



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 September 2015
EMA/619987/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: hydrochlorothiazide, ramipril

Procedure no.: PSUSA/00001660/201501



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
Cardace	DE/H/2628/001	11541	Sanofi Oy	FI
Cardace Forte	DE/H/2628/003	799112	Sanofi-Aventis Estonia Oü	EE
Cardace Forte	DE/H/2628/004	799012	Sanofi-Aventis Estonia Oü	EE
Cardace Comp	DE/H/2628/001	142596	Sanofi-Aventis Estonia Oü	EE
Cardace Plus	DE/H/2628/002	424303	Sanofi-Aventis Estonia Oü	EE
Cotriatec	FR/H/0574/001	369 626-1	Sanofi-Aventis France	FR
Cotriatec	FR/H/0574/001	369 627-8	Sanofi-Aventis France	FR
Cotriatec	FR/H/0574/001	369 628-4	Sanofi-Aventis France	FR
Cotriatec	FR/H/0574/001	369 629-0	Sanofi-Aventis France	FR
Cotriatec	FR/H/0574/001	369 630-9	Sanofi-Aventis France	FR
Cotriatec	FR/H/0574/001	369 631-5	Sanofi-Aventis France	FR
Cotriatec	FR/H/0574/001	369 632-1	Sanofi-Aventis France	FR
Cotriatec	FR/H/0574/001	369 633-8	Sanofi-Aventis France	FR
Cotriatec	FR/H/0574/001	567 144-3	Sanofi-Aventis France	FR

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Delix Plus	DE/H/2628/001	DE/H/2628/001	Sanofi-Aventis Deutschland Gmbh	DE
Delix Plus	DE/H/2628/002	DE/H/2628/002	Sanofi-Aventis Deutschland Gmbh	DE
Hydrochlorothiazide + Ramipril Astrazeneca		1-20396	Astrazeneca Osterreich Gmbh	AT
Hydrochlorothiazide + Ramipril Astrazeneca		1-20400	Astrazeneca Osterreich Gmbh	AT
Hydrochlorothiazide + Ramipril Astrazeneca		26623.00.00	Astrazeneca Gmbh	DE
Hydrochlorothiazide + Ramipril Astrazeneca		26623.01.00	Astrazeneca Gmbh	DE
Hydrochlorothiazide + Ramipril Astrazeneca		28532012	Astrazeneca S.P.A.	IT
Hydrochlorothiazide + Ramipril Astrazeneca		28532024	Astrazeneca S.P.A.	IT
Idroquark		028533014	Polifarma S.P.A	IT
Idroquark		028533026	Polifarma S.P.A	IT
Ramilich Comp	DE/H/2629/001	62981.00.00	Winthrop Arzneimittel Gmbh	DE
Ramilich Comp	DE/H/2629/002	62982.00.00	Winthrop Arzneimittel Gmbh	DE
Ramipril Hct	DE/H/2629/001	037742018	Zentiva Italia Srl	IT
Ramipril Hct	DE/H/2629/001	OGYI-T-10606/02	Zentiva Hu Kft	HU

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Ramipril Hct	DE/H/2629/002	037742020	Zentiva Italia Srl	IT
Ramipril Hct	DE/H/2629/002	OGYI-T-10606/01	Zentiva Hu Kft	HU
Ramipril Hydrochlorothiazide		34009 224 461 1 0	Sanofi-Aventis France	FR
Ramipril Hydrochlorothiazide		34009 224 462 8 8	Sanofi-Aventis France	FR
Ramipril Hydrochlorothiazide		34009 224 463 4 9	Sanofi-Aventis France	FR
Ramipril Hydrochlorothiazide		34009 224 464 0 0	Sanofi-Aventis France	FR
Ramipril Hydrochlorothiazide		34009 224 465 7 8	Sanofi-Aventis France	FR
Ramipril Hydrochlorothiazide		34009 224 466 3 9	Sanofi-Aventis France	FR
Ramipril Hydrochlorothiazide		34009 224 468 6 8	Sanofi-Aventis France	FR
Ramipril Hydrochlorothiazide		34009 224 469 2 9	Sanofi-Aventis France	FR
Ramipril Hydrochlorothiazide		34009 583 071 7 1	Sanofi-Aventis France	FR
Ramipril Ratiopharm		84993.00.00	Ratiopharm Gmbh	DE
Sonetac		21155	Delorbis Pharmaceuticals Ltd	CY
Triatec HCT	DE/H/2628/001	028531010 028531174	Sanofi Spa	IT

