



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

30 March 2016  
EMA/319353/2016  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance: paracetamol / tramadol

Procedure no.: PSUSA/00002310/201508



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 Teva 75 mg/650 mg comprimidos recubiertos con película		77382	TEVA PHARMA S.L.U	ES
Zaldiar® 37,5 mg/325 mg filmsko obložene tablete	FR/H/0212/001	5363-I-638/13	STADA ARZNEIMITTEL AG	SI
Zaldiar® 37,5 mg/325 mg filmsko obložene tablete	FR/H/0212/001	5363-I-639/13	STADA ARZNEIMITTEL AG	SI
ZALDIAR, 37,5 mg/325 mg, comprimidos revestidos por película	FR/H/0212/E01	5359583	GRÜNENTHAL S.A.	PT
ZALDIAR, 37,5 mg/325 mg, comprimidos revestidos por película	FR/H/0212/E01	5983085	GRÜNENTHAL S.A.	PT
ZALDIAR, 37,5 mg/325 mg, comprimidos revestidos por película	FR/H/0212/E01	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, comprimidos revestidos por película	FR/H/0212/E01	5319884	GRÜNENTHAL S.A.	PT
ZALDIAR, 37,5 mg/325 mg, comprimidos revestidos por película	FR/H/0212/E01	5359682	GRÜNENTHAL S.A.	PT
ZALDIAR, 37,5 mg/325 mg, comprimidos revestidos por película	FR/H/0212/E01	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 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	BE244553	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg Filmtabletten	FR/H/0212/001	55310.00.00	GRÜNENTHAL GMBH	DE
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002/DC	BE332771	SA GRÜNENTHAL N.V.	BE
ZALDIAR 37,5 mg/325 mg, bruistabletten	FR/H/0212/002/DC	BE332787	SA GRÜNENTHAL N.V.	BE
Zaldiar Bruis, 37,5 mg/325 mg, bruistabletten	FR/H/0212/002/DC	RVG 101592	GRÜNENTHAL B.V.	NL

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Diliban Retard 75 mg	IS/H/0168/001/DC	IS/1/10/092/01	Gebro Pharma GmbH Fieberbrunn Austria	IS
Diliban Retard 75 mg	IS/H/0168/001/DC	73638	Paladin Labs Eudrope Limited (Endo) Dublin Ireland	ES
Diliban Retard 75 mg	IS/H/0168/001/DC	5361852, 5361860	Jaba recordati, S.A Porto Salvo Portugal	PT
Tramadol+Paracetamol Bluepharma		5493556, 5493564	Bluepharma Genericos - Comercio de Medicamentos, S.A.	PT
Zaldiar		65/107/11-C, 65/237/02-C	STADA ARZNEIMITTEL AG	CS
Zaldiar 37.5 mg/325 mg film-coated tablets		437704	STADA ARZNEIMITTEL AG	EE
Zaldiar 37.5 mg/ 325mg filmtabletta		04-0185	STADA ARZNEIMITTEL AG	LV
Zaldiar effervescent		16461	STADA ARZNEIMITTEL AG	PL
Zaldiar		10733	STADA ARZNEIMITTEL AG	PL
Zaldiar 37.5 mg		5186/2005/01-12	STADA ARZNEIMITTEL AG	RO
Zaldiar effeescens		65/080/11-S	STADA ARZNEIMITTEL AG	SK
Zaldiar		65/0152/04-S	STADA ARZNEIMITTEL AG	SK
Pontalistic	FR/H/0211/002	BE332796, BE332805	SA GRÜNENTHAL N.V.	BE
Pontalistic	FR/H/0211/001	BE254536	SA GRÜNENTHAL N.V.	BE
IXPRIM	FR/H/0211/002	NL35216	LABORATOIRES	FR

