14 March 2019
EMA/193293/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: paracetamol / tramadol

Procedure no.: PSUSA/00002310/201808

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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
Tramadol + Paracetamol Aristo 75 mg + 650 mg comprimidos efervescentes	PT/H/1210/002	5669775	ARISTO PHARMA IBERIA, S.L.	PT
Tramadol + Paracetamol Aristo 75 mg + 650 mg comprimidos efervescentes	PT/H/1210/002	5669809	ARISTO PHARMA IBERIA, S.L.	PT
Clanderon 75 mg/650 mg comprimidos efervescentes	PT/H/1210/002	80416	ARISTO PHARMA IBERIA, S.L.	ES
Zilpen 75 mg / 650 mg comprimidos	PT/H/0631/002	5456025	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Zilpen 75 mg / 650 mg comprimidos	PT/H/0631/002	5456017	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Poltram Combo Forte, 75 mg + 650 mg, tabletki powlekane	not available	23297	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	PL
Tramadol + Paracetamol Verum Pharma LP 75 mg + 650 mg comprimidos de libertação prolongada	not available	15/H/0134/001	VERUM PHARMA- PRODUTOS FARMACÊUTICOS, UNIPESSOAL, LDA.	PT
Tramadol + Paracetamol Verum Pharma LP 75 mg + 650 mg comprimidos de libertação prolongada	not available	15/H/0134/001	VERUM PHARMA- PRODUTOS FARMACÊUTICOS, UNIPESSOAL, LDA.	PT
Tramadol + Paracetamol Verum Pharma LP 75 mg + 650 mg comprimidos de libertação prolongada	not available	15/H/0134/001	VERUM PHARMA- PRODUTOS FARMACÊUTICOS, UNIPESSOAL, LDA.	PT
Tramadol + Paracetamol Verum Pharma LP 75 mg	not available	15/H/0134/001	VERUM PHARMA- PRODUTOS FARMACÊUTICOS,	PT

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**
+ 650 mg comprimidos de libertação prolongada			UNIPESSOAL, LDA.	
Tramadol + Paracetamol Verum Pharma LP 75 mg + 650 mg comprimidos de libertação prolongada	not available	15/H/0134/001	VERUM PHARMA- PRODUTOS FARMACÊUTICOS, UNIPESSOAL, LDA.	PT
Tramadol + Paracetamol Verum Pharma LP 75 mg + 650 mg comprimidos de libertação prolongada	not available	15/H/0134/001	VERUM PHARMA- PRODUTOS FARMACÊUTICOS, UNIPESSOAL, LDA.	PT
Tramadol + Paracetamol Verum Pharma LP 75 mg + 650 mg comprimidos de libertação prolongada	not available	15/H/0134/001	VERUM PHARMA- PRODUTOS FARMACÊUTICOS, UNIPESSOAL, LDA.	PT
Tramadol + Paracetamol Verum Pharma LP 75 mg + 650 mg comprimidos de libertação prolongada	not available	5680723	VERUM PHARMA- PRODUTOS FARMACÊUTICOS, UNIPESSOAL, LDA.	PT
Tramadol + Paracetamol Verum Pharma LP 75 mg + 650 mg comprimidos de libertação prolongada	not available	5680715	VERUM PHARMA- PRODUTOS FARMACÊUTICOS, UNIPESSOAL, LDA.	PT
Tramadol + Paracetamol Verum Pharma LP 75 mg + 650 mg comprimidos de libertação prolongada	not available	5680731	VERUM PHARMA- PRODUTOS FARMACÊUTICOS, UNIPESSOAL, LDA.	PT
Tramadol + Paracetamol Verum Pharma LP 75 mg + 650 mg comprimidos de libertação prolongada	not available	15/H/0134/001	VERUM PHARMA- PRODUTOS FARMACÊUTICOS, UNIPESSOAL, LDA.	PT
Tramadol + Paracetamol Verum Pharma LP 75 mg + 650 mg comprimidos de libertação prolongada	not available	15/H/0134/001	VERUM PHARMA- PRODUTOS FARMACÊUTICOS, UNIPESSOAL, LDA.	PT

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Tramadol + Paracetamol Verum Pharma LP 75 mg + 650 mg comprimidos de libertação prolongada	not available	15/H/0134/001	VERUM PHARMA- PRODUTOS FARMACÊUTICOS, UNIPESSOAL, LDA.	PT
Tramadol + Paracetamol Verum Pharma LP 75 mg + 650 mg comprimidos de libertação prolongada	not available	15/H/0134/001	VERUM PHARMA- PRODUTOS FARMACÊUTICOS, UNIPESSOAL, LDA.	PT
Tramadol/Paracetamol 75 mg / 650 mg tablets	UK/H/6405/002	PL35533/0043	ASPIRE PHARMA LIMITED	UK
ZALDIAR® 37,5 mg/ 325 mg filmom obložene tablete	not available	UP/I-530-09/09-02/404	STADA D.O.O.	HR
Tramadol/Paracetamol Sandoz 75 mg/650 mg tablett	PT/H/0919/002	15-10684	SANDOZ A/S	NO
Trampara 75 mg/650 mg tablett	PT/H/0919/002	52914	SANDOZ A/S	SE
Tramadolor Plus 75 mg/650 mg tabletta	PT/H/0919/002	OGYI-T-22942/05	SANDOZ HUNGÁRIA KFT	HU
Tramadolor Plus 75 mg/650 mg tabletta	PT/H/0919/002	OGYI-T-22942/06	SANDOZ HUNGÁRIA KFT	HU
Tramadolor Plus 75 mg/650 mg tabletta	PT/H/0919/002	OGYI-T-22942/07	SANDOZ HUNGÁRIA KFT	HU
Tramadol/Paracetamol Sandoz 75 mg/650 mg comprimate	PT/H/0919/002	8751/2016/01	S.C. SANDOZ S.R.L.	RO
Tramadol/Paracetamol Sandoz 75 mg/650 mg comprimate	PT/H/0919/002	8751/2016/02	S.C. SANDOZ S.R.L.	RO
Tramadol/Paracetamol Sandoz 75 mg/650 mg comprimate	PT/H/0919/002	8751/2016/03	S.C. SANDOZ S.R.L.	RO
Tramadol/Paracetamol	PT/H/0919/002	8751/2016/04	S.C. SANDOZ S.R.L.	RO

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Sandoz 75 mg/650 mg comprimate				
Tramadol/Paracetamol Sandoz 75 mg/650 mg comprimate	PT/H/0919/002	8751/2016/05	S.C. SANDOZ S.R.L.	RO
Tramadol/Paracetamol Sandoz 75 mg/650 mg comprimate	PT/H/0919/002	8751/2016/06	S.C. SANDOZ S.R.L.	RO
Tramadol/Paracetamol Sandoz 75 mg/650 mg comprimate	PT/H/0919/002	8751/2016/07	S.C. SANDOZ S.R.L.	RO
Tramadol/Paracetamol Sandoz 75 mg/650 mg comprimate	PT/H/0919/002	8751/2016/08	S.C. SANDOZ S.R.L.	RO
Tramadol/Paracetamol Sandoz 75 mg/650 mg comprimate	PT/H/0919/002	8751/2016/09	S.C. SANDOZ S.R.L.	RO
Tramadol/Paracetamol Sandoz 75 mg/650 mg comprimate	PT/H/0919/002	8751/2016/10	S.C. SANDOZ S.R.L.	RO
Tramadol/Paracetamol Sandoz 75 mg/650 mg comprimate	PT/H/0919/002	8751/2016/11	S.C. SANDOZ S.R.L.	RO
Tramadol/Paracetamol Sandoz 75 mg/650 mg comprimate	PT/H/0919/002	8751/2016/12	S.C. SANDOZ S.R.L.	RO
Tramadolor plus Paracetamol 75 mg/650 mg Tabletten	PT/H/0919/002	95378.00.00	HEXAL AG	DE
Tramadolor Plus 75 mg/650 mg tabletta	PT/H/0919/002	OGYI-T-22942/10	SANDOZ HUNGÁRIA KFT	HU
Tramadol/paracetamol "Sandoz", tabletter 75 mg/650 mg	PT/H/0919/002	55874	SANDOZ A/S	DK

