



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 June 2015  
EMA/448789/2015  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance: tapentadol

Procedure no.: PSUSA/00002849/201411



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
Palexia	DE/H/2020/001	75043.00.00 ENR: 2175043	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	DE (RMS)
Palexia	DE/H/2020/002	75044.00.00 ENR: 2175044		
Palexia	DE/H/2020/003	75045.00.00 ENR: 2175045		
Palexia	DE/H/2020/010	85576.00.00 ENR: 2185576		
Palexia	DE/H/2020/011	85576.00.00 ENR: 2185577		
Palexia	DE/H/2020/001	1-31061	Grünenthal GmbH Liebermannstraße A01/501 2345 Brunn am Gebirge Austria	AT
Palexia	DE/H/2020/002	1-31062		
Palexia	DE/H/2020/003	1-31063		
Palexia 50 mg filmomhulde tabletten	DE/H/2020/001	BE382803	S.A. Grünenthal N.V. Lenneke Marelaan 8 1932 Sint-Stevens-Woluwe Belgium	BE
Palexia 75 mg filmomhulde tabletten	DE/H/2020/002	BE382812		
Palexia 100 mg filmomhulde tabletten	DE/H/2020/003	BE382821		
Palexia 4 mg/ml drank	DE/H/2020/010	BE429703		
Palexia 20 mg/ml drank	DE/H/2020/011	BE429712		
Palexia 50 mg film-coated tablets	DE/H/2020/001	20110170	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	BG
Palexia 75 mg film-coated tablets	DE/H/2020/002	20110171		
Palexia 100 mg film-coated tablets	DE/H/2020/003	20110172		
Palexia 4 mg/ml oral solution	DE/H/2020/010	20120765		
Palexia 20 mg/ml oral solution	DE/H/2020/011	20120766		
Palexia	DE/H/2020/001	21253	Grünenthal GmbH Zieglerstraße 6	CY
Palexia	DE/H/2020/002	21254		

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
Palexia	DE/H/2020/003	21255	52078 Aachen	
Palexia	DE/H/2020/010	*	Germany	
Palexia	DE/H/2020/011	*		
Palexia 50 mg potahované tablet	DE/H/2020/001	65/008/11-C	Grünenthal GmbH Zieglerstraße 6	CZ
Palexia 75 mg potahované tablety	DE/H/2020/002	65/009/11-C	52078 Aachen	
Palexia 100 mg potahované tablety	DE/H/2020/003	65/010/11-C	Germany	
Palexia 4 mg/ml perorální roztok	DE/H/2020/010	65/009/13-C		
Palexia 20 mg/ml perorální roztok	DE/H/2020/011	65/010/13-C		
Palexia	DE/H/2020/001	45151	Grünenthal GmbH	DK
Palexia	DE/H/2020/002	45152	Zieglerstraße 6	
Palexia	DE/H/2020/003	45153	52078 Aachen	
Palexia	DE/H/2020/010	49341	Germany	
Palexia	DE/H/2020/011	49342		
Palexia	DE/H/2020/001	711510	Grünenthal GmbH	EE
Palexia	DE/H/2020/002	711410	Zieglerstraße 6	
Palexia	DE/H/2020/003	711610	52078 Aachen	
Palexia	DE/H/2020/010	800412	Germany	
Palexia	DE/H/2020/011	800512		
Palexia	DE/H/2020/001	19215/15-3-2011	Grünenthal GmbH	EL
Palexia	DE/H/2020/002	19216/15-3-2011	Zieglerstraße 6	
Palexia	DE/H/2020/003	19218/15-3-2011	52078 Aachen	
Palexia	DE/H/2020/010	70805/16-9-2013	Germany	
Palexia	DE/H/2020/011	70806/16-9-2013		
Palexia 50 mg comprimidos recubiertos con película	DE/H/2020/001	73242	Grünenthal Pharma S.A C/ Doctor Zamenhof No. 36	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
Palexia 75 mg comprimidos recubiertos con película	DE/H/2020/002	73241	28027 Madrid Spain	
Palexia 100 mg comprimidos recubiertos con película	DE/H/2020/003	73239		
Palexia 4 mg/ml solución oral	DE/H/2020/010	76793		
Palexia 20 mg/ml solución oral	DE/H/2020/011	76792		
Palexia 50 mg tabletti, kalvopäällysteinen	DE/H/2020/001	27580	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	FI
Palexia 75 mg tabletti, kalvopäällysteinen	DE/H/2020/002	27581		
Palexia 100 mg tabletti, kalvopäällysteinen	DE/H/2020/003	27582		
Palexia 4 mg/ml oraalliuos	DE/H/2020/010	30044		
Palexia 20 mg/ml oraalliuos	DE/H/2020/011	30045		
Palexia 50 mg, comprimé pelliculé	DE/H/2020/001	NL40881	Laboratoires Grünenthal Immeuble Eureka 19, rue Ernest Renan – CS 90001 92024 Nanterre Cedex France	FR
Palexia 75 mg, comprimé pelliculé	DE/H/2020/002	NL40882		
Palexia 100 mg, comprimé pelliculé	DE/H/2020/003	NL40883		
Palexia	DE/H/2020/010	*		
Palexia	DE/H/2020/011	*		
Palexia 50 mg filmom obložene tablete	DE/H/2020/001	UP/I-530-09/14-01/10	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	HR
Palexia 75 mg filmom obložene tablete	DE/H/2020/002	UP/I-530-09/14-01/11		
Palexia 100 mg filmom obložene tablete	DE/H/2020/003	UP/I-530-09/14-01/12		
Palexia 4 mg/ml oralna otopina	DE/H/2020/010	UP/I-530-09/14-01/13		