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			GRÜNENTHAL S.A.S.	
Ixprim	FR/H/0211/001	NL25970	LABORATOIRES GRÜNENTHAL S.A.S.	FR
Zaldiar	FR/H/0212/002	NL35215	LABORATOIRES GRÜNENTHAL S.A.S.	FR
Zaldiar	FR/H/0212/001	NL25971	LABORATOIRES GRÜNENTHAL S.A.S.	FR
DOLEVAR	FR/H/0211/001	54830.00.00	GRÜNENTHAL GMBH	DE
Zaldiar	FR/H/0212/002	72105.00.00	GRÜNENTHAL GMBH	DE
Zaldiar	FR/H/0212/001	55373/8-8-2013	GRÜNENTHAL GMBH	GR
Zaldiar	FR/H/0212/001	OGYI-T-20557/01-06	STADA ARZNEIMITTEL AG	HU
Zaldiar	FR/H/0212/002	OGYI-T-20557/07-10	STADA ARZNEIMITTEL AG	HU
Ixprim	FR/H/0212/001	PA 1189/5/1	Grunenthal Ltd	IR
Ixprim effervescent	FR/H/0212/002	PA1189/005/002	Grunenthal Ltd	IR
ZALDIAR 37,5 mg / 325 mg, comprimés effervescents	FR/H/0212/002	0477/09010049	SA GRÜNENTHAL N.V.	LU
ZALDIAR 37,5 mg / 325 mg, comprimés pelliculés	FR/H/0212/001	0477/03/01/0017	SA GRÜNENTHAL N.V.	LU
Zaldiar EFE	FR/H/0212/002	5190509, 5190517, 5190525	Gruhenthal, S.A.	PT
Zaldiar	FR/H/0212/002	5363-I-641/13, 5363-I-642/13	STADA ARZNEIMITTEL AG	SI
Zaldiar® 37,5 mg/325 mg filmsko obložene tablete	FR/H/0212/001	5363-I-640/13	STADA ARZNEIMITTEL AG	SI
Pontalsic	FR/H/0211/001	65158	Zambon S.A.U.	ES
Zaldiar	FR/H/0212/002	70584	GRÜNENTHAL PHARMA S.A.	ES

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Tramacet	FR/H/0211/001	PL 21727/0039	Grunenthal Ltd	UK
Tramacet	FR/H/0211/002	PL 21727/0040	Grunenthal Ltd	UK
Tramadol/Paracetamol Krka	HU/H/0190/002/E/002	136152	KRKA, d.d., Novo mesto	AT
Дорета	HU/H/0190/002/E/002	20110723	KRKA, d.d., Novo mesto	BG
Doreta	HU/H/0190/002	65/185/12-C	KRKA, d.d., Novo mesto	CS
Doreta	HU/H/0190/002/E/002	772412	KRKA, d.d., Novo mesto	EE
Tramadol/Paracetamol Krka	HU/H/0190/002/E/002	NL 42263, CIS: 6 2444 619 4 (34009 267 199 7 5)	KRKA, d.d., Novo mesto	FR
Tramadol/Paracetamol Krka	HU/H/0190/002/E/002	NL 42263, CIS: 6 2444 619 4 (34009 267 200 5 6)	KRKA, d.d., Novo mesto	FR
Tramadol/Paracetamol Krka	HU/H/0190/002/E/002	NL 42263, CIS: 6 2444 619 4 (34009 267 202 8 5)	KRKA, d.d., Novo mesto	FR
Tramadol/Paracetamol Krka	HU/H/0190/002/E/002	NL 42263, CIS: 6 244 619 4 (34009 267 203 4 6)	KRKA, d.d., Novo mesto	FR
Tramadol/Paracetamol Krka	HU/H/0190/002/E/002	NL 42263, CIS: 6 244 619 4 (34009 267 204 0 7)	KRKA, d.d., Novo mesto	FR
Tramadol/Paracetamol Krka	HU/H/0190/002/E/002	NL 42263, CIS: 6 244 619 4 (34009 267 205 7 5)	KRKA, d.d., Novo mesto	FR
Tramadol/Paracetamol Krka	HU/H/0190/002/E/002	NL 42263, CIS: 6 244 619 4 (34009 267 206 3 6)	KRKA, d.d., Novo mesto	FR
Tramadol/Paracetamol Krka	HU/H/0190/002/E/002	NL 42263, CIS: 6 244 619 4 (34009 267 208 6 5)	KRKA, d.d., Novo mesto	FR
Tramadol/Paracetamol Krka	HU/H/0190/002/E/002	NL 42263, CIS: 6 244 619 4 (34009 267 209 2 6)	KRKA, d.d., Novo mesto	FR
Tramadol/Paracetamol Krka	HU/H/0190/002/E/002	NL 42263, CIS: 6 244 619 4 (34009 267 210 0 8)	KRKA, d.d., Novo mesto	FR
Tramabian	HU/H/0190/002/E/002	93508.00.00	KRKA, d.d., Novo mesto	DE
Doreta	HU/H/0190/002/E/002	OGYI-21059/12	KRKA, d.d., Novo mesto	HU
Doreta	HU/H/0190/002/E/002	OGYI-21059/13	KRKA, d.d., Novo mesto	HU