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Triatec HCT	DE/H/2628/002	028531022 028531186	Sanofi Spa	IT
Triatec Composto	DE/H/2629/001	2311082	Sanofi - Produtos Farmaceuticos Lda	PT
Triatec Composto	DE/H/2629/001	2311181	Sanofi - Produtos Farmaceuticos Lda	PT
Triatec Composto	DE/H/2629/001	5907084	Sanofi - Produtos Farmaceuticos Lda	PT
Triatec Composto	DE/H/2629/002	2311280	Sanofi - Produtos Farmaceuticos Lda	PT
Triatec Composto	DE/H/2629/002	2311389	Sanofi - Produtos Farmaceuticos Lda	PT
Triatec Composto	DE/H/2629/002	5907183	Sanofi - Produtos Farmaceuticos Lda	PT
Triatec Plus	DE/H/2628/002	19071	Sanofi-Aventis Cyprus Ltd	CY
Triatec Plus	DE/H/2628/002	224030201	Sanofi-Aventis Aebe	GR
Tritace PLUS	DE/H/2628/002	20030628	Sanofi-Aventis Bulgaria Eood	BG
Tritace PLUS	DE/H/2628/002	7445/2006/01-14	Sanofi-Aventis Romania Srl	RO
Tritace PLUS	DE/H/2628/004	20120437	Sanofi-Aventis Bulgaria Eood	BG
Tritace Comb	DE/H/2628/001	8853	Sanofi-Aventis Deutschland Gmbh	PL
Tritace Comb	DE/H/2628/002	8854	Sanofi-Aventis Deutschland Gmbh	PL

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Tritace Hct	DE/H/2628/001	OGYI-T-9094/01	Sanofi-Aventis Private Co Ltd	HU
Tritace Hct	DE/H/2628/002	OGYI-T-9094/02	Sanofi-Aventis Private Co Ltd	HU
Tritace Plus	DE/H/2628/001	7444/2006/01	Sanofi-Aventis Romania Srl	RO
Tritazide		UP/I-530-09/11-02/214	Sanofi-Aventis Croatia D.O.O.	HR
Tritazide		UP/I-530-09/11-02/215	Sanofi-Aventis Croatia D.O.O.	HR
Tritazide	DE/H/2628/001	1-20398	Sanofi-Aventis Gmbh Österreich	AT
Tritazide	DE/H/2628/001	5363-I-133/08	Sanofi-Aventis D.O.O.	SI
Tritazide	DE/H/2628/001	58/0002/99-S	Sanofi-Aventis Slovakia Sro	SK
Tritazide	DE/H/2628/001	58/255/00-C	Sanofi-Aventis Sro	CZ
Tritazide	DE/H/2628/002	1-20395	Sanofi-Aventis Gmbh Österreich	AT
Tritazide	DE/H/2628/002	1699/06119121	Sanofi Belgium	LU
Tritazide	DE/H/2628/002	5363-I-1806/11	Sanofi-Aventis D.O.O.	SI
Tritazide	DE/H/2628/002	58/0085/11-S	Sanofi-Aventis Slovakia Sro	SK
Tritazide	DE/H/2628/002	58/254/00-C	Sanofi-Aventis Sro	CZ

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Tritazide	DE/H/2628/002	BE167815	Sanofi Belgium	BE
Tritazide	DE/H/2628/002	RVG 15551	Sanofi-Aventis Netherlands B.V.	NL
Ramipiril comp-CT 5		84995.00.00	Abz-Pharma Gmbh, Graf-Arco-Str. 3	DE
Ramipiril HCT Doc Generici	NL/H/0721/001/MR	RVG 30670	DOC Generici s.r.l.	NL
Ramipiril E Idroclorotiazide DOC Generici	NL/H/721/01/MR	037626013-6025-6037-6049-6052-6064-6076-6088-6090-6102-	DOC Generici s.r.l.	IT
Ramipiril comp-CT 5		84994.00.00	Abz-Pharma GmbH, Graf-Arco-Str. 3	DE
Delix Plus HCT	DE/H/2628/003	84311.00.00	Sanofi-Aventis Deutschland GmbH	DE
Tritace HCT	DE/H/2628/003	OGYI-T-9094/03	Sanofi-Aventis Private Co Ltd	HU
Triatec HCT	DE/H/2628/003	0258531034-1046-1059-1061-1073-1085-1097	SANOFI SPA	IT
Delix Plus HCT	DE/H/2628/004	84312.00.00	Sanofi-Aventis Deutschland GmbH	DE
Tritace HCT	DE/H/2628/004	OGYI-T-9094/04	Sanofi-Aventis Private Co Ltd	HU
Triatec HCT	DE/H/2628/004	028531109-1111-1123-1135-1147-1150-1162	SANOFI SPA	IT
Ramilich Comp	FR/H/0574/001	92543.00.00	Zentiva Pharma GmbH	DE
Ramilife Hct	DE/H/1597/001	5363-I-1889/10-5363-L-1890/10	Actavis Group Ptc Ehf.	SI

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Ramipiril/Hydrochlorothiazide Actavis	DE/H/1597/001	RVG 102366	Actavis Group Ptc Ehf.	NL
Ramipiril/HCT Actavis		1-29014	Actavis Group Ptc Ehf.	AT