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
Palexia 20 mg/ml oralna otopina	DE/H/2020/011	JP/I-530-09/14-01/14		
Palexias 50 mg filmtabletta	DE/H/2020/001	OGYI-T-21638/01	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	HU
Palexias 75 mg filmtabletta	DE/H/2020/002	OGYI-T-21638/02		
Palexias 100 mg filmtabletta	DE/H/2020/003	OGYI-T-21638/03		
Palexias 4 mg/ml belsőleges oldat	DE/H/2020/010	OGYI/27319-7/2010		
Palexias 20 mg/ml belsőleges oldat	DE/H/2020/011	OGYI/27321-7/2011		
Palexia 50 mg film-coated tablets	DE/H/2020/001	PA1189/007/001	Grünenthal Ltd. Regus Lakeside House 1 Furzeground Way Stockley Park East Uxbridge, Middlesex UB11 1BD United Kingdom	IE
Palexia 75 mg film-coated tablets	DE/H/2020/002	PA1189/007/002		
Palexia 100 mg film-coated tablets	DE/H/2020/003	PA1189/007/003		
Palexia 4 mg/ml oral solution	DE/H/2020/010	PA1189/007/010		
Palexia 20 mg/ml oral solution	DE/H/2020/011	PA1189/007/011		
Palexia	DE/H/2020/001	IS/1/10/009/01	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	IS
Palexia	DE/H/2020/002	IS/1/10/009/02		
Palexia	DE/H/2020/003	IS/1/10/009/03		
Palexia 4 mg/ml mixtúra, lausn	DE/H/2020/010	IS/1/12/107/01		
Palexia 20 mg/ml mixtúra, lausn	DE/H/2020/011	IS/1/121/07/02		
Palexia 50 mg compresse rivestite con film	DE/H/2020/001	040422014/040422127 040422976/040423079	Grünenthal Italia S.r.l. Via Carlo Bo n. 11 20143 Milano Italy	IT
Palexia 75 mg compresse rivestite con film	DE/H/2020/002	040422139/040422242 040423081/040423170		

