



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 June 2025
EMADOC-1700519818-2305404
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): benzydamine

EURD list No. PSUSA/00000375/202410



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
Actusept	CZ/H/0668/001	24047	Dr. Max Pharma s.r.o.	Republic of Poland
Belozyme	HR/H/0118/001	69/1035/16-C	BELUPO Lijekovi I Kozmetika d.d.	Czech Republic
Belozyme	HR/H/0117/001	69/1036/16-C	BELUPO Lijekovi I Kozmetika d.d.	Czech Republic
Bensydamin Geiser	AT/H/0680/001	54499	[INACTIVE] Geiser Pharma S.L.	Kingdom of Sweden
Bensydamin Geiser	AT/H/0680/001	54498	[INACTIVE] Geiser Pharma S.L.	Kingdom of Sweden
BENZIDAMINA ANGELINI		038984011	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Italian Republic
Benzidamina Mylan Pharma	DE/H/5722/001	045138017	Mylan S.p.A.	Italian Republic
Benzydamine Focus Pharmaceuticals		PL 20046/ 0048	Focus Pharmaceuticals Limited	United Kingdom (Northern Ireland)
Benzydamine Hydrochloride Abdi Farma	UK/H/6557/001		Abdi Farma Unipessoal Lda.	United Kingdom (Northern Ireland)
Benzydamine Hydrochloride Manx Healthcare	UK/H/6635/001	PL 14251/0056	Manx Healthcare Limited	United Kingdom (Northern Ireland)
Benzydamine Hydrochloride Manx Healthcare	UK/H/6636/001	PL 14251/0055	Manx Healthcare Limited	United Kingdom (Northern Ireland)
Benzydamine Phoenix Labs	IE/H/0973/001	PL 35104/0019	Phoenix Labs Unlimited Company	United Kingdom (Northern Ireland)
Bertolix	PL/H/0407/001	15-10776	Bausch Health Ireland Limited	Kingdom of Norway
Bertolix	PL/H/0407/001	33557	Bausch Health Ireland Limited	Republic of Finland
Biramine	AT/H/0680/002	138556	[INACTIVE] Geiser Pharma S.L.	Republic of Austria
Biramine	AT/H/0680/001	138555	[INACTIVE] Geiser Pharma S.L.	Republic of Austria

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
Dracosan	DE/H/6761/001/DC	87187	Aristo Pharma GmbH	Kingdom of Spain
GINETANTUM		023399013	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Italian Republic
GINETANTUM			Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Italian Republic
INALDIN Gardło MAX	PL/H/0407/001	23583	Bausch Health Ireland Limited	Republic of Poland
Larymed	CZ/H/0668/001	69/845/15-C	Dr. Max Pharma s.r.o.	Czech Republic
Larynox	CZ/H/0668/001	69/0129/17-S	Dr. Max Pharma s.r.o.	Slovak Republic
Lolisept	AT/H/0680/001	OGYI-T-23137/04	Goodwill Pharma Zrt.	Republic of Hungary
Lolisept Forte	AT/H/0680/002	OGYI-T-23137/06	Goodwill Pharma Zrt.	Republic of Hungary
Med-angin	AT/H/0681/001	138498	Cassella-Med GmbH & Co. KG	Republic of Austria
Med-angin	AT/H/0681/002	138499	Cassella-Med GmbH & Co. KG	Republic of Austria
Nagardlan	DE/H/6761/001	27255	Aristo Pharma Sp. z o.o.	Republic of Poland
neo-angin	AT/H/0681/001/DC	97243.00.00	Cassella-Med GmbH & Co. KG	Federal Republic of Germany
neo-angin	AT/H/0681/002/DC	97244.00.00	Cassella-Med GmbH & Co. KG	Federal Republic of Germany
neo-angin	AT/H/0681/002	26142	M. C. M. Klosterfrau Healthcare Sp. z o.o.	Republic of Poland
neo-angin	AT/H/0681/001	26141	M. C. M. Klosterfrau Healthcare Sp. z o.o.	Republic of Poland
neo-angin Benzydamin	ES/H/0324/001/DC		Cassella-Med GmbH & Co. KG	Federal Republic of Germany
neo-angin Benzydamin		2200183.00.00	Cassella-Med GmbH & Co. KG	Federal Republic of Germany
OPALGYNE			Laboratoire Innotech International	French Republic
Oral Soothe and Sore Throat	UK/H/6636/001	PL 14251/0055	Manx Healthcare Limited	United Kingdom (Northern Ireland)
Orocalm	CZ/H/1125/001	69/473/21-C	Cassella-Med GmbH & Co.	Czech Republic