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Doreta	HU/H/0190/002/E/002	OGYI-21059/14	KRKA, d.d., Novo mesto	HU
Doreta	HU/H/0190/002/E/002	OGYI-21059/15	KRKA, d.d., Novo mesto	HU
Doreta	HU/H/0190/002/E/002	OGYI-21059/16	KRKA, d.d., Novo mesto	HU
Doreta	HU/H/0190/002/E/002	OGYI-21059/17	KRKA, d.d., Novo mesto	HU
Doreta	HU/H/0190/002/E/002	OGYI-21059/18	KRKA, d.d., Novo mesto	HU
Doreta	HU/H/0190/002/E/002	OGYI-21059/19	KRKA, d.d., Novo mesto	HU
Doreta	HU/H/0190/002/E/002	OGYI-21059/20	KRKA, d.d., Novo mesto	HU
Doreta	HU/H/0190/002/E/002	OGYI-21059/21	KRKA, d.d., Novo mesto	HU
Doreta	HU/H/0190/002/E/002	12-0062	KRKA, d.d., Novo mesto	LV
Doreta	HU/H/0190/002/E/002	LT/1/09/1638/012	KRKA, d.d., Novo mesto	LT
Doreta	HU/H/0190/002/E/002	LT/1/09/1638/013	KRKA, d.d., Novo mesto	LT
Doreta	HU/H/0190/002/E/002	LT/1/09/1638/014	KRKA, d.d., Novo mesto	LT
Doreta	HU/H/0190/002/E/002	LT/1/09/1638/015	KRKA, d.d., Novo mesto	LT
Doreta	HU/H/0190/002/E/002	LT/1/09/1638/016	KRKA, d.d., Novo mesto	LT
Doreta	HU/H/0190/002/E/002	LT/1/09/1638/017	KRKA, d.d., Novo mesto	LT
Doreta	HU/H/0190/002/E/002	LT/1/09/1638/018	KRKA, d.d., Novo mesto	LT
Doreta	HU/H/0190/002/E/002	LT/1/09/1638/019	KRKA, d.d., Novo mesto	LT
Doreta	HU/H/0190/002/E/002	LT/1/09/1638/020	KRKA, d.d., Novo mesto	LT