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
Palexia 100 mg comprimés rivestiti con film	DE/H/2020/003	040422255/040422368 040423182/040423271		
Palexia	DE/H/2020/010	*		
Palexia	DE/H/2020/011	*		
Palexia 50 mg plévele dengtos tabletés	DE/H/2020/001	LT/1/10/2341/001-022	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	LT
Palexia 75 mg plévele dengtos tabletés	DE/H/2020/002	LT/1/10/2341/023-044		
Palexia 100 mg plévele dengtos tabletés	DE/H/2020/003	LT/1/10/2341/045-066		
Palexia 4 mg/ml geriamasis tirpalas	DE/H/2020/010	LT/1/10/2341/067		
Palexia 20 mg/ml geriamasis tirpalas	DE/H/2020/011	LT/1/10/2341/068-069		
Palexia 50 mg filmomhulde tabletten	DE/H/2020/001	2010110039	S.A. Grünenthal N.V. Lenneke Marelaan 8 1932 Sint-Stevens Woluwe Belgium	LU
Palexia 75mg filmomhulde tabletten	DE/H/2020/002	2010110040		
Palexia 100 mg filmomhulde tabletten	DE/H/2020/003	2010110041		
Palexia	DE/H/2020/010	*		
Palexia	DE/H/2020/011	*		
Palexia 50 mg film- coated tablets	DE/H/2020/001	10-0612	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	LV
Palexia 75 mg film- coated tablets	DE/H/2020/002	10-0613		
Palexia 100 mg film- coated tablets	DE/H/2020/003	10-0614		
Palexia 4 mg/ml oral solution	DE/H/2020/010	13-0003		
Palexia 20 mg/ml oral solution	DE/H/2020/011	13-0002		
Palexia 50 mg film- coated tablets	DE/H/2020/001	MA840/00101	Grünenthal GmbH	MT

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
Palexia 75 mg film-coated tablets	DE/H/2020/002	MA840/00102	Zieglerstraße 6 52078 Aachen Germany	
Palexia 100 mg film-coated tablets	DE/H/2020/003	MA840/00103		
Palexia 4 mg/ml oral solution	DE/H/2020/010	MA840/00110		
Palexia 20 mg/ml oral solution	DE/H/2020/011	MA840/00111		
Palexia	DE/H/2020/001	RVG 110721	Grünenthal B.V. De Corridor 21K 3621 ZA Breukelen The Netherlands	NL
Palexia	DE/H/2020/002	RVG 110722		
Palexia	DE/H/2020/003	RVG 110723		
Palexia 50 mg tablett, filmdrasjert	DE/H/2020/001	09-6802	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	NO
Palexia 75 mg tablett, filmdrasjert	DE/H/2020/002	09-6803		
Palexia 100 mg tablett, filmdrasjert	DE/H/2020/003	09-6804		
Palexia 4 mg/ml mikstur, oppløsning	DE/H/2020/010	11-8505		
Palexia 20 mg/ml mikstur, oppløsning	DE/H/2020/011	11-8506		
Palexia	DE/H/2020/001	18208		
Palexia	DE/H/2020/002	18209		
Palexia	DE/H/2020/003	18210		
Palexia	DE/H/2020/010	20900		
Palexia	DE/H/2020/011	20901		
Palexia	DE/H/2020/001	5334313 (20) 5334321 (30) 5334339 (60)	Grünenthal, S.A. Rua Alfredo da Silva,16 2610-016 Amadora Portugal	PT
Palexia	DE/H/2020/002	5334347 (20) 5334354 (30) 5334362 (60)		

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
Palexia	DE/H/2020/003	5334370 (20) 5334404 (30) 5334412 (60)		
Palexia	DE/H/2020/010	5490503 (100 ml)		
Palexia	DE/H/2020/011	5490511 (100 ml) 5490529 (200 ml)		
Palexia 50 mg comprimate filmate	DE/H/2020/001	3279/2011/01-22	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	RO
Palexia 75 mg comprimate filmate	DE/H/2020/002	3280/2011/01-22		
Palexia 100 mg comprimate filmate	DE/H/2020/003	3281/2011/01-22		
Palexia 4 mg/ml soluție orală	DE/H/2020/010	5292/2013/01		
Palexia 20 mg/ml soluție orală	DE/H/2020/011	5293/2013/01-02		
Palexia 50 mg filmdragerad tablett	DE/H/2020/001	42621		
Palexia 75 mg filmdragerad tablett	DE/H/2020/002	42622		
Palexia 100 mg filmdragerad tablett	DE/H/2020/003	42623		
Palexia, 4 mg/ml oral lösning	DE/H/2020/010	46560		
Palexia, 20 mg/ml oral lösning	DE/H/2020/011	46561		
Palexia 50 mg filmsko obložene tablete	DE/H/2020/001	5363-I-2336/12	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	SI
Palexia 75 mg filmsko obložene tablete	DE/H/2020/002	5363-I-2337/12		
Palexia 100 mg filmsko obložene tablete	DE/H/2020/003	5363-I-2338/12		
Palexia 4 mg/ml peroralna raztopina	DE/H/2020/010	5363-I-1111/13		
Palexia 20 mg/ml peroralna raztopina	DE/H/2020/011	5363-I-112/13 (100 ml) 5363-I-113/13 (200 ml)		