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Tramadol + Paracetamol Litexil	PT/H/0919/002	5449343	SANDOZ FARMACÊUTICA LDA.	PT
Tramadol + Paracetamol Litexil	PT/H/0919/002	5449350	SANDOZ FARMACÊUTICA LDA.	PT
Tramadol + Paracetamol Litexil	PT/H/0919/002	5449368	SANDOZ FARMACÊUTICA LDA.	PT
Tramadol + Paracetamol Litexil	PT/H/0919/002	5449376	SANDOZ FARMACÊUTICA LDA.	PT
Tramadol + Paracetamol Litexil	PT/H/0919/002	5449400	SANDOZ FARMACÊUTICA LDA.	PT
Tramadol + Paracetamol Litexil	PT/H/0919/002	5449418	SANDOZ FARMACÊUTICA LDA.	PT
Tramadol + Paracetamol Litexil	PT/H/0919/002	5449426	SANDOZ FARMACÊUTICA LDA.	PT
Tramadol + Paracetamol Litexil	PT/H/0919/002	5449434	SANDOZ FARMACÊUTICA LDA.	PT
Tramadol + Paracetamol Litexil	PT/H/0919/002	5449442	SANDOZ FARMACÊUTICA LDA.	PT
Tramadol + Paracetamol Litexil	PT/H/0919/002	5449459	SANDOZ FARMACÊUTICA LDA.	PT
Tramadol HCl/Paracetamol Sandoz 75/650 mg, tabletten	PT/H/0919/002	RVG 117332	SANDOZ B.V.	NL
Delparan MAX, 75 mg + 650 mg, tabletki	PT/H/0919/002	23272	SANDOZ GMBH	PL
Tramadol/Paracetamol ratiopharm 75mg/650mg comprimidos recubiertos con película	not available	77385	RATIOPHARM ESPAÑA S.A.,	ES
Zaldiar effervescens 37,5 mg/325 mg šumivé tab	not available	65/0080/11-S	STADA ARZNEIMITTEL AG	SK
ZALDIAR 37,5 mg/325 mg, õhukese polümeerikattega	not available	437704	STADA ARZNEIMITTEL AG	EE

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tabletid				
Tramadol + Paracetamol KRKA 75 mg + 650 mg comprimidos de libertação prolongada	HU/H/0190/003	5667019	KRKA, D.D., NOVO MESTO	PT
Tramadol + Paracetamol KRKA 75 mg + 650 mg comprimidos de libertação prolongada	HU/H/0190/003	5667027	KRKA, D.D., NOVO MESTO	PT
Tramadol + Paracetamol KRKA 75 mg + 650 mg comprimidos de libertação prolongada	HU/H/0190/003	5667035	KRKA, D.D., NOVO MESTO	PT
Doreta SR 75 mg/650 mg tablety s predĺženým uvoľňovaním	HU/H/0190/003	65/0452/15-S	KRKA, D.D., NOVO MESTO	SK
Doreta SR 75 mg/650 mg retard tabletta	HU/H/0190/003	OGYI-T-21059/43	KRKA, D.D., NOVO MESTO	HU
Doreta SR 75 mg/650 mg retard tabletta	HU/H/0190/003	OGYI-T-21059/44	KRKA, D.D., NOVO MESTO	HU
Doreta SR 75 mg/650 mg retard tabletta	HU/H/0190/003	OGYI-T-21059/45	KRKA, D.D., NOVO MESTO	HU
Doreta SR 75 mg/650 mg retard tabletta	HU/H/0190/003	OGYI-T-21059/46	KRKA, D.D., NOVO MESTO	HU
Doreta SR 75 mg/650 mg retard tabletta	HU/H/0190/003	OGYI-T-21059/47	KRKA, D.D., NOVO MESTO	HU
Doreta SR 75 mg/650 mg retard tabletta	HU/H/0190/003	OGYI-T-21059/48	KRKA, D.D., NOVO MESTO	HU
Doreta SR 75 mg/650 mg retard tabletta	HU/H/0190/003	OGYI-T-21059/49	KRKA, D.D., NOVO MESTO	HU
Doreta SR 75 mg/650 mg retard tabletta	HU/H/0190/003	OGYI-T-21059/50	KRKA, D.D., NOVO MESTO	HU
Doreta SR 75 mg/650 mg retard tabletta	HU/H/0190/003	OGYI-T-21059/51	KRKA, D.D., NOVO MESTO	HU

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
Doreta SR 75 mg/650 mg retard tabletta	HU/H/0190/003	OGYI-T-21059/52	KRKA, D.D., NOVO MESTO	HU
Doreta 75 mg/650 mg pailginto atpalaidavimo tabletės	HU/H/0190/003	LT/1/09/1638/022	KRKA, D.D., NOVO MESTO	LT
Doreta 75 mg/650 mg pailginto atpalaidavimo tabletės	HU/H/0190/003	LT/1/09/1638/023	KRKA, D.D., NOVO MESTO	LT
Doreta 75 mg/650 mg pailginto atpalaidavimo tabletės	HU/H/0190/003	LT/1/09/1638/024	KRKA, D.D., NOVO MESTO	LT
Doreta 75 mg/650 mg pailginto atpalaidavimo tabletės	HU/H/0190/003	LT/1/09/1638/025	KRKA, D.D., NOVO MESTO	LT
Doreta 75 mg/650 mg pailginto atpalaidavimo tabletės	HU/H/0190/003	LT/1/09/1638/026	KRKA, D.D., NOVO MESTO	LT
Doreta 75 mg/650 mg pailginto atpalaidavimo tabletės	HU/H/0190/003	LT/1/09/1638/027	KRKA, D.D., NOVO MESTO	LT
Doreta 75 mg/650 mg pailginto atpalaidavimo tabletės	HU/H/0190/003	LT/1/09/1638/028	KRKA, D.D., NOVO MESTO	LT
Дорета SR 75 mg/650 mg таблетки с удължено освобождаване	HU/H/0190/003	20150413	KRKA, D.D., NOVO MESTO	BG
Doreta Prolong 75 mg/650 mg tablety s prodlouženým uvolňováním	HU/H/0190/003	65/575/15-C	KRKA, D.D., NOVO MESTO	CZ
Doreta, 75 mg/650 mg toimeainet prolongeeritult	HU/H/0190/003	898615	KRKA, D.D., NOVO MESTO	EE

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vabastavad tabletid				
Doreta 75 mg/650 mg ilgstošās darbības tabletes	HU/H/0190/003	15-0311	KRKA, D.D., NOVO MESTO	LV
Doreta SR, 75 mg + 650 mg, tabletki o przedłużonym uwalnianiu	HU/H/0190/003	22895	KRKA, D.D., NOVO MESTO	PL
Doreta SR 75 mg/650 mg tablete s podaljšanim sproščanjem	HU/H/0190/003	H/09/00506/045	KRKA, D.D., NOVO MESTO	SI
Doreta SR 75 mg/650 mg tablete s podaljšanim sproščanjem	HU/H/0190/003	H/09/00506/046	KRKA, D.D., NOVO MESTO	SI
Doreta SR 75 mg/650 mg tablete s podaljšanim sproščanjem	HU/H/0190/003	H/09/00506/047	KRKA, D.D., NOVO MESTO	SI
Doreta SR 75 mg/650 mg tablete s podaljšanim sproščanjem	HU/H/0190/003	H/09/00506/048	KRKA, D.D., NOVO MESTO	SI
Doreta SR 75 mg/650 mg tablete s podaljšanim sproščanjem	HU/H/0190/003	H/09/00506/049	KRKA, D.D., NOVO MESTO	SI
Doreta SR 75 mg/650 mg tablete s podaljšanim sproščanjem	HU/H/0190/003	H/09/00506/050	KRKA, D.D., NOVO MESTO	SI
Doreta SR 75 mg/650 mg tablete s podaljšanim sproščanjem	HU/H/0190/003	H/09/00506/051	KRKA, D.D., NOVO MESTO	SI
Doreta SR 75 mg/650 mg tablete s podaljšanim sproščanjem	HU/H/0190/003	H/09/00506/052	KRKA, D.D., NOVO MESTO	SI
Doreta SR 75 mg/650 mg tablete s podaljšanim sproščanjem	HU/H/0190/003	H/09/00506/053	KRKA, D.D., NOVO MESTO	SI

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Doreta SR 75 mg/650 mg tablete s podaljšanim sproščanjem	HU/H/0190/003	H/09/00506/054	KRKA, D.D., NOVO MESTO	SI
Doreta SR 75 mg/650 mg tablete s podaljšanim sproščanjem	HU/H/0190/003	H/09/00506/055	KRKA, D.D., NOVO MESTO	SI
Doreta SR 75 mg/650 mg tablete s podaljšanim sproščanjem	HU/H/0190/003	H/09/00506/056	KRKA, D.D., NOVO MESTO	SI
Doreta SR 75 mg/650 mg tablete s podaljšanim sproščanjem	HU/H/0190/003	H/09/00506/057	KRKA, D.D., NOVO MESTO	SI
Doreta SR 75 mg/650 mg tablete s podaljšanim sproščanjem	HU/H/0190/003	H/09/00506/058	KRKA, D.D., NOVO MESTO	SI
Doreta EP 75 mg/650 mg comprimate cu eliberare prelungită	HU/H/0190/003	8527/2016/01	KRKA, D.D., NOVO MESTO	RO
Doreta EP 75 mg/650 mg comprimate cu eliberare prelungită	HU/H/0190/003	8527/2016/02	KRKA, D.D., NOVO MESTO	RO
Doreta EP 75 mg/650 mg comprimate cu eliberare prelungită	HU/H/0190/003	8527/2016/03	KRKA, D.D., NOVO MESTO	RO
Doreta EP 75 mg/650 mg comprimate cu eliberare prelungită	HU/H/0190/003	8527/2016/04	KRKA, D.D., NOVO MESTO	RO
Doreta EP 75 mg/650 mg comprimate cu eliberare prelungită	HU/H/0190/003	8527/2016/05	KRKA, D.D., NOVO MESTO	RO
Doreta EP 75 mg/650 mg comprimate cu eliberare prelungită	HU/H/0190/003	8527/2016/06	KRKA, D.D., NOVO MESTO	RO
Doreta EP 75 mg/650 mg	HU/H/0190/003	8527/2016/07	KRKA, D.D., NOVO MESTO	RO