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Doreta	HU/H/0190/002/E/002	LT/1/09/1638/021	KRKA, d.d., Novo mesto	LT
Doreta	HU/H/0190/002/E/002	19609	KRKA, d.d., Novo mesto	PL
Doreta	HU/H/0190/002/E/002	6992/2014/01	KRKA, d.d., Novo mesto	RO
Doreta	HU/H/0190/002/E/002	6992/2014/02	KRKA, d.d., Novo mesto	RO
Doreta	HU/H/0190/002/E/002	6992/2014/03	KRKA, d.d., Novo mesto	RO
Doreta	HU/H/0190/002/E/002	6992/2014/04	KRKA, d.d., Novo mesto	RO
Doreta	HU/H/0190/002/E/002	6992/2014/05	KRKA, d.d., Novo mesto	RO
Doreta	HU/H/0190/002/E/002	6992/2014/06	KRKA, d.d., Novo mesto	RO
Doreta	HU/H/0190/002/E/002	6992/2014/07	KRKA, d.d., Novo mesto	RO
Doreta	HU/H/0190/002/E/002	6992/2014/08	KRKA, d.d., Novo mesto	RO
Doreta	HU/H/0190/002/E/002	6992/2014/09	KRKA, d.d., Novo mesto	RO
Doreta	HU/H/0190/002/E/002	6992/2014/10	KRKA, d.d., Novo mesto	RO
Doreta	HU/H/0190/002/E/002	65/0742/11-S	KRKA, d.d., Novo mesto	SK
Doreta	HU/H/0190/002/E/002	H/09/00506/012	KRKA, d.d., Novo mesto	SI
Doreta	HU/H/0190/002/E/002	H/09/00506/013	KRKA, d.d., Novo mesto	SI
Doreta	HU/H/0190/002/E/002	H/09/00506/014	KRKA, d.d., Novo mesto	SI
Doreta	HU/H/0190/002/E/002	H/09/00506/015	KRKA, d.d., Novo mesto	SI
Doreta	HU/H/0190/002/E/002	H/09/00506/037	KRKA, d.d., Novo mesto	SI

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Doreta	HU/H/0190/002/E/002	H/09/00506/040	KRKA, d.d., Novo mesto	SI	
Doreta	HU/H/0190/002/E/002	H/09/00506/043	KRKA, d.d., Novo mesto	SI	
Doreta	HU/H/0190/002/E/002	H/09/00506/044	KRKA, d.d., Novo mesto	SI	
Tramadol/Paracetamol Krka	HU/H/0190/002/E/002	76781	KRKA, d.d., Novo mesto	ES	
Diliban		75633	Laboratorios Gebro Pharma, S.A.	ES	
Pazital		66853	Laboratorios Gebro Pharma, S.A.	ES	
Tramadol/Paracetamol ratiopharm		77385	ratiopharm Espana SA	ES	
Zilpen		5456017, 5456025	Tecnimedede, Sociedade Tecnico-Medicinal, S.A.	PT	
Tramadol+Paracetamol toLife	PT/H/631-632/01-02/DC	5488721, 5488713	toLife - productos Farmaceuticos, S.A.	PT	
Kolibri		036993069, 036993083, 036993107, 036993121, 036993133	036993071, 036993095, 036993119, 036993133	Alfa Wassermann S.p.A.	IT
Kolibri		036993018, 036993032, 036993057	036993020, 036993044,	Alfa Wassermann S.p.A.	IT
Patrol		036996066, 036996080, 036996104, 036996130	036996078, 036996092, 036996128,	Alfa Wassermann S.p.A.	IT
Patrol		036996015, 036996039, 036996054	036996027, 036996041,	Alfa Wassermann S.p.A.	IT
PALGOTAL	IS/H/0220/001/DC	7424/2015/01-03	ZENTIVA, k.s.,	RO	



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Tramadol/Pracetamol Tarbis		75630	Tarbis Farma, S.L.	ES
Palgotal	IS/H/0220/001	65/252/14-C	Zentiva, k.s.	CS
Palgotal	IS/H/0220/001/DC	22121	Zentiva, k.s.	PL
Tramadol+Paracetamol Litexil	PT/H919/002/MR	5449343, 5449350, 5449368, 5449376, 5449400, 5449418, 5449426, 5449434, 5449442, 5449459, 5449467, 5449475	PTR Pharma Consulting, Lda	PT