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
Palexia 50 mg filmom obalené tablety tbl flm	DE/H/2020/001	65/0667/10-S	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	SK
Palexia 75 mg filmom obalené tablety tbl flm	DE/H/2020/002	65/0668/10-S		
Palexia 100 mg filmom obalené tablety tbl flm	DE/H/2020/003	65/0669/10-S		
Palexia 4 mg/ml perorálny roztok	DE/H/2020/010	65/0411/12-S		
Palexia 20 mg/ml perorálny roztok	DE/H/2020/011	65/0412/12-S		
Palexia 50 mg film-coated tablets	DE/H/2020/001	PL 21727/0032	Grünenthal Ltd. Regus Lakeside House 1 Furzeground Way Stockley Park East Uxbridge, Middlesex UB11 1BD United Kingdom	UK
Palexia 75 mg film-coated tablets	DE/H/2020/002	PL 21727/0033		
Palexia 100 mg film-coated tablets	DE/H/2020/003	PL 21727/0034		
Palexia 4 mg/ml oral solution	DE/H/2020/010	PL 21727/0053		
Palexia 20 mg/ml oral solution	DE/H/2020/011	PL 21727/0054		
Palexia retard	DE/H/2020/009	84738.00.00 ENR: 2184738	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	DE (RMS)
Palexia retard	DE/H/2020/004	76261.00.00 ENR: 2176261		
Palexia retard	DE/H/2020/005	76262.00.00 ENR: 2176262		
Palexia retard	DE/H/2020/006	76263.00.00 ENR: 2176263		
Palexia retard	DE/H/2020/007	76264.00.00 ENR: 2176264		
Palexia retard	DE/H/2020/008	76265.00.00 ENR: 2176265		
Palexia retard	DE/H/2020/004	1-31064		
Palexia retard	DE/H/2020/005	1-31065		

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
Palexia retard	DE/H/2020/006	1-31066	2345 Brunn am Gebirge	
Palexia retard	DE/H/2020/007	1-31067	Austria	
Palexia retard	DE/H/2020/008	1-31068		
Palexia retard 25 mg tabletten met verlengde afgifte	DE/H/2020/009	BE425241	S.A. Grünenthal N.V. Lenneke Marelaan 8 1932	BE
Palexia retard 50 mg tabletten met verlengde afgifte	DE/H/2020/004	BE382837	Sint-Stevens-Woluwe Belgium	
Palexia retard 100 mg tabletten met verlengde afgifte	DE/H/2020/005	BE382846		
Palexia retard 150 mg tabletten met verlengde afgifte	DE/H/2020/006	BE382855		
Palexia retard 200 mg tabletten met verlengde afgifte	DE/H/2020/007	BE382864		
Palexia retard 250 mg tabletten met verlengde afgifte	DE/H/2020/008	BE382873		
Palexia retard 25 mg prolonged-release tablets	DE/H/2020/009	20120304	Grünenthal GmbH Zieglerstraße 6 52078 Aachen	BG
Palexia retard 50 mg prolonged-release tablets	DE/H/2020/004	20110165	Germany	
Palexia retard 100 mg prolonged-release tablets	DE/H/2020/005	20110166		
Palexia retard 150 mg prolonged-release tablets	DE/H/2020/006	20110167		
Palexia retard 200 mg prolonged-release tablets	DE/H/2020/007	20110168		

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
Palexia retard 250 mg prolonged-release tablets	DE/H/2020/008	20110169		
Palexia	DE/H/2020/009	*	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	CY
Palexia	DE/H/2020/004	21256		
Palexia	DE/H/2020/005	21257		
Palexia	DE/H/2020/006	21258		
Palexia	DE/H/2020/007	21259		
Palexia	DE/H/2020/008	21260		
Palexia retard 25 mg tablety s prodlouženým uvolňováním	DE/H/2020/009	65/310/12-C		
Palexia retard 50 mg tablety s prodlouženým uvolňováním	DE/H/2020/004	65/015/11-C		
Palexia retard 100 mg tablety s prodlouženým uvolňováním	DE/H/2020/005	65/016/11-C		
Palexia retard 150 mg tablety s prodlouženým uvolňováním	DE/H/2020/006	65/017/11-C		
Palexia retard 200 mg tablety s prodlouženým uvolňováním	DE/H/2020/007	65/018/11-C		
Palexia retard 250 mg tablety s prodlouženým uvolňováním	DE/H/2020/008	65/019/11-C		
Palexia Depot	DE/H/2020/009	48784	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	DK
Palexia Depot	DE/H/2020/004	45154		
Palexia Depot	DE/H/2020/005	45155		
Palexia Depot	DE/H/2020/006	45156		