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comprimate cu eliberare prelungită				
Doreta EP 75 mg/650 mg comprimate cu eliberare prelungită	HU/H/0190/003	8527/2016/08	KRKA, D.D., NOVO MESTO	RO
Doreta EP 75 mg/650 mg comprimate cu eliberare prelungită	HU/H/0190/003	8527/2016/09	KRKA, D.D., NOVO MESTO	RO
Doreta EP 75 mg/650 mg comprimate cu eliberare prelungită	HU/H/0190/003	8527/2016/10	KRKA, D.D., NOVO MESTO	RO
Doreta EP 75 mg/650 mg comprimate cu eliberare prelungită	HU/H/0190/003	8527/2016/11	KRKA, D.D., NOVO MESTO	RO
Doreta EP 75 mg/650 mg comprimate cu eliberare prelungită	HU/H/0190/003	8527/2016/12	KRKA, D.D., NOVO MESTO	RO
Doreta EP 75 mg/650 mg comprimate cu eliberare prelungită	HU/H/0190/003	8527/2016/13	KRKA, D.D., NOVO MESTO	RO
Doreta EP 75 mg/650 mg comprimate cu eliberare prelungită	HU/H/0190/003	8527/2016/14	KRKA, D.D., NOVO MESTO	RO
Tramadol + Paracetamol KRKA 75 mg + 650 mg comprimidos de libertação prolongada	HU/H/0190/003	5679469	KRKA, D.D., NOVO MESTO	PT
Tramadol + Paracetamol Bluepharma 75 mg + 650 mg comprimidos	not available	5493564	BLUEPHARMA GENÉRICOS - COMÉRCIO DE MEDICAMENTOS, S.A.	PT
Tramadol + Paracetamol Bluepharma 75 mg + 650 mg comprimidos	not available	5493556	BLUEPHARMA GENÉRICOS - COMÉRCIO DE MEDICAMENTOS, S.A.	PT
Pazital 37,5 mg/325 mg	not available	66853	GRÜNENTHAL PHARMA S.A.	ES

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comprimidos recubiertos con película				
IXPRIM® 37.5 mg/325 mg, comprimé pelliculé.	FR/H/0211/001	34009 358 573 9 2	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM® 37.5 mg/325 mg, comprimé pelliculé.	FR/H/0211/001	34009 563 605 6 7	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM® 37.5 mg/325 mg, comprimé pelliculé.	FR/H/0211/001	34009 563 599 6 7	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM® 37.5 mg/325 mg, comprimé pelliculé.	FR/H/0211/001	34009 563 606 2 8	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM® 37.5 mg/325 mg, comprimé pelliculé.	FR/H/0211/001	34009 563 615 1 9	LABORATOIRES GRÜNENTHAL S.A.S.	FR
TRAMACET 37.5mg/325mg Film coated tablets	FR/H/0211/001	PL 21727/0039	GRÜNENTHAL LTD.	UK
IXPRIM® 37.5 mg/325 mg, comprimé pelliculé.	FR/H/0211/001	34009 563 618 0 9	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM® 37.5 mg/325 mg, comprimé pelliculé.	FR/H/0211/001	34009 563 616 8 7	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM® 37.5 mg/325 mg, comprimé pelliculé.	FR/H/0211/001	34009 359 228 3 0	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM® 37.5 mg/325 mg, comprimé pelliculé.	FR/H/0211/001	34009 563 614 5 8	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM® 37.5 mg/325 mg, comprimé pelliculé.	FR/H/0211/001	34009 563 617 4 8	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM® 37.5 mg/325 mg, comprimé pelliculé.	FR/H/0211/001	34009 359 230 8 0	LABORATOIRES GRÜNENTHAL S.A.S.	FR
PONTALSIC 37,5 mg/325 mg, filmomhulde tabletten	FR/H/0211/001	BE254536	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg / 325 mg, comprimés pelliculés	FR/H/0211/001	BE254536	SA GRÜNENTHAL N.V.	BE
Pontalsic 37,5 mg/325	FR/H/0211/001	65158	GRÜNENTHAL PHARMA S.A.	ES

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mg comprimidos recubiertos con película				
ZALDIAR 37,5 mg/325 mg potahované tablety	not available	65/237/02-C	STADA ARZNEIMITTEL AG	CZ
Diliban75 mg/650 mg comprimidos	not available	75633	LABORATORIOS GEBRO PHARMA, S.A.	ES
Tramadol/Paracetamol Krka 75 mg/650 mg filmomhulde tabletten	HU/H/0463/002	BE511377	KRKA, D.D., NOVO MESTO	BE
Tramadol/Paracetamol Krka 75 mg/650 mg filmtabletta	HU/H/0463/ 002	OGYI-T-23201/01	KRKA, D.D., NOVO MESTO	HU
Tramadol/Paracetamol Krka 75 mg/650 mg filmtabletta	HU/H/0463/ 002	OGYI-T-23201/02	KRKA, D.D., NOVO MESTO	HU
Tramadol/Paracetamol Krka 75 mg/650 mg filmtabletta	HU/H/0463/ 002	OGYI-T-23201/03	KRKA, D.D., NOVO MESTO	HU
ZARACET 75 mg/650 mg filmom obložene tablete	not available	HR-H-549246288	BELUPO D.D.	HR
ZARACET 75 mg/650 mg filmom obložene tablete	not available	HR-H-549246288	BELUPO D.D.	HR
ZARACET 75 mg/650 mg filmom obložene tablete	not available	HR-H-549246288	BELUPO D.D.	HR
ZALDIAR EFFERVESCENS 37,5 mg/325 mg šumivé tablety	not available	65/107/11-C	STADA ARZNEIMITTEL AG	CZ
Zaldiar 37,5 mg/325 mg filmtabletta	FR/H/0212/001	OGYI-T-20557/01	STADA ARZNEIMITTEL AG	HU
Zaldiar 37,5 mg/325 mg filmtabletta	FR/H/0212/001	OGYI-T-20557/02	STADA ARZNEIMITTEL AG	HU
Zaldiar 37,5 mg/325 mg filmtabletta	FR/H/0212/001	OGYI-T-20557/05	STADA ARZNEIMITTEL AG	HU

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
Zaldiar 37,5 mg/325 mg filmtabletta	FR/H/0212/001	OGYI-T-20557/06	STADA ARZNEIMITTEL AG	HU
Zaldiar 37,5 mg/325 mg filmtabletta	FR/H/0212/001	OGYI-T-20557/03	STADA ARZNEIMITTEL AG	HU
Zaldiar 37,5 mg/325 mg filmsko obložene tablete	FR/H/0212/001	H/05/01692/003	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg filmsko obložene tablete	FR/H/0212/001	H/05/01692/002	STADA ARZNEIMITTEL AG	SI
ZALDIAR 37,5 mg/325 mg, comprimidos revestidos por película	FR/H/0212/001	5359583	GRÜNENTHAL S.A.	PT
ZALDIAR 37,5 mg/325 mg, comprimidos revestidos por película	FR/H/0212/001	5983085	GRÜNENTHAL S.A.	PT
ZALDIAR 37,5 mg/325 mg, comprimidos revestidos por película	FR/H/0212/001	5319785	GRÜNENTHAL S.A.	PT
ZALDIAR 37,5 mg/325 mg, filmuhúðaðar töflur	FR/H/0212/001	IS/1/02/038/01	GRÜNENTHAL GMBH	IS
Zaldiar 37,5 mg/325 mg filmsko obložene tablete	FR/H/0212/001	H/05/01692/001	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg filmsko obložene tablete	FR/H/0212/001	H/05/01692/009	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg filmsko obložene tablete	FR/H/0212/001	H/05/01692/006	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg filmsko obložene tablete	FR/H/0212/001	H/05/01692/008	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg filmsko obložene tablete	FR/H/0212/001	H/05/01692/007	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg filmsko obložene tablete	FR/H/0212/001	H/05/01692/005	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg filmsko obložene tablete	FR/H/0212/001	H/05/01692/010	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg	FR/H/0212/001	H/05/01692/011	STADA ARZNEIMITTEL AG	SI