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
			KG	
Orocalm	AT/H/0681/002/DC	69/548/16-C	Cassella-Med GmbH & Co. KG	Czech Republic
Orocalm	AT/H/0681/001/DC	69/547/16-C	Cassella-Med GmbH & Co. KG	Czech Republic
Orocalm	CZ/H/1126/001	69/472/21-C	Cassella-Med GmbH & Co. KG	Czech Republic
Orocalm	CZ/H/1125/001	69/0051/24-S	Cassella-Med GmbH & Co. KG	Slovak Republic
Orocalm	CZ/H/1126/001	69/0052/24-S	Cassella-Med GmbH & Co. KG	Slovak Republic
Orocalm	AT/H/0681/002/DC	69/0233/18-S	Cassella-Med GmbH & Co. KG	Slovak Republic
Orocalm	AT/H/0681/001/DC	69/0232/18-S	Cassella-Med GmbH & Co. KG	Slovak Republic
Orocalm goût Miel et Orange	CZ/H/1126/001	BE662128	Melisana	Kingdom of Belgium
Orocalm mit Honig- und Orangengeschmack	CZ/H/1126/001	2024030080	Melisana	Grand Duchy of Luxembourg
Orocalm mit Zitronengeschmack	CZ/H/1125/001	2024050117	Melisana	Grand Duchy of Luxembourg
Orocalm mit Zitronengeschmack	CZ/H/1125/001	BE662357	Melisana	Kingdom of Belgium
Orocalmin	RO/H/0215/001		Zentiva k.s.	Romania
Orocalmin	RO/H/0215/002		Zentiva k.s.	Romania
Oroeze		PL 20046/ 0048	Focus Pharmaceuticals Limited	United Kingdom (Northern Ireland)
Orosoothe	IE/H/0973/001	PA1113/016/001	Phoenix Labs Unlimited Company	Ireland
Orovox Spray	AT/H/0680/001	5753769	Cuidafarma Lda.	Portuguese Republic
Orovox Spray	AT/H/0680/001/DC		[INACTIVE] Cuidafarma Lda.	Portuguese Republic
Orovox Spray	AT/H/0680/002	5753835	Cuidafarma Lda.	Portuguese Republic
ROSALGIN		54/343/99-C	Angelini Pharma Česká Republika s.r.o.	Czech Republic
Rosalgin		56.573	Angelini Pharma Espana S.L.	Kingdom of Spain

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
Rosalgin		1-18486	Angelini Pharma Österreich GmbH	Republic of Austria
Rosalgin		1-23893	Angelini Pharma Österreich GmbH	Republic of Austria
Rosalgin		1-23893	Angelini Pharma Österreich GmbH	Republic of Austria
Rosalgin Easy		54/038/14-C	Angelini Pharma Česká Republika s.r.o.	Czech Republic
ROSALGIN EASY		54/0059/93-S	Angelini Pharma Österreich GmbH	Slovak Republic
ROSALGIN EASY		54/0059/93-S	Angelini Pharma Österreich GmbH	Slovak Republic
Rosalgin pronto		59.541	Angelini Pharma Espana S.L.	Kingdom of Spain
RUBISEPT	HR/H/0118/001	H/19/02532/001	BELUPO Lijekovi I Kozmetika d.d.	Republic of Slovenia
RUBISEPT	HR/H/0117/001	H/19/02531/001	BELUPO Lijekovi I Kozmetika d.d.	Republic of Slovenia
Septogard	PL/H/0664/001	25408	Farmak International Sp. z o.o.	Republic of Poland
Soril Throat Spray		023434	Sapiens Pharmaceuticals Limited	Republic of Cyprus
Tantum		46221	Angelini Pharma Espana S.L.	Kingdom of Spain
Tantum			Angelini Pharma Espana S.L.	Kingdom of Spain
TANTUM LEMON			Angelini Pharma Österreich GmbH	Republic of Lithuania
TANTUM ROSA			Angelini Pharma Österreich GmbH	Republic of Lithuania
TANTUM ROSA		R/0278	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Republic of Poland
TANTUM ROSA		22943	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Republic of Poland
TANTUM VERDE		69/293/02-C	Angelini Pharma Česká Republika s.r.o.	Czech Republic
TANTUM VERDE		69/358/98-C	Angelini Pharma Česká	Czech Republic

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
			Republika s.r.o.	
Tantum Verde		87023.00.00	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Federal Republic of Germany
Tantum Verde		852.00.00	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Federal Republic of Germany
TANTUM VERDE		82512/22/18-07-23	[INACTIVE] Angelini Pharma Hellas S.A.	Hellenic Republic
Tantum Verde		80884/20/16-3-2021		Hellenic Republic
TANTUM VERDE		30723/03-05-2012	[INACTIVE] Angelini Pharma Hellas S.A.	Hellenic Republic
TANTUM VERDE		32089/15/31-1-2018	[INACTIVE] Angelini Pharma Hellas S.A.	Hellenic Republic
Tantum Verde		22030/16-3-2021	Angelini Pharma Hellas S.A.	Hellenic Republic
TANTUM VERDE		30723/03-05-2012	[INACTIVE] Angelini Pharma Hellas S.A.	Hellenic Republic
Tantum Verde		022088064	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Italian Republic
Tantum Verde		022088088	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Italian Republic
Tantum Verde			Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Italian Republic
Tantum verde		58.900	Angelini Pharma Espana S.L.	Kingdom of Spain
TANTUM VERDE		77.753	Angelini Pharma Espana S.L.	Kingdom of Spain
Tantum Verde		14505	Angelini Pharma Osterreich GmbH	Republic of Austria
Tantum Verde		14505	Angelini Pharma Osterreich GmbH	Republic of Austria
Tantum Verde		1-20985	Angelini Pharma Osterreich GmbH	Republic of Austria
TANTUM VERDE			Angelini Pharma Osterreich GmbH	Republic of Lithuania

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
TANTUM VERDE		LT/1/01/0257/005	Angelini Pharma Österreich GmbH	Republic of Lithuania
TANTUM VERDE			Angelini Pharma Österreich GmbH	Republic of Lithuania
Tantum Verde		R/0184	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Republic of Poland
Tantum Verde		R/0181	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Republic of Poland
TANTUM VERDE		69/0701/94-S	Angelini Pharma Österreich GmbH	Slovak Republic
Tantum Verde cu aromă de mentă		7149/2014/01	Angelini Pharma Österreich GmbH	Romania
Tantum Verde Dental		028821027	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Italian Republic
TANTUM VERDE EUCALYPTUS		69/430/13-C	Angelini Pharma Česká Republika s.r.o.	Czech Republic
TANTUM VERDE FORTE		69/294/02-C	Angelini Pharma Česká Republika s.r.o.	Czech Republic
Tantum Verde forte		1-25420	Angelini Pharma Österreich GmbH	Republic of Austria
TANTUM VERDE forte		LT/1/01/0257/006	Angelini Pharma Österreich GmbH	Republic of Lithuania
Tantum Verde Forte		12434	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Republic of Poland
Tantum Verde Forte		7616/2015/01	Angelini Pharma Österreich GmbH	Romania
TANTUM VERDE LEMON		69/084/04-C	Angelini Pharma Česká Republika s.r.o.	Czech Republic
TANTUM VERDE Lemon		69/0136/04-S	Angelini Pharma Österreich GmbH	Slovak Republic
TANTUM VERDE MINT		69/147/99-C	Angelini Pharma Česká Republika s.r.o.	Czech Republic

