



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 January 2022
EMA/26959/2022
Human Medicines Evaluation Division

List of the nationally authorised medicinal products

Active Substance: ranitidine

Procedure No: PSUSA/00002610/202105



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
AZANTAC INJECTABLE 50 mg/2 ml, solution injectable en ampoule	not available	NL13488	LABORATOIRE GLAXOSMITHKLINE	FR
ardoral 75 mg comprimidos recubiertos	not available	63.445	LABORATORIOS CINFA, S.A.	ES
RaniCalm 75mg film coated tablets	not available	PL 17907/0247	BRISTOL LABORATORIES LIMITED	XI
Ranitidine 75mg film coated tablets	not available	PL 17907/0247	BRISTOL LABORATORIES LIMITED	XI
RANIBLOC® 300 mg Compresse rivestite con film	not available	025490057	I.B.N. SAVIO S.R.L.	IT
RANIBLOC® 150 mg Compresse rivestite con film	not available	025490018	I.B.N. SAVIO S.R.L.	IT
Alquén 150 mg comprimidos efervescentes	not available	60.298	SMITHKLINE BEECHAM FARMA, S.A.	ES
Zantac 300 mg comprimidos recubiertos con película	not available	57.835	GLAXOSMITHKLINE S.A.	ES
Zantac 10 mg/ml solución inyectable	not available	56.072	GLAXOSMITHKLINE, S.A.	ES

Zantac 150 mg comprimidos recubiertos con película	not available	56.004	GLAXOSMITHKLINE S.A.	ES
Zantac 25 mg/ml Solution for Injection/Infusion	not available	PA 1077/13/1	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Ulsal 300 mg - Filmtabletten	not available	1-18559	GEBRO PHARMA GMBH	AT
Ulsal 150 mg - Filmtabletten	not available	1-17368	GEBRO PHARMA GMBH	AT
Ulsal 300 mg Brausetabletten	not available	1-19711	GEBRO PHARMA GMBH	AT
Zantac	not available	1864504	GLAXOSMITHKLINE AEBE	GR
ZANTAC	not available	1864502	GLAXOSMITHKLINE AEBE	GR
Zantac® 75 mg tableter.	not available	95- 1132	GLAXOSMITHKLINE AS	NO
Zantac 150 mg brusetabletter	not available	7518	GLAXOSMITHKLINE AS	NO
Zantac 25 mg/ml injeksjonsvæske, oppløsning	not available	7030	GLAXOSMITHKLINE AS	NO
Zantac® 75 mg brusetabletter.	not available	99-5788	GLAXOSMITHKLINE AS	NO
Zantac 150 mg tabletter	not available	6897	GLAXOSMITHKLINE AS	NO
Ulceran 150 mg filmtabletta	not available	OGYI-T-3680/01	TEVA GYÓGYSZERGYÁR ZRT	HU

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Ulceran 150 mg filmtabletta	not available	OGYI-T-3680/02	TEVA GYÓGYSZERGYÁR ZRT	HU
Ranitidine 75mg Tablets	not available	PL 16028/0122	GALPHARM HEALTHCARE LIMITED	XI
Kirkland Signature Indigestion Relief 75mg Tablets	not available	PL 16028/0122	GALPHARM HEALTHCARE LIMITED	XI
Boots Heartburn & Indigestion Relief 75 mg Tablets	not available	PL 16028/0122	GALPHARM HEALTHCARE LIMITED	XI
Galpharm Indigestion Relief 75mg Tablets	not available	PL 16028/0122	GALPHARM HEALTHCARE LIMITED	XI
Morrisons Heartburn & Indigestion Relief 75mg Tablets	not available	PL 16028/0122	GALPHARM HEALTHCARE LIMITED	XI
Asda Indigestion Relief 75mg Tablets	not available	PL 16028/0122	GALPHARM HEALTHCARE LIMITED	XI
RANIDIL 150 mg Compresse effervescenti	not available	024447070	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
RANIDIL 150 mg Compresse rivestite con film	not available	024447029	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
Ranidil 75 mg compresse rivestite con film	not available	024447 169	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT

RANIDIL 300 mg Comprese rivestite con film	not available	024447056	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
Ranidil 75 mg compresse rivestite con film	not available	024447 157	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
RANIDIL 150 mg/10ml Sciroppo	not available	024447068	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
RANIDIL 300 mg Comprese effervescenti	not available	024447094	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
RANIDIL 50 mg/5 ml Soluzione iniettabile per uso endovenoso	not available	024447031	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
Ranitidine 75mg Tablets	not available	PL 16028/0123	GALPHARM HEALTHCARE LIMITED	XI
Boots Heartburn & Indigestion Relief 75 mg Tablet	not available	PL 16028/0123	GALPHARM HEALTHCARE LIMITED	XI
Galpharm Indigestion Relief 75mg Tablets	not available	PL 16028/0123	GALPHARM HEALTHCARE LIMITED	XI
ULCEX 150 mg Comprese rivestite con film	not available	025084017	LABORATORI GUIDOTTI S.P.A.	IT

ULCEX 300 mg Compresses rivestite con film	not available	025084056	LABORATORI GUIDOTTI S.P.A.	IT
Rafitaz Πόσιμο Διάλυμα 30mg/ml	CZ/H/491/01	4197/03-02-2015	RAFARM SA.	GR
Verlost Πόσιμο Διάλυμα 30mg/ml	CZ/H/0491/001	022234	RAFARM SA.	CY
ZANTAC 75, tabletten 75 mg	NL/H/0112/001	RVG 18864	OMEGA PHARMA NEDERLAND B.V.	NL
RANIBEN 150 mg Compresses rivestite con film	not available	025241050	FABBRICA ITALIANA RITROVATI MEDICINALI ED AFFINI F.I.R.M.A. - S.P.A.	IT
RANIBEN 300 mg Compresses rivestite con film	not available	025241086	FABBRICA ITALIANA RITROVATI MEDICINALI ED AFFINI F.I.R.M.A. - S.P.A.	IT
Zantac Solution for Injection or infusion 25mg/ml	not available	MA192/01101	GLAXOSMITHKLINE (IRELAND) LIMITED	MT
Zantac 150 mg Film- Coated Tablets	not available	MA192/01102	GLAXOSMITHKLINE (IRELAND) LIMITED	MT
AZANTAC 150 mg, comprimé effervescent	not available	NL16208	LABORATOIRE GLAXOSMITHKLINE	FR
AZANTAC 300 mg, comprimé effervescent	not available	NL17391	LABORATOIRE GLAXOSMITHKLINE	FR
Zantac 75	not available	PL 02855/0082	OMEGA PHARMA LTD	XI

Ulsal 50 mg/2 ml - Ampullen	not available	1-17369	GEBRO PHARMA GMBH	AT
RANITAL 150 mg, Filmom obalené tablety	not available	09/0007/87-S	SANDOZ PHARMACEUTICALS D.D.	SK
Zantac 25 mg/ml stungulyf, lausn.	not available	812720	GLAXOSMITHKLINE PHARMA A/S	IS
Ranitidine-ratiopharm Bruis 300 mg, bruistabletten	NL/H/0264/002	RVG 26604	RATIOPHARM GMBH	NL
Ranitidine 300 mg Effervescent Tablets	NL/H/0264/002	PL 00289/2480	TEVA UK LIMITED	XI
Ranitidine 75mg Tablets	UK/H/0540/001	PL 15773/0405	RATIOPHARM GMBH	XI
Zantac Injection 50 mg/2 ml	not available	20098	GLAXOSMITHKLINE (IRELAND) LIMITED	CY
Ranitidine 150mg Tablets	not available	PL 20416/0321	CRESCENT PHARMA LIMITED	XI
Ranitidine 300mg Tablets	not available	PL 20416/0322	CRESCENT PHARMA LIMITED	XI
Ranitidin ratiopharm 75 mg tableter	NO/H/0298/001	02-1175	RATIOPHARM GMBH	NO
Ulsal 150 mg Brausetabletten	not available	1-19713	GEBRO PHARMA GMBH	AT
Ranitidine 30mg/ml Oral Solution	EL/H/0237/001	PL 17780/1000	ZENTIVA PHARMA UK LIMITED	XI
RANITAL 300 mg, Filmom obalené tablety	not available	09/0007/87-S	SANDOZ PHARMACEUTICALS D.D.	SK

Ulceran 300 mg filmtabletta	not available	OGYI-T-3680/03	TEVA GYÓGYSZERGYÁR ZRT	HU
RANITIDINE BIOGARAN 150 mg, comprimé effervescent	not available	NL16207	LABORATOIRES SAINT- GERMAIN	FR
RANITIDINE BIOGARAN 300 mg, comprimé effervescent	not available	NL17397	LABORATOIRES SAINT- GERMAIN	FR