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
filmsko obložene tablete				
Zaldiar 37,5 mg/325 mg filmsko obložene tablete	FR/H/0212/001	H/05/01692/004	STADA ARZNEIMITTEL AG	SI
ZALDIAR® 37.5 mg/325 mg, comprimé pelliculé	FR/H/0212/001	34009 563 603-3 8	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR® 37.5 mg/325 mg, comprimé pelliculé	FR/H/0212/001	34009 563 597-3 8	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR® 37.5 mg/325 mg, comprimé pelliculé	FR/H/0212/001	34009 563 602-7 7	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR® 37.5 mg/325 mg, comprimé pelliculé	FR/H/0212/001	34009 358 569-1 3	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR 37,5 mg/325 mg, comprimidos revestidos por película	FR/H/0212/001	5319884	GRÜNENTHAL S.A.	PT
ZALDIAR 37,5 mg/325 mg, comprimidos revestidos por película	FR/H/0212/001	5359682	GRÜNENTHAL S.A.	PT
ZALDIAR 37,5 mg/325 mg, comprimidos revestidos por película	FR/H/0212/001	5359484	GRÜNENTHAL S.A.	PT
Zaldiar 37,5 mg/325 mg comprimidos recubiertos con película	FR/H/0212/001	65149	GRÜNENTHAL PHARMA S.A.	ES
ZALDIAR 37,5 mg/325 mg, filmomhulde tabletten	FR/H/0212/001	RVG 28113	GRÜNENTHAL B.V.	NL
ZALDIAR 37,5 mg / 325 mg, comprimés pelliculés	FR/H/0212/001	2003010017	SA GRÜNENTHAL N.V.	LU
Zaldiar 37,5 mg/325 mg Filmtabletten	FR/H/0212/001	1-25827	GRÜNENTHAL GES. M.B.H.	AT
ZALDIAR 37,5 mg / 325 mg, comprimés pelliculés	FR/H/0212/001	BE 244553	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg, filmomhulde	FR/H/0212/001	BE 244553	SA GRÜNENTHAL N.V.	BE

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
tabletten				
ZALDIAR 37,5 mg/325 mg Filmtabletten	FR/H/0212/001	55310.00.00	GRÜNENTHAL GMBH	DE
ZALDIAR 37,5 mg/325 mg, επικαλυμμένα με λεπτό υμένιο δισκία	FR/H/0212/001	62964/11-07-2017	GRÜNENTHAL GMBH	GR
Ixprim 37.5 mg/325 mg film coated-tablets	FR/H/0212/001	PA 2242/6/1	GRÜNENTHAL PHARMA LTD.	IE
Zaldiar, (37,5 mg + 325 mg), tabletki powlekane	not available	10733	STADA ARZNEIMITTEL AG	PL
Diliban Retard 75 mg/650 mg comprimidos de liberación prolongada	IS/H/0168/001	73638	LABORATORIOS GEBRO PHARMA, S.A.	ES
Tramadol + Paracetamol Aristo 75 mg + 650 mg comprimidos revestidos por película	PT/H/1315/002	5659206	ARISTO PHARMA IBERIA, S.L.	PT
Tramadol + Paracetamol Aristo 75 mg + 650 mg comprimidos revestidos por película	PT/H/1315/002	5659214	ARISTO PHARMA IBERIA, S.L.	PT
Tramadol + Paracetamol Aristo 75 mg + 650 mg comprimidos revestidos por película	PT/H/1315/002	5659222	ARISTO PHARMA IBERIA, S.L.	PT
Clanderon 75 mg / 650 mg comprimidos recubiertos con pelicula	PT/H/1315/002	81005	ARISTO PHARMA IBERIA, S.L.	ES
Tramadolo e Paracetamolo Aristo 75 mg / 650 mg compresse rivestite con film	PT/H/1315/002	043580048	ARISTO PHARMA GMBH (ART 57)	IT
Tramadolo e Paracetamolo Aristo 75	PT/H/1315/002	043580051	ARISTO PHARMA GMBH (ART 57)	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
mg / 650 mg compresse rivestite con film				
Tramadolo e Paracetamolo Aristo 75 mg / 650 mg compresse rivestite con film	PT/H/1315/002	043580063	ARISTO PHARMA GMBH (ART 57)	IT
Tramadol / Paracetamol Aristo® 75 mg/650 mg Filmtabletten	PT/H/1315/002	93453.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Tramadolo e Paracetamolo Aristo 75 mg / 650 mg compresse rivestite con film	PT/H/1315/002	043580087	ARISTO PHARMA GMBH (ART 57)	IT
Tramadol + Paracetamol toLife 75 mg + 650 mg comprimidos	PT/H/632/02	5488721	TOLIFE - PRODUTOS FARMACÊUTICOS, S.A.	PT
Tramadol + Paracetamol toLife 75 mg + 650 mg comprimidos	PT/H/632/02	5488713	TOLIFE - PRODUTOS FARMACÊUTICOS, S.A.	PT
Diliban 75 mg/650 mg Tabletten	not available	137919	GEBRO PHARMA GMBH	AT
Zaldiar Effervescent, (37,5 mg + 325 mg), tabletki musujące	not available	16461	STADA ARZNEIMITTEL AG	PL
Tramabian® 75 mg/650 mg Filmtabletten	HU/H/0190/002	93508.00.00	TAD PHARMA GMBH	DE
Tramadol/Paracetamol Krka 75 mg/650 mg Filmtabletten	HU/H/0190/002	136152	KRKA, D.D., NOVO MESTO	AT
Дорета 75 mg/650 mg филмирани таблетки	HU/H/0190/002	20110723	KRKA, D.D., NOVO MESTO	BG
Doreta 75 mg/650 mg plėvele dengtos tabletės	HU/H/0190/002	LT/1/09/1638/012	KRKA, D.D., NOVO MESTO	LT
Doreta 75 mg/650 mg	HU/H/0190/002	LT/1/09/1638/013	KRKA, D.D., NOVO MESTO	LT

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
plėvele dengtos tabletės				
Doreta 75 mg/650 mg plėvele dengtos tabletės	HU/H/0190/002	LT/1/09/1638/014	KRKA, D.D., NOVO MESTO	LT
Doreta 75 mg/650 mg plėvele dengtos tabletės	HU/H/0190/002	LT/1/09/1638/015	KRKA, D.D., NOVO MESTO	LT
Doreta 75 mg/650 mg plėvele dengtos tabletės	HU/H/0190/002	LT/1/09/1638/016	KRKA, D.D., NOVO MESTO	LT
Doreta 75 mg/650 mg plėvele dengtos tabletės	HU/H/0190/002	LT/1/09/1638/017	KRKA, D.D., NOVO MESTO	LT
Doreta 75 mg/650 mg plėvele dengtos tabletės	HU/H/0190/002	LT/1/09/1638/018	KRKA, D.D., NOVO MESTO	LT
Doreta 75 mg/650 mg plėvele dengtos tabletės	HU/H/0190/002	LT/1/09/1638/019	KRKA, D.D., NOVO MESTO	LT
Doreta 75 mg/650 mg plėvele dengtos tabletės	HU/H/0190/002	LT/1/09/1638/020	KRKA, D.D., NOVO MESTO	LT
Doreta 75 mg/650 mg plėvele dengtos tabletės	HU/H/0190/002	LT/1/09/1638/021	KRKA, D.D., NOVO MESTO	LT
Doreta, 75 mg/650 mg õhukese polümeerikattega tabletid	HU/H/0190/002	772412	KRKA, D.D., NOVO MESTO	EE
Doreta 75 mg/650 mg apvalkotās tabletes	HU/H/0190/002	12-0062	KRKA, D.D., NOVO MESTO	LV
Doreta, 75 mg + 650 mg, tabletki powlekane	HU/H/0190/002	19609	KRKA, D.D., NOVO MESTO	PL
Doreta 75 mg/650 mg filmom obalené tablety	HU/H/0190/002	65/0742/11-S	KRKA, D.D., NOVO MESTO	SK
Doreta 75 mg/650 mg potahované tablety	HU/H/0190/002	65/185/12-C	KRKA, D.D., NOVO MESTO	CZ
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/ 002	H/09/00506/012	KRKA, D.D., NOVO MESTO	SI
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/ 002	H/09/00506/013	KRKA, D.D., NOVO MESTO	SI
Doreta 75 mg/650 mg	HU/H/0190/ 002	H/09/00506/014	KRKA, D.D., NOVO MESTO	SI

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
filmsko obložene tablete				
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/ 002	H/09/00506/015	KRKA, D.D., NOVO MESTO	SI
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/ 002	H/09/00506/016	KRKA, D.D., NOVO MESTO	SI
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/ 002	H/09/00506/017	KRKA, D.D., NOVO MESTO	SI
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/ 002	H/09/00506/018	KRKA, D.D., NOVO MESTO	SI
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/ 002	H/09/00506/019	KRKA, D.D., NOVO MESTO	SI
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/ 002	H/09/00506/020	KRKA, D.D., NOVO MESTO	SI
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/ 002	H/09/00506/021	KRKA, D.D., NOVO MESTO	SI
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/ 002	H/09/00506/022	KRKA, D.D., NOVO MESTO	SI
Doreta 75 mg/650 mg filmtabletta	HU/H/0190/002	OGYI-T-21059/12	KRKA, D.D., NOVO MESTO	HU
Doreta 75 mg/650 mg filmtabletta	HU/H/0190/002	OGYI-T-21059/13	KRKA, D.D., NOVO MESTO	HU
Doreta 75 mg/650 mg filmtabletta	HU/H/0190/002	OGYI-T-21059/14	KRKA, D.D., NOVO MESTO	HU
Doreta 75 mg/650 mg filmtabletta	HU/H/0190/002	OGYI-T-21059/15	KRKA, D.D., NOVO MESTO	HU
Doreta 75 mg/650 mg filmtabletta	HU/H/0190/002	OGYI-T-21059/16	KRKA, D.D., NOVO MESTO	HU
Doreta 75 mg/650 mg filmtabletta	HU/H/0190/002	OGYI-T-21059/17	KRKA, D.D., NOVO MESTO	HU
Doreta 75 mg/650 mg filmtabletta	HU/H/0190/002	OGYI-T-21059/18	KRKA, D.D., NOVO MESTO	HU
Doreta 75 mg/650 mg filmtabletta	HU/H/0190/002	OGYI-T-21059/19	KRKA, D.D., NOVO MESTO	HU
Doreta 75 mg/650 mg	HU/H/0190/002	OGYI-T-21059/20	KRKA, D.D., NOVO MESTO	HU

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
filmtabletta				
Doreta 75 mg/650 mg filmtabletta	HU/H/0190/002	OGYI-T-21059/21	KRKA, D.D., NOVO MESTO	HU
Doreta 75 mg/650 mg filmtabletta	HU/H/0190/002	OGYI-T-21059/33	KRKA, D.D., NOVO MESTO	HU
Doreta 75 mg/650 mg filmtabletta	HU/H/0190/002	OGYI-T-21059/34	KRKA, D.D., NOVO MESTO	HU
Doreta 75 mg/650 mg filmtabletta	HU/H/0190/002	OGYI-T-21059/35	KRKA, D.D., NOVO MESTO	HU
Doreta 75 mg/650 mg filmtabletta	HU/H/0190/002	OGYI-T-21059/36	KRKA, D.D., NOVO MESTO	HU
Doreta 75 mg/650 mg filmtabletta	HU/H/0190/002	OGYI-T-21059/37	KRKA, D.D., NOVO MESTO	HU
Doreta 75 mg/650 mg filmtabletta	HU/H/0190/002	OGYI-T-21059/38	KRKA, D.D., NOVO MESTO	HU
Doreta 75 mg/650 mg filmtabletta	HU/H/0190/002	OGYI-T-21059/39	KRKA, D.D., NOVO MESTO	HU
Doreta 75 mg/650 mg filmtabletta	HU/H/0190/002	OGYI-T-21059/40	KRKA, D.D., NOVO MESTO	HU
Doreta 75 mg/650 mg filmtabletta	HU/H/0190/002	OGYI-T-21059/41	KRKA, D.D., NOVO MESTO	HU
Doreta 75 mg/650 mg filmtabletta	HU/H/0190/002	OGYI-T-21059/42	KRKA, D.D., NOVO MESTO	HU
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/ 002	H/09/00506/036	KRKA, D.D., NOVO MESTO	SI
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/ 002	H/09/00506/038	KRKA, D.D., NOVO MESTO	SI
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/ 002	H/09/00506/043	KRKA, D.D., NOVO MESTO	SI
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/ 002	H/09/00506/044	KRKA, D.D., NOVO MESTO	SI
TRAMADOL/PARACETAMOL KRKA 75 mg/650 mg, comprimé pelliculé	HU/H/0190/002	NL42263, CIS: 6 244 619 4 (34009 300 842 1 2)	KRKA, D.D., NOVO MESTO	FR

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
sécable				
TRAMADOL/PARACETAMOL KRKA 75 mg/650 mg, comprimé pelliculé sécable	HU/H/0190/002	NL42263, CIS: 6 244 619 4 (34009 300 842 2 9)	KRKA, D.D., NOVO MESTO	FR
TRAMADOL/PARACETAMOL KRKA 75 mg/650 mg, comprimé pelliculé sécable	HU/H/0190/002	NL42263, CIS: 6 244 619 4 (34009 300 842 3 6)	KRKA, D.D., NOVO MESTO	FR
TRAMADOL/PARACETAMOL KRKA 75 mg/650 mg, comprimé pelliculé sécable	HU/H/0190/002	NL42263, CIS: 6 244 619 4 (34009 300 842 4 3)	KRKA, D.D., NOVO MESTO	FR
TRAMADOL/PARACETAMOL KRKA 75 mg/650 mg, comprimé pelliculé sécable	HU/H/0190/002	NL42263, CIS: 6 244 619 4 (34009 300 842 5 0)	KRKA, D.D., NOVO MESTO	FR
TRAMADOL/PARACETAMOL KRKA 75 mg/650 mg, comprimé pelliculé sécable	HU/H/0190/002	NL42263, CIS: 6 244 619 4 (34009 300 842 6 7)	KRKA, D.D., NOVO MESTO	FR
TRAMADOL/PARACETAMOL KRKA 75 mg/650 mg, comprimé pelliculé sécable	HU/H/0190/002	NL42263, CIS: 6 244 619 4 (34009 300 842 8 1)	KRKA, D.D., NOVO MESTO	FR
TRAMADOL/PARACETAMOL KRKA 75 mg/650 mg, comprimé pelliculé sécable	HU/H/0190/002	NL42263, CIS: 6 244 619 4 (34009 300 842 9 8)	KRKA, D.D., NOVO MESTO	FR
TRAMADOL/PARACETAMOL KRKA 75 mg/650 mg, comprimé pelliculé sécable	HU/H/0190/002	NL42263, CIS: 6 244 619 4 (34009 300 843 0 4)	KRKA, D.D., NOVO MESTO	FR
TRAMADOL/PARACETAM	HU/H/0190/002	NL42263, CIS: 6 244 619 4 (34009	KRKA, D.D., NOVO MESTO	FR

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
OL KRKA 75 mg/650 mg, comprimé pelliculé sécable		300 843 1 1)		
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/002	H/09/00506/034	KRKA, D.D., NOVO MESTO	SI
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/002	H/09/00506/035	KRKA, D.D., NOVO MESTO	SI
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/002	H/09/00506/037	KRKA, D.D., NOVO MESTO	SI
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/002	H/09/00506/039	KRKA, D.D., NOVO MESTO	SI
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/002	H/09/00506/040	KRKA, D.D., NOVO MESTO	SI
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/002	H/09/00506/041	KRKA, D.D., NOVO MESTO	SI
Doreta 75 mg/650 mg filmsko obložene tablete	HU/H/0190/002	H/09/00506/042	KRKA, D.D., NOVO MESTO	SI
Doreta 75 mg/650 mg comprimate filmate	HU/H/0190/002	6992/2014/01	KRKA, D.D., NOVO MESTO	RO
Doreta 75 mg/650 mg comprimate filmate	HU/H/0190/002	6992/2014/02	KRKA, D.D., NOVO MESTO	RO
Doreta 75 mg/650 mg comprimate filmate	HU/H/0190/002	6992/2014/03	KRKA, D.D., NOVO MESTO	RO
Doreta 75 mg/650 mg comprimate filmate	HU/H/0190/002	6992/2014/04	KRKA, D.D., NOVO MESTO	RO
Doreta 75 mg/650 mg comprimate filmate	HU/H/0190/002	6992/2014/05	KRKA, D.D., NOVO MESTO	RO
Doreta 75 mg/650 mg comprimate filmate	HU/H/0190/002	6992/2014/06	KRKA, D.D., NOVO MESTO	RO
Doreta 75 mg/650 mg comprimate filmate	HU/H/0190/002	6992/2014/07	KRKA, D.D., NOVO MESTO	RO
Doreta 75 mg/650 mg comprimate filmate	HU/H/0190/002	6992/2014/08	KRKA, D.D., NOVO MESTO	RO
Doreta 75 mg/650 mg	HU/H/0190/002	6992/2014/09	KRKA, D.D., NOVO MESTO	RO

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
comprimate filmate				
Doreta 75 mg/650 mg comprimate filmate	HU/H/0190/002	6992/2014/10	KRKA, D.D., NOVO MESTO	RO
Tramadol/Paracetamol Krka 75 mg/650 mg comprimidos recubiertos con película	HU/H/0190/002	76781	KRKA, D.D., NOVO MESTO	ES
TRAMADOL/PARACETAMOL KRKA 75 mg/650 mg, comprimé pelliculé sécable	HU/H/0190/002	NL 42263, CIS: 6 244 619 4 (34009 267 199 7 5)	KRKA, D.D., NOVO MESTO	FR
TRAMADOL/PARACETAMOL KRKA 75 mg/650 mg, comprimé pelliculé sécable	HU/H/0190/002	NL 42263, CIS: 6 244 619 4 (34009 267 200 5 6)	KRKA, D.D., NOVO MESTO	FR
TRAMADOL/PARACETAMOL KRKA 75 mg/650 mg, comprimé pelliculé sécable	HU/H/0190/002	NL 42263, CIS: 6 244 619 4 (34009 267 202 8 5)	KRKA, D.D., NOVO MESTO	FR
TRAMADOL/PARACETAMOL KRKA 75 mg/650 mg, comprimé pelliculé sécable	HU/H/0190/002	NL 42263, CIS: 6 244 619 4 (34009 267 203 4 6)	KRKA, D.D., NOVO MESTO	FR
TRAMADOL/PARACETAMOL KRKA 75 mg/650 mg, comprimé pelliculé sécable	HU/H/0190/002	NL 42263, CIS: 6 244 619 4 (34009 267 204 0 7)	KRKA, D.D., NOVO MESTO	FR
TRAMADOL/PARACETAMOL KRKA 75 mg/650 mg, comprimé pelliculé sécable	HU/H/0190/002	NL 42263, CIS: 6 244 619 4 (34009 267 205 7 5)	KRKA, D.D., NOVO MESTO	FR
TRAMADOL/PARACETAMOL KRKA 75 mg/650 mg, comprimé pelliculé	HU/H/0190/002	NL 42263, CIS: 6 244 619 4 (34009 267 206 3 6)	KRKA, D.D., NOVO MESTO	FR

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
sécable				
TRAMADOL/PARACETAMOL KRKA 75 mg/650 mg, comprimé pelliculé sécable	HU/H/0190/002	NL 42263, CIS: 6 244 619 4 (34009 267 208 6 5)	KRKA, D.D., NOVO MESTO	FR
TRAMADOL/PARACETAMOL KRKA 75 mg/650 mg, comprimé pelliculé sécable	HU/H/0190/002	NL 42263, CIS: 6 244 619 4 (34009 267 209 2 6)	KRKA, D.D., NOVO MESTO	FR
TRAMADOL/PARACETAMOL KRKA 75 mg/650 mg, comprimé pelliculé sécable	HU/H/0190/002	NL 42263, CIS: 6 244 619 4 (34009 267 210 0 8)	KRKA, D.D., NOVO MESTO	FR
Tramadol/Paracetamol Farmalid 75mg/650mg comprimidos recubiertos con película	not available	78174	FARMALIDER, S.A.	ES
Captor 75 mg/650 mg comprimidos	not available	75630	FERRER INTERNACIONAL, S.A.	ES
ZALDIAR 37,5 mg/325 mg comprimate filmate	not available	9695/2017/01	STADA ARZNEIMITTEL AG	RO
ZALDIAR 37,5 mg/325 mg comprimate filmate	not available	9695/2017/03	STADA ARZNEIMITTEL AG	RO
ZALDIAR 37,5 mg/325 mg comprimate filmate	not available	9695/2017/02	STADA ARZNEIMITTEL AG	RO
ZALDIAR 37,5 mg/325 mg comprimate filmate	not available	9695/2017/04	STADA ARZNEIMITTEL AG	RO
Zaldiar 37,5 mg/325 mg pezsgőtabletta	FR/H/0212/002	OGYI-T-20557/10	STADA ARZNEIMITTEL AG	HU
Zaldiar 37,5 mg/325 mg šumeče tablete	FR/H/0212/002	H/05/01692/018	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg pezsgőtabletta	FR/H/0212/002	OGYI-T-20557/09	STADA ARZNEIMITTEL AG	HU
Zaldiar 37,5 mg/325 mg	FR/H/0212/002	OGYI-T-20557/07	STADA ARZNEIMITTEL AG	HU

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
pezsgőtabletta				
Zaldiar 37,5 mg/325 mg pezsgőtabletta	FR/H/0212/002	OGYI-T-20557/08	STADA ARZNEIMITTEL AG	HU
Zaldiar 37,5 mg/325 mg šumeče tablete	FR/H/0212/002	H/05/01692/015	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg šumeče tablete	FR/H/0212/002	H/05/01692/013	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg šumeče tablete	FR/H/0212/002	H/05/01692/016	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg šumeče tablete	FR/H/0212/002	H/05/01692/014	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg šumeče tablete	FR/H/0212/002	H/05/01692/022	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg šumeče tablete	FR/H/0212/002	H/05/01692/024	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg šumeče tablete	FR/H/0212/002	H/05/01692/025	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg šumeče tablete	FR/H/0212/002	H/05/01692/027	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg šumeče tablete	FR/H/0212/002	H/05/01692/026	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg šumeče tablete	FR/H/0212/002	H/05/01692/020	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg šumeče tablete	FR/H/0212/002	H/05/01692/017	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg šumeče tablete	FR/H/0212/002	H/05/01692/032	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg šumeče tablete	FR/H/0212/002	H/05/01692/028	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg šumeče tablete	FR/H/0212/002	H/05/01692/029	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg šumeče tablete	FR/H/0212/002	H/05/01692/030	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg	FR/H/0212/002	H/05/01692/019	STADA ARZNEIMITTEL AG	SI

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
šumeče tablete				
Zaldiar 37,5 mg/325 mg šumeče tablete	FR/H/0212/002	H/05/01692/012	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg šumeče tablete	FR/H/0212/002	H/05/01692/021	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg šumeče tablete	FR/H/0212/002	H/05/01692/031	STADA ARZNEIMITTEL AG	SI
Zaldiar 37,5 mg/325 mg šumeče tablete	FR/H/0212/002	H/05/01692/023	STADA ARZNEIMITTEL AG	SI
ZALDIAR 37,5 mg/325 mg, comprimé effervescent	FR/H/0212/002	34009 574819-2 6	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR 37,5 mg/325 mg, comprimé effervescent	FR/H/0212/002	34009 574827-5 6	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR 37,5 mg/325 mg, comprimé effervescent	FR/H/0212/002	34009 391876-7 9	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR 37,5 mg/325 mg, comprimé effervescent	FR/H/0212/002	34009 574822-3 7	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	2009010049	SA GRÜNENTHAL N.V.	LU
ZALDIAR EFE 37,5 mg/325 mg, comprimidos efervescentes	FR/H/0212/002	5190509	GRÜNENTHAL S.A.	PT
ZALDIAR EFE 37,5 mg/325 mg, comprimidos efervescentes	FR/H/0212/002	5190517	GRÜNENTHAL S.A.	PT
ZALDIAR EFE 37,5 mg/325 mg,	FR/H/0212/002	5190525	GRÜNENTHAL S.A.	PT

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
comprimidos efervescentes				
Zaldiar 37,5 mg/325 mg comprimidos efervescentes	FR/H/0212/002	70.584	GRÜNENTHAL PHARMA S.A.	ES
ZALDIAR 37,5 mg/325 mg, comprimé effervescent	FR/H/0212/002	34009 574833-5 7	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg, comprimé effervescent	FR/H/0212/002	34009 574832-9 6	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	BE332787	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	BE332787	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332787	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325	FR/H/0212/002	34009 574820-0 8	LABORATOIRES	FR

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
mg, comprimé effervescent			GRÜNENTHAL S.A.S.	
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	BE332787	SA GRÜNENTHAL N.V.	BE
ZALDIAR® 37,5 mg/325 mg Brausetabletten	FR/H/0212/002	72105.00.00	GRÜNENTHAL GMBH	DE
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332787	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332787	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332787	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332787	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332787	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332787	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332787	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332787	SA GRÜNENTHAL N.V.	BE

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
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332787	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg, comprimé effervescent	FR/H/0212/002	34009 574835-8 6	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR 37,5 mg/325 mg, comprimé effervescent	FR/H/0212/002	34009 574830-6 7	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR 37,5 mg/325 mg, comprimé effervescent	FR/H/0212/002	34009 574831-2 8	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR 37,5 mg/325 mg, comprimé effervescent	FR/H/0212/002	34009 391874-4 0	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR 37,5 mg/325 mg, comprimé effervescent	FR/H/0212/002	34009 391888-5 0	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR 37,5 mg/325 mg, comprimé effervescent	FR/H/0212/002	34009 574829-8 5	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR 37,5 mg/325 mg, comprimé effervescent	FR/H/0212/002	34009 574825-2 7	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR 37,5 mg/325 mg, comprimé effervescent	FR/H/0212/002	34009 574828-1 7	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR 37,5 mg/325 mg, comprimé effervescent	FR/H/0212/002	34009 574834-1 8	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR 37,5 mg/325	FR/H/0212/002	34009 391889-1 1	LABORATOIRES	FR

