16 December 2021
EMA/76996/2022
Pharmacovigilance Risk Assessment Committee (PRAC)

List of nationally authorised medicinal products

Active substance(s): hydrochlorothiazide / quinapril

Procedure No.: PSUSA/00002592/202104

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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
ACCUPRO COMP 10 mg / 12,5 mg tabletti, kalvopäällysteinen	not available	11619	PFIZER OY	FI
Accupro comp 10 mg/12,5 mg filmdragerade tabletter	not available	11859	PFIZER AB	SE
ACCUPRO COMP 20 mg / 12,5 mg tabletti, kalvopäällysteinen	not available	11620	PFIZER OY	FI
Accupro comp 20 mg/12,5 mg filmdragerade tabletter	not available	11860	PFIZER AB	SE
Accuretic 10 mg/12,5 mg Filmtabletten	not available	BE164367	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 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
Accuretic 20 mg/12,5 mg Filmtabletten	not available	BE164376	PFIZER S.A. (BELGIUM)	BE
Accuretic 20 mg/12,5 mg Filmtabletten	not available	2004098397	PFIZER S.A. (BELGIUM)	LU
Accuretic 20 mg/12.5 mg film-coated tablets	not available	PA 822/8/2	PFIZER HEALTHCARE IRELAND	IE
Accuretic επικαλυμμένα με λεπτό υμένιο δισκία (20+12,5) mg/tab	not available	42503/15-10-2008	PFIZER HELLAS, A.E.	GR
ACCUZIDE 10 filmom obalené tablety	not available	58/0065/98–S	PFIZER EUROPE MA EEIG	SK
Accuzide 10 mg/ 12,5 mg 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 EUROPE MA EEIG	LV
Accuzide 10 mg/12,5 mg comprimate filmate	not available	11497/2019/01	PFIZER EUROPE MA EEIG	RO
Accuzide 10 mg/12,5 mg filmtabletta	not available	OGYI-T-7968/01	PFIZER KFT.	HU
ACCUZIDE 10/12,5 mg plėvele dengtos tabletės	not available	LT/1/2000/0926/002	PFIZER EUROPE MA EEIG	LT
ACCUZIDE 10/12,5 mg plėvele dengtos tabletės	not available	LT/1/2000/0926/001	PFIZER EUROPE MA EEIG	LT
ACCUZIDE 20 filmom obalené tablety	not available	58/0056/02–S	PFIZER EUROPE MA EEIG	SK
Accuzide 20 mg/ 12,5 mg potahované	not available	58/560/00-C	PFIZER, SPOL. S R.O.	CZ

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tablety				
Accuzide 20 mg/12,5 mg apvalkotās tabletes	not available	01-0280	PFIZER EUROPE MA EEIG	LV
Accuzide 20 mg/12,5 mg filmtabletta	not available	OGYI-T-7968/04	PFIZER KFT.	HU
Accuzide 20 mg/25 mg apvalkotās tabletes	not available	09-0488	PFIZER EUROPE MA EEIG	LV
ACCUZIDE 20/12,5 mg plėvele dengtos tabletės	not available	LT/1/2000/0926/005	PFIZER EUROPE MA EEIG	LT
ACCUZIDE 20/12,5 mg plėvele dengtos tabletės	not available	LT/1/2000/0926/003	PFIZER EUROPE MA EEIG	LT
ACCUZIDE 20/12,5 mg plėvele dengtos tabletės	not available	LT/1/2000/0926/004	PFIZER EUROPE MA EEIG	LT
Accuzide Forte 20 mg/12,5 mg comprimate filmate	not available	11498/2019/01	PFIZER EUROPE MA EEIG	RO
Accuzide Forte Plus 20 mg/25 mg comprimate filmate	not available	11499/2019/01	PFIZER EUROPE MA EEIG	RO
Accuzide® 10 mg/12,5 mg Filmtabletten	not available	26902.00.00	PFIZER PHARMA GMBH	DE
Accuzide® 20 mg/12,5 mg Filmtabletten	not available	26902.02.00	PFIZER PHARMA GMBH	DE
Accuzide® 20 mg/25 mg diuplus Filmtabletten	not available	26904.01.00	PFIZER PHARMA GMBH	DE
Accuzide® Filmtabletten	not available	1-20206	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Accuzide® forte Filmtabletten	not available	1-20208	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
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	028317030	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

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
ACUILIX 20 mg/12,5 mg, comprimé pelliculé sécable	not available	34009 372 439 4 0	PFIZER HOLDING FRANCE	FR
ACUILIX 20 mg/12,5 mg, comprimé pelliculé sécable	not available	34009 336 408 5 9	PFIZER HOLDING FRANCE	FR
ACUILIX 20 mg/12,5 mg, comprimé pelliculé sécable	not available	34009 336 407 9 8	PFIZER HOLDING FRANCE	FR
Bicetil 20 mg / 12,5 mg comprimidos recubiertos con película	not available	60.455	LABORATORIOS MENARINI, S.A.	ES
LIDALTRIN-DIU comprimidos recubiertos con película	not available	60.439	LACER S.A.	ES
Quinapril Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177014	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177026	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	DE/H/5766/001	040177038	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	DE/H/5766/001	040177040	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177053	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177065	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177077	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177089	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177091	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	DE/H/5766/001	040177103	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177115	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177127	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177139	AUROBINDO PHARMA (ITALIA) S.R.L.	IT

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Quinapril Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	DE/H/5766/001	040177141	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177154	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177166	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 10/12,5 mg compresse rivestite con film	DE/H/5766/001	040177178	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	DE/H/5766/003	040177356	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177368	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	DE/H/5766/003	040177370	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	DE/H/5766/003	040177382	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177394	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177406	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177418	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177420	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177432	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	DE/H/5766/003	040177444	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177457	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	DE/H/5766/003	040177469	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177471	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177483	AUROBINDO PHARMA (ITALIA) S.R.L.	IT

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Quinapril Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177495	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177507	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Quinapril Idroclorotiazide Aurobindo 20/25 mg compresse rivestite con film	DE/H/5766/001-003/DC	040177519	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
QUINAPRIL/HYDROCHLOROTHIAZIDE MYLAN 20 mg/12,5 mg, comprimé pelliculé sécable	not available	NL 30171	MYLAN S.A.S	FR
QUINAPRIL/HYDROCHLOROTHIAZIDE MYLAN 20 mg/12,5 mg, comprimé pelliculé sécable	not available	NL 30171	MYLAN S.A.S	FR
QUINAZIDE 20 mg + 12,5 mg COMPRESSE RIVESTITE CON FILM	not available	028331039	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
QUINAZIDE 20 mg + 6,25 mg COMPRESSE RIVESTITE CON FILM	not available	028331027	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT