



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 January 2016
EMA/51946/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: ranitidine

Procedure no.: PSUSA/00002610/201505



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
Alquén		60.298	Smithkline Beecham Farma, S.A.	Spain
Ardoral		63445	Laboratorios Cinfa, S.A.	Spain
Azantac		NL12566	Laboratoire Glaxosmithkline	France
Azantac		NL13488	Laboratoire Glaxosmithkline	France
Azantac		NL14236	Laboratoire Glaxosmithkline	France
Azantac		NL16208 \$ NL17391	Laboratoire Glaxosmithkline	France
Azantac		NL22422	Laboratoire Glaxosmithkline	France
Gastridina		9549220 \$ 9549253 \$ 9549261 \$ 9549287	Medibial - Produtos Médicos E Farmacêuticos, S.A.	Portugal
Raniben		025241050 \$ 025241086	Fabbrica Italiana Ritrovati Medicinali Ed Affini F.I.R.M.A. - S.P.A.	Italy
Ranibloc		025490018 \$ 025490057	Istituto Biochimico Nazionale Savio S.R.L	Italy
Ranicalm		PL 17907/0247	Bristol Laboratories Ltd (Berkhamsted)	United Kingdom
Ranidil		024447 157 \$ 024447 169	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Italy
Ranidil		024447029 \$ 024447056	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Italy
Ranidil		024447031	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Italy
Ranidil		024447068	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Italy
Ranidil		024447070 \$ 024447094	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Italy
Raniplex		332 286-2 \$ 332 287-9 \$ 333 442-8 \$ 340 829-1 \$ 340 831-6 \$ 343 692-7 \$ 343 693-3	Abbott Products Sas (Suresnes)	France
Raniplex		334 538-9 \$ 334 561-0 \$ 340 964-6 \$ 340 965-2 \$ 343 695-6 \$ 343 696-2 \$ 354 443-3 \$ 354 445-6	Abbott Products Sas (Suresnes)	France
Ranital		09/0007/87-S	Sandoz Pharmaceuticals D.D.	Slovakia
Ranital		09/0007/87-S	Sandoz Pharmaceuticals D.D.	Slovakia
Ranital		09/0048/88-S	Sandoz Pharmaceuticals D.D.	Slovakia

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Ranitidin-Teva		OGYI-T-5671/01 \$ OGYI-T-5671/02 \$ OGYI-T-5671/03 \$ OGYI-T-5671/04	TEVA PHARMACEUTICAL WORKS PRIVATE LIMITED COMPANY	Portugal
Ranitidine Biogaran		NL16207	Laboratoires Saint-Germain	France
Ranitidine Biogaran		NL17397	Laboratoires Saint-Germain	France
Ranitidine Film-Coated Tablets		PL 21880/0022 \$ PL 21880/0133	Medreich Plc	United Kingdom
Ranitidine Film-Coated Tablets		PL 21880/0023	Medreich Plc	United Kingdom
Ranitidine Film-Coated Tablets		PL 21880/0024	Medreich Plc	United Kingdom
Ranitidine		PL 39484-0045 \$ PL 39484-0046	Fourrts (UK) Pharmacare Limited	United Kingdom
Ranzac		PL 39484-0047	Fourrts (UK) Pharmacare Limited	United Kingdom
Ranitidine Sandoz B.V.	UK/H/0235/001 \$ UK/H/0235/002	PL 15627/0005 \$ PL 15627/0006	Sandoz B.V.	United Kingdom
Ranitidine Tablets		PL 21880/0091 \$ PL 21880/0092	Medreich Plc	United Kingdom
Ranitil		PL 11311/0138 \$ PL 11311/0139	Tillomed Laboratories Ltd	United Kingdom
Tanidina		56040	Ferrer Internacional, S.A.	Spain
Ulceran		OGYI-T-3680/01 \$ OGYI-T-3680/02 \$ OGYI-T-3680/03	TEVA PHARMACEUTICAL WORKS PRIVATE LIMITED COMPANY	Hungary
Ulcex		025084017 \$ 025084056	Laboratori Guidotti S.P.A.	Italy
Ulsal		1-17368	Gebro Pharma Gmbh	Austria
Ulsal		1-17369	Gebro Pharma Gmbh	Austria
Ulsal		1-18559	Gebro Pharma Gmbh	Austria
Ulsal		1-19711	Gebro Pharma Gmbh	Austria
Ulsal		1-19713	Gebro Pharma Gmbh	Austria
Zantac		024448021 \$ 024448058	Glaxosmithkline S.P.A.	Italy

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Zantac		024448033	Glaxosmithkline S.P.A.	Italy
Zantac		024448060	Glaxosmithkline S.P.A.	Italy
Zantac		024448072 \$ 024448096	Glaxosmithkline S.P.A.	Italy
Zantac		09909-0 \$ 10279-0	Glaxosmithkline Ab	Sweden
Zantac		1-17373	Glaxosmithkline Pharma Gmbh.	Austria
Zantac		1-18558	Glaxosmithkline Pharma Gmbh.	Austria
Zantac		1-19710	Glaxosmithkline Pharma Gmbh.	Austria
Zantac		1-19712	Glaxosmithkline Pharma Gmbh.	Austria
Zantac		10125	Glaxosmithkline Ab	Sweden
Zantac		10503	Laboratoire Glaxosmithkline	Finland
Zantac		10503	Laboratoire Glaxosmithkline	Finland
Zantac		10725 \$ 11956	Glaxosmithkline Pharma A/S	Denmark
Zantac		10809	Glaxosmithkline Ab	Sweden
Zantac		10997	Laboratoire Glaxosmithkline	Finland
Zantac		10997	Laboratoire Glaxosmithkline	Finland
Zantac		11089	Glaxosmithkline Ab	Sweden
Zantac		11460	Glaxosmithkline Pharma A/S	Denmark
Zantac		13410/28-2-11	Glaxosmithkline Aebe	Greece
Zantac		13558 \$ 14120	Glaxosmithkline Pharma A/S	Denmark
Zantac 75		168097	Glaxosmithkline Export Ltd	Estonia
Zantac		16837	Glaxo Group Limited	Cyprus
Zantac		16838	Glaxo Group Limited	Cyprus
Zantac		1864508	Glaxosmithkline Aebe	Greece
Zantac		18762/19-3-10	Glaxosmithkline Aebe	Greece
Zantac		19572	Glaxo Group Limited	Cyprus
Zantac		1989 09 0747	Glaxosmithkline Pharmaceuticals Sa	Luxembourg

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Zantac		1989 09 0747	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Zantac		1990 02 1682	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Zantac		1990 02 1683	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Zantac		1990 12 0871	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Zantac		1998 08 4607	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Zantac		20098	Glaxo Group Limited	Cyprus
Zantac		215298	Glaxosmithkline Export Ltd	Estonia
Zantac		215398	Glaxosmithkline Export Ltd	Estonia
Zantac		39320/9-9-08	Glaxosmithkline Aebe	Greece
Zantac		448/2007/01 \$ 448/2007/02	Glaxo Wellcome UK Limited	Romania
Zantac		5585187	Glaxosmithkline - Produtos Farmaceuticos, Limitada	Portugal
Zantac		56.004 \$ 57.835	Glaxosmithkline S.A.	Spain
Zantac		56.072	Glaxosmithkline S.A.	Spain
Zantac		6897 \$ 7031	Glaxosmithkline As	Norway
Zantac		7030	Glaxosmithkline As	Norway
Zantac		7518	Glaxosmithkline As	Norway
Zantac		7771	Glaxosmithkline As	Norway
Zantac		812720 (IS)	Glaxosmithkline Ehf.	Iceland
Zantac		8541607 \$ 8541615 \$ 8541631	Glaxosmithkline - Produtos Farmaceuticos, Limitada	Portugal
Zantac		8541714	Glaxosmithkline - Produtos Farmaceuticos, Limitada	Portugal
Zantac		8708	Glaxo Operations Uk Ltd	Finland
Zantac		8708 \$ 9141	Glaxo Operations Uk Ltd	Finland
Zantac		9141	Glaxo Operations Uk Ltd	Finland
Zantac		95-1132	Glaxosmithkline As	Norway
Zantac		9885	Glaxo Operations Uk Ltd	Finland