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
mg, comprimé effervescent			GRÜNENTHAL S.A.S.	
ZALDIAR 37,5 mg/325 mg, comprimé effervescent	FR/H/0212/002	34009 574824-6 6	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR 37,5 mg/325 mg, comprimé effervescent	FR/H/0212/002	34009 574826-9 5	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR 37,5 mg/325 mg, comprimé effervescent	FR/H/0212/002	34009 574821-7 6	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR 37,5 mg/325 mg, comprimé effervescent	FR/H/0212/002	34009 391875-0 1	LABORATOIRES GRÜNENTHAL S.A.S.	FR
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	BE332787	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	BE332787	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	BE332787	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	BE332787	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg / 325 mg, comprimés	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE

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
effervescents				
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	BE332787	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	BE332787	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	BE332787	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
Zaldiar Bruis, 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	RVG 101592	GRÜNENTHAL B.V.	NL
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002	BE332771	SA GRÜNENTHAL N.V.	BE
Ixprim effervescent 37.5 mg/325 mg effervescent tablets	FR/H/0212/002	PA 2242/6/2	GRÜNENTHAL PHARMA LTD.	IE
Tramadol/Paracetamol	not available	75.632	LABORATORIO STADA, S.L.	ES

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
Stadagen 75 mg/650 mg comprimidos				
ZALDIAR 37,5 mg/325 mg apvalkotās tabletes	not available	04-0185	STADA ARZNEIMITTEL AG	LV
IXPRIM 37,5 mg/325 mg, comprimé effervescent	FR/H/0211/002	34009 574809-7 4	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM 37,5 mg/325 mg, comprimé effervescent	FR/H/0211/002	34009 391900-5 1	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM 37,5 mg/325 mg, comprimé effervescent	FR/H/0211/002	34009 574802-2 6	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM 37,5 mg/325 mg, comprimé effervescent	FR/H/0211/002	34009 574805-16	LABORATOIRES GRÜNENTHAL S.A.S.	FR
PONTALSIC 37,5 mg / 325 mg, comprimés effervescents	FR/H/0211/002	BE332805	SA GRÜNENTHAL N.V.	BE
IXPRIM 37,5 mg/325 mg, comprimé effervescent	FR/H/0211/002	34009 574815-7 5	LABORATOIRES GRÜNENTHAL S.A.S.	FR
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332805	SA GRÜNENTHAL N.V.	BE

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
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332805	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332805	SA GRÜNENTHAL N.V.	BE
TRAMACET® 37.5 mg/325 mg effervescent tablets	FR/H/0211/002	PL 21727/0040	GRÜNENTHAL LTD.	UK
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332805	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332805	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332805	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332805	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332805	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332805	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332805	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg/325 mg, bruistabletten	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
IXPRIM 37,5 mg/325	FR/H/0211/002	34009 391912-3 2	LABORATOIRES	FR

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
mg, comprimé effervescent			GRÜNENTHAL S.A.S.	
IXPRIM 37,5 mg/325 mg, comprimé effervescent	FR/H/0211/002	34009 574816-3 6	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM 37,5 mg/325 mg, comprimé effervescent	FR/H/0211/002	34009 574818-6 5	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM 37,5 mg/325 mg, comprimé effervescent	FR/H/0211/002	34009 574808-0 6	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM 37,5 mg/325 mg, comprimé effervescent	FR/H/0211/002	34009 574812-8 5	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM 37,5 mg/325 mg, comprimé effervescent	FR/H/0211/002	34009 574806-8 4	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM 37,5 mg/325 mg, comprimé effervescent	FR/H/0211/002	34009 391911-7 1	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM 37,5 mg/325 mg, comprimé effervescent	FR/H/0211/002	34009 574813-4 6	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM 37,5 mg/325 mg, comprimé effervescent	FR/H/0211/002	34009 391898-0 2	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM 37,5 mg/325 mg, comprimé effervescent	FR/H/0211/002	34009 574804-5 5	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM 37,5 mg/325 mg, comprimé effervescent	FR/H/0211/002	34009 574814-0 7	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM 37,5 mg/325 mg, comprimé	FR/H/0211/002	34009 391899-7 0	LABORATOIRES GRÜNENTHAL S.A.S.	FR

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
effervescent				
IXPRIM 37,5 mg/325 mg, comprimé effervescent	FR/H/0211/002	34009 574810-56	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM 37,5 mg/325 mg, comprimé effervescent	FR/H/0211/002	34009 574803-9 4	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM 37,5 mg/325 mg, comprimé effervescent	FR/H/0211/002	34009 574811-17	LABORATOIRES GRÜNENTHAL S.A.S.	FR
IXPRIM 37,5 mg/325 mg, comprimé effervescent	FR/H/0211/002	34009 574807-4 5	LABORATOIRES GRÜNENTHAL S.A.S.	FR
PONTALSIC 37,5 mg / 325 mg, comprimés effervescents	FR/H/0211/002	BE332805	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg / 325 mg, comprimés effervescents	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg / 325 mg, comprimés effervescents	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg / 325 mg, comprimés effervescents	FR/H/0211/002	BE332805	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg / 325 mg, comprimés effervescents	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg / 325 mg, comprimés effervescents	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg / 325 mg, comprimés effervescents	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE

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
PONTALSIC 37,5 mg / 325 mg, comprimés effervescents	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg / 325 mg, comprimés effervescents	FR/H/0211/002	BE332805	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg / 325 mg, comprimés effervescents	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg / 325 mg, comprimés effervescents	FR/H/0211/002	BE332805	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg / 325 mg, comprimés effervescents	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg / 325 mg, comprimés effervescents	FR/H/0211/002	BE332805	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg / 325 mg, comprimés effervescents	FR/H/0211/002	BE332805	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg / 325 mg, comprimés effervescents	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg / 325 mg, comprimés effervescents	FR/H/0211/002	BE332805	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg / 325 mg, comprimés effervescents	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg / 325 mg, comprimés effervescents	FR/H/0211/002	BE332805	SA GRÜNENTHAL N.V.	BE
PONTALSIC 37,5 mg /	FR/H/0211/002	BE332805	SA GRÜNENTHAL N.V.	BE

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
325 mg, comprimés effervescents				
PONTALSIC 37,5 mg / 325 mg, comprimés effervescents	FR/H/0211/002	BE332796	SA GRÜNENTHAL N.V.	BE
Tracimol 75 mg/650 mg comprimidos	not available	75708	ACINO AG	ES
KOLIBRI 37,5 mg / 325 mg, compresse rivestite con film	not available	036993044	ALFASIGMA S.P.A.	IT
KOLIBRI 37,5 mg / 325 mg, compresse rivestite con film	not available	036993020	ALFASIGMA S.P.A.	IT
KOLIBRI 37,5 mg / 325 mg, compresse rivestite con film	not available	036993032	ALFASIGMA S.P.A.	IT
KOLIBRI 37,5 mg / 325 mg, compresse rivestite con film	not available	036993018	ALFASIGMA S.P.A.	IT
KOLIBRI 37,5 mg / 325 mg, compresse rivestite con film	not available	036993057	ALFASIGMA S.P.A.	IT
KOLIBRI 37,5 mg / 325 mg, compresse effervescenti	not available	036993071	ALFASIGMA S.P.A.	IT
KOLIBRI 37,5 mg / 325 mg, compresse effervescenti	not available	036993121	ALFASIGMA S.P.A.	IT
KOLIBRI 37,5 mg / 325 mg, compresse effervescenti	not available	036993069	ALFASIGMA S.P.A.	IT
KOLIBRI 37,5 mg / 325 mg, compresse effervescenti	not available	036993095	ALFASIGMA 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
KOLIBRI 37,5 mg / 325 mg, compresse effervescenti	not available	036993083	ALFASIGMA S.P.A.	IT
KOLIBRI 37,5 mg / 325 mg, compresse effervescenti	not available	036993119	ALFASIGMA S.P.A.	IT
KOLIBRI 37,5 mg / 325 mg, compresse effervescenti	not available	036993107	ALFASIGMA S.P.A.	IT
KOLIBRI 37,5 mg / 325 mg, compresse effervescenti	not available	036993133	ALFASIGMA S.P.A.	IT
PATROL 37,5 mg / 325 mg, compresse rivestite con film	not available	036996041	ALFASIGMA S.P.A.	IT
PATROL 37,5 mg / 325 mg, compresse rivestite con film	not available	036996027	ALFASIGMA S.P.A.	IT
PATROL 37,5 mg / 325 mg, compresse rivestite con film	not available	036996039	ALFASIGMA S.P.A.	IT
PATROL 37,5 mg / 325 mg, compresse rivestite con film	not available	036996015	ALFASIGMA S.P.A.	IT
PATROL 37,5 mg / 325 mg, compresse rivestite con film	not available	036996054	ALFASIGMA S.P.A.	IT
PATROL 37,5 mg / 325 mg, compresse effervescenti	not available	036996066	ALFASIGMA S.P.A.	IT
PATROL 37,5 mg / 325 mg, compresse effervescenti	not available	036996078	ALFASIGMA S.P.A.	IT
PATROL 37,5 mg / 325	not available	036996080	ALFASIGMA 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
mg, compresse effervescenti				
PATROL 37,5 mg / 325 mg, compresse effervescenti	not available	036996092	ALFASIGMA S.P.A.	IT
PATROL 37,5 mg / 325 mg, compresse effervescenti	not available	036996104	ALFASIGMA S.P.A.	IT
PATROL 37,5 mg / 325 mg, compresse effervescenti	not available	036996116	ALFASIGMA S.P.A.	IT
PATROL 37,5 mg / 325 mg, compresse effervescenti	not available	036996128	ALFASIGMA S.P.A.	IT
PATROL 37,5 mg / 325 mg, compresse effervescenti	not available	036996130	ALFASIGMA S.P.A.	IT
Tramadol/Paracetamol Zentiva 75 mg/650 mg comprimidos recubiertos con película	CZ/H/0688/001	78780	ZENTIVA, K.S.	ES
Palgotal, 75 mg + 650 mg, tabletki powlekane	CZ/H/0688/001	22121	ZENTIVA, K.S.	PL
Palgotal, 75 mg + 650 mg, tabletki powlekane	CZ/H/0688/001	22121	ZENTIVA, K.S.	PL
Palgotal, 75 mg + 650 mg, tabletki powlekane	CZ/H/0688/001	22121	ZENTIVA, K.S.	PL
Palgotal 75 mg/650 mg film-coated tablets	CZ/H/0688/001	MA 082/07701	ZENTIVA, K.S.	MT
Palgotal 75 mg/650 mg film-coated tablets	CZ/H/0688/001	MA 082/07701	ZENTIVA, K.S.	MT
Palgotal 75 mg/650 mg film-coated tablets	CZ/H/0688/001	MA 082/07701	ZENTIVA, K.S.	MT
Palgotal 75 mg/650 mg	CZ/H/0688/001	7424/2015/02	ZENTIVA, K.S.	RO

