide Aurobindo 20/25 mg plėvele dengtos tabletės	UK/H/1168/003	LT/1/10/2166/050	AUROBINDO PHARMA LIMITED	LT
Quinapril/Hydrochlorothiazide Aurobindo 20/25 mg plėvele dengtos tabletės	UK/H/1168/003	LT/1/10/2166/051	AUROBINDO PHARMA LIMITED	LT
Quinapril/Hydrochlorothiazid Aurobindo 20 mg/25 mg apvalkotās tabletes	UK/H/1168/003	11-0159	AUROBINDO PHARMA LIMITED	LV
Quinapril/Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	UK/H/1168/001	040177014	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	UK/H/1168/001	040177026	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	UK/H/1168/001	040177038	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con	UK/H/1168/001	040177040	AUROBINDO PHARMA (ITALIA) S.R.L.	IT

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film				
Quinapril/Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	UK/H/1168/001	040177053	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	UK/H/1168/001	040177065	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	UK/H/1168/001	040177077/M	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	UK/H/1168/001	040177089	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	UK/H/1168/001	040177091	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	UK/H/1168/001	040177103	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	UK/H/1168/001	040177115	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	UK/H/1168/001	040177127	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	UK/H/1168/001	040177139	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con	UK/H/1168/001	040177141	AUROBINDO PHARMA (ITALIA) S.R.L.	IT

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film				
Quinapril/Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	UK/H/1168/001	040177154	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	UK/H/1168/001	040177166	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	UK/H/1168/001	040177178	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	UK/H/1168/003	040177356	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	UK/H/1168/003	040177368	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	UK/H/1168/003	040177370	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	UK/H/1168/003	040177382	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	UK/H/1168/003	040177394	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	UK/H/1168/003	040177406	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	UK/H/1168/003	040177418	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	UK/H/1168/003	040177420	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	UK/H/1168/003	040177432	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	UK/H/1168/003	040177444	AUROBINDO PHARMA (ITALIA) S.R.L.	IT

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Quinapril/Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	UK/H/1168/003	040177457	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	UK/H/1168/003	040177469	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	UK/H/1168/003	040177471	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	UK/H/1168/003	040177483	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	UK/H/1168/003	040177495	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	UK/H/1168/003	040177507	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril/Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	UK/H/1168/003	040177519	AUROBINDO PHARMA (ITALIA) S.R.L.	IT