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Zantac		9885	Glaxo Operations Uk Ltd	Finland
Zantac		99-5788	Glaxosmithkline As	Norway
Zantac		BE121432	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zantac		BE143647	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zantac		BE143647	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zantac		BE147813	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zantac		BE147822	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zantac		BE156974	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zantac		BE157665	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zantac		BE157665	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zantac		BE157665	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zantac		IS/1/13/002/01	Glaxosmithkline Ehf.	Iceland
Zantac		MA 167/01301	Glaxo Wellcome Uk Limited	Malta
Zantac		MA 167/01303	Glaxo Wellcome Uk Limited	Malta
Zantac		MA192/01101	Glaxosmithkline (Ireland) Limited	Malta
Zantac		OGYI-T-1534/01	Glaxosmithkline Kft.	Hungary
Zantac		OGYI-T-1534/02	Glaxosmithkline Kft.	Hungary
Zantac		OGYI-T-1534/03	Glaxosmithkline Kft.	Hungary
Zantac		PA 1077/13/1	Glaxosmithkline (Ireland) Limited	Ireland
Zantac		PA 1077/13/2	Glaxosmithkline (Ireland) Limited	Ireland
Zantac		PA 1077/13/3	Glaxosmithkline (Ireland) Limited	Ireland
Zantac		PA 1077/13/4	Glaxosmithkline (Ireland) Limited	Ireland
Zantac		PA 1077/13/5	Glaxosmithkline (Ireland) Limited	Ireland
Zantac		PL 10949/0042	Glaxo Wellcome Uk Limited	United Kingdom
Zantac		PL 10949/0043	Glaxo Wellcome Uk Limited	United Kingdom
Zantac		PL 10949/0108	Glaxo Wellcome Uk Limited	United Kingdom

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Zantac		PL 10949/0109	Glaxo Wellcome Uk Limited	United Kingdom
Zantac		PL 10949/0137	Glaxo Wellcome Uk Limited	United Kingdom
Zantac		PL 10949/0138	Glaxo Wellcome Uk Limited	United Kingdom
Zantac		R/2839	Glaxosmithkline Export Ltd	Poland
Zantac		R/2840	Glaxosmithkline Export Ltd	Poland
Zantac		RVG 09265	Glaxosmithkline B.V.	Netherlands
Zantac		RVG 11141	Glaxosmithkline B.V.	Netherlands
Zantac		RVG 11161	Glaxosmithkline B.V.	Netherlands
Zantac		RVG 13064	Glaxosmithkline B.V.	Netherlands
Zantic		26170.00.01	Glaxosmithkline Gmbh & Co. Kg	Germany
Ranitidine 75mg Tablets		PL 16028/0122 \$ PL 16028/0123	Galpharm Healthcare Limited	United Kingdom
RANUBER 150 mg COMPRIMIDOS		56008	MEDA Pharma SAU	Spain
RANUBER 300 mg COMPRIMIDOS		57827	MEDA Pharma SAU	Spain
Zantac 75, tabletten 75 mg	NL/H/0112/001	RVG 18864	Omega Pharma Nederland B.V.	Netherlands
Zantac 75 Bruis, bruistabletten 75 mg	NL/H/0112/002	RVG 24636	Omega Pharma Nederland B.V.	Netherlands
Zantac		MA192/01101	Glaxosmithkline (Ireland) Limited	Malta
Zantac Tablets 150mg		MA167/01301	Glaxo Wellcome Uk Limited	Malta
Zantac syrup		MA167/01303	Glaxo Wellcome Uk Limited	Malta
Zantac Solution for Injection or infusion 25mg/ml		MA192/01101	Glaxo SmithKline Ireland Limited	Malta
Zantac		MA 1005/00201	Chefaro Ireland Limited	Malta
Zantac		PL 02855/0082	Omega Pharma Ltd	United Kingdom
Zantac		PL 02855/0082	Omega Pharma Ltd	United Kingdom

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Ranitidine Alice oral solution 30mg/ml	CZ/H/0491/001	09/261/14-C	Alice Loren Co. Ltd	Czech Republic
Kirkland Signature Indigestion Relief 75mg Tablets		PL 16028/0122	Galpharm Healthcare Limited	United Kingdom