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
comprimate filmate				
Palgotal 75 mg/650 mg comprimate filmate	CZ/H/0688/001	7424/2015/01	ZENTIVA, K.S.	RO
Palgotal 75 mg/650 mg comprimate filmate	CZ/H/0688/001	7424/2015/03	ZENTIVA, K.S.	RO
Tramadol/Paracetamol Zentiva 75 mg/650 mg filmom obalené tablety	CZ/H/0688/001	65/0195/14-S	ZENTIVA, K.S.	SK
Palgotal 75 mg/650 mg potahované tablety	CZ/H/0688/001	65/252/14-C	ZENTIVA, K.S.	CZ
Palgotal, 75 mg + 650 mg, tabletki powlekane	CZ/H/0688/001	22121	ZENTIVA, K.S.	PL
Palgotal 75 mg/650 mg film-coated tablets	CZ/H/0688/001	MA 082/07701	ZENTIVA, K.S.	MT
Palgotal, 75 mg + 650 mg, tabletki powlekane	CZ/H/0688/001	22121	ZENTIVA, K.S.	PL
Palgotal 75 mg/650 mg potahované tablety	CZ/H/0688/001	65/252/14-C	ZENTIVA, K.S.	CZ
Palgotal 75 mg/650 mg comprimate filmate	CZ/H/0688/001	7424/2015/02	ZENTIVA, K.S.	RO
Tramadol/Paracetamol Zentiva 75 mg/650 mg comprimidos recubiertos con película	CZ/H/0688/001	78780	ZENTIVA, K.S.	ES
Palgotal 75 mg/650 mg comprimate filmate	CZ/H/0688/001	7424/2015/01	ZENTIVA, K.S.	RO
Palgotal 75 mg/650 mg comprimate filmate	CZ/H/0688/001	7424/2015/03	ZENTIVA, K.S.	RO
Tramadol + Paracetamol Labesfal 75 mg + 650 mg comprimidos	PT/H/0633/002	5488655	GENERIS FARMACÊUTICA, S.A.	PT
Tramadol + Paracetamol Labesfal 75 mg + 650 mg comprimidos	PT/H/0633/002	5488663	GENERIS FARMACÊUTICA, S.A.	PT

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Tracimol 75 mg/650 mg comprimidos	not available	75708	ACINO AG	ES
Tramadol + Paracetamol Krka 75 mg + 650 mg comprimidos revestidos por película	not available	5678909	KRKA FARMACÊUTICA, UNIPESSOAL LDA.	PT
Tramadol/Paracetamol Teva 75mg/650mg comprimidos recubiertos con película	not available	77382	TEVA PHARMA S.L.U.,	ES
Tramadol/Paracetamol Teva 75 mg/650 mg comprimés	ES/H/0434/001	BE520186	TEVA PHARMA BELGIUM N.V./S.A	BE
Tramadol/Paracetamol Teva 75mg/650mg tabletten	ES/H/0434/001	BE520186	TEVA PHARMA BELGIUM N.V./S.A	BE
Tramadol/Paracetamol Teva 75 mg/650 mg comprimés	ES/H/0434/001	BE520177	TEVA PHARMA BELGIUM N.V./S.A	BE
Tramadol/Paracetamol Teva 75mg/650mg tabletten	ES/H/0434/001	BE520177	TEVA PHARMA BELGIUM N.V./S.A	BE
Tramadol/Paracetamol Teva 75 mg/650 mg Tabletten	ES/H/0434/001	BE520177	TEVA PHARMA BELGIUM N.V./S.A	BE
Zotramid 75 mg/650 mg tablete	ES/H/0434/001	HR-H-605800702	PLIVA HRVATSKA D.O.O.	HR
Tramadol + Paracetamol ratiopharm 75 mg + 650 mg comprimidos	ES/H/0434/001	5729561	RATIOPHARM-COMERCIO E INDUSTRIA DE PRODUTOS FARMACEUTICOS LDA	PT
Tramadol + Paracetamol ratiopharm 75 mg + 650 mg comprimidos	ES/H/0434/001	5729553	RATIOPHARM-COMERCIO E INDUSTRIA DE PRODUTOS FARMACEUTICOS LDA	PT
Tramadol + Paracetamol	ES/H/0434/001	5729579	RATIOPHARM-COMERCIO E	PT

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ratiopharm 75 mg + 650 mg comprimidos			INDUSTRIA DE PRODUTOS FARMACEUTICOS LDA	
Tramadol/paracetamol Teva 75 mg/650 mg tablete	ES/H/0434/001	H/18/02434/002	TEVA B.V	SI
Tramadol/paracetamol Teva 75 mg/650 mg tablete	ES/H/0434/001	H/18/02434/005	TEVA B.V	SI
Tramadol/paracetamol Teva 75 mg/650 mg tablete	ES/H/0434/001	H/18/02434/003	TEVA B.V	SI
Tramadol/paracetamol Teva 75 mg/650 mg tablete	ES/H/0434/001	H/18/02434/006	TEVA B.V	SI
Tramadol/paracetamol Teva 75 mg/650 mg tablete	ES/H/0434/001	H/18/02434/008	TEVA B.V	SI
Tramadol/paracetamol Teva 75 mg/650 mg tablete	ES/H/0434/001	H/18/02434/004	TEVA B.V	SI
Tramadol/paracetamol Teva 75 mg/650 mg tablete	ES/H/0434/001	H/18/02434/001	TEVA B.V	SI
Tramadol/paracetamol Teva 75 mg/650 mg tablete	ES/H/0434/001	H/18/02434/007	TEVA B.V	SI
Tramadol/paracetamol Teva 75 mg/650 mg tablete	ES/H/0434/001	H/18/02434/009	TEVA B.V	SI
Tramadol/paracetamol Teva 75 mg/650 mg tablete	ES/H/0434/001	H/18/02434/010	TEVA B.V	SI
Tramadol/Paracetamol Teva 75 mg/650 mg	ES/H/0434/001	BE520186	TEVA PHARMA BELGIUM N.V./S.A	BE

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
Tabletten				
Tramadol/Paracetamol Davur 75 mg/650 mg comprimidos	ES/H/0434/001	83142	LABORATORIOS DAVUR S.L.U.,	ES
ZALDIAR	not available	65/0152/04-S	STADA ARZNEIMITTEL AG	SK
ZALDIAR® 37,5 mg / 325 mg šumeće tablete	not available	UP/I-530-09/09-01/433	STADA D.O.O.	HR