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
TANTUM VERDE Mint		69/0702/94-S	Angelini Pharma Österreich GmbH	Slovak Republic
Tantum Verde mit Honig- und Orangengeschmack		1-23219	Angelini Pharma Österreich GmbH	Republic of Austria
Tantum Verde mit Minzgeschmack		1-18192	Angelini Pharma Österreich GmbH	Republic of Austria
Tantum Verde mit Zitronengeschmack		1-24820	Angelini Pharma Österreich GmbH	Republic of Austria
TANTUM VERDE ORANGE AND HONEY		69/431/13-C	Angelini Pharma Česká Republika s.r.o.	Czech Republic
Tantum Verde smak cytrynowy		14487	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Republic of Poland
Tantum Verde smak eukaliptusowy		19589	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Republic of Poland
Tantum Verde smak miętowy		4264	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Republic of Poland
Tantum Verde smak miodowo-pomarańczowy		19588	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Republic of Poland
Tantum Verde z okusom limone		H/01/01921/010	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Republic of Slovenia
Tantum Verde z okusom mentola		H/01/01921/009	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Republic of Slovenia
Tantum Verde z okusom pomaranče in medu		H/01/01921/011	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Republic of Slovenia
Tonsino	DE/H/6761/001		Aristo Pharma GmbH	Italian Republic
Tonsino Gurgellösung bei Halsschmerzen	DE/H/6761/001	7000381.00.00	Aristo Pharma GmbH	Federal Republic of Germany
Zotrina	CZ/H/0668/001	15253/2023/01	Dr. Max Pharma s.r.o.	Romania

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
ZYNOL	HR/H/0118/001	HR-H-333342911	BELUPO Lijekovi I Kozmetika d.d.	Republic of Croatia
ZYNOL	HR/H/0118/001	HR-H-487590140	BELUPO Lijekovi I Kozmetika d.d.	Republic of Croatia
Розалгин		9700590	[INACTIVE] Angelini Pharma Bulgaria EOOD	Republic of Bulgaria
Розалгин Изи		9700591	[INACTIVE] Angelini Pharma Bulgaria EOOD	Republic of Bulgaria
Тантум Верде		9700587	[INACTIVE] Angelini Pharma Bulgaria EOOD	Republic of Bulgaria
ТАНТУМ ВЕРДЕ		9700592	[INACTIVE] Angelini Pharma Bulgaria EOOD	Republic of Bulgaria
ТАНТУМ ВЕРДЕ		20110371	[INACTIVE] Angelini Pharma Bulgaria EOOD	Republic of Bulgaria
ТАНТУМ ВЕРДЕ		20110377	[INACTIVE] Angelini Pharma Bulgaria EOOD	Republic of Bulgaria
ТАНТУМ ВЕРДЕ		9700592	[INACTIVE] Angelini Pharma Bulgaria EOOD	Republic of Bulgaria
Тантум Верде с вкус на лимон		20030745	[INACTIVE] Angelini Pharma Bulgaria EOOD	Republic of Bulgaria
Тантум Верде с вкус на мента		9800129	[INACTIVE] Angelini Pharma Bulgaria EOOD	Republic of Bulgaria
ТАНТУМ ВЕРДЕ ФОРТЕ		20060833	[INACTIVE] Angelini Pharma Bulgaria EOOD	Republic of Bulgaria