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
Palexia Depot	DE/H/2020/007	45157		
Palexia Depot	DE/H/2020/008	45158		
Palexia retard	DE/H/2020/009	784612	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	EE
Palexia retard	DE/H/2020/004	712010		
Palexia retard	DE/H/2020/005	711710		
Palexia retard	DE/H/2020/006	711810		
Palexia retard	DE/H/2020/007	711910		
Palexia retard	DE/H/2020/008	711310		
Palexia retard	DE/H/2020/009	33651/25-4-2013	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	EL
Palexia retard	DE/H/2020/004	19219/15-3-2011, as amended 20-4-2011		
Palexia retard	DE/H/2020/005	19220/15-3-2011		
Palexia retard	DE/H/2020/006	19221/15-3-2011		
Palexia retard	DE/H/2020/007	19222/15-3-2011		
Palexia retard	DE/H/2020/008	19223/15-3-2011		
Palexia retard 25 mg comprimidos de liberación prolongada	DE/H/2020/009	75917	Grünenthal Pharma S.A C/ Doctor Zamenhof No. 36 28027 Madrid Spain	ES
Palexia retard 50 mg comprimidos de liberación prolongada	DE/H/2020/004	73243		
Palexia retard 100 mg comprimidos de liberación prolongada	DE/H/2020/005	73244		
Palexia retard 150 mg comprimidos de liberación prolongada	DE/H/2020/006	73245		

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
Palexia retard 200 mg comprimidos de liberación prolongada	DE/H/2020/007	73246		
Palexia retard 250 mg comprimidos de liberación prolongada	DE/H/2020/008	73247		
Palexia Depot 25 mg depottabletti	DE/H/2020/009	29798	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	FI
Palexia Depot 50 mg depottabletti	DE/H/2020/004	27583		
Palexia Depot 100 mg depottabletti	DE/H/2020/005	27584		
Palexia Depot 150 mg depottabletti	DE/H/2020/006	27585		
Palexia Depot 200 mg depottabletti	DE/H/2020/007	27586		
Palexia Depot 250 mg depottabletti	DE/H/2020/008	27587		
Palexia LP 50 mg, comprimé à libération prolongée	DE/H/2020/004	NL40884		
Palexia LP 100 mg, comprimé à libération prolongée	DE/H/2020/005	NL40885		
Palexia LP 150 mg, comprimé à libération prolongée	DE/H/2020/006	NL40886		
Palexia LP 200 mg, comprimé à libération prolongée	DE/H/2020/007	NL40887		
Palexia LP 250 mg, comprimé à libération prolongée	DE/H/2020/008	NL40888		

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
Palexia 25 mg tablete s produljenim oslobađanjem	DE/H/2020/009	UP/I-530-09/14-01/15	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	HR
Palexia 50 mg tablete s produljenim oslobađanjem	DE/H/2020/004	UP/I-530-09/14-01/16		
Palexia 100 mg tablete s produljenim oslobađanjem	DE/H/2020/005	UP/I-530-09/14-01/17		
Palexia 150 mg tablete s produljenim oslobađanjem	DE/H/2020/006	UP/I-530-09/14-01/18		
Palexia 200 mg tablete s produljenim oslobađanjem	DE/H/2020/007	UP/I-530-09/14-01/19		
Palexia 250 mg tablete s produljenim oslobađanjem	DE/H/2020/008	UP/I-530-09/14-01/20		
Palexias 25 mg retard tableta	DE/H/2020/009	OGYI-T-21638/09	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	HU
Palexias 50 mg retard tableta	DE/H/2020/004	OGYI-T-21638/04		
Palexias 100 mg retard tableta	DE/H/2020/005	OGYI-T-21638/05		
Palexias 150 mg retard tableta	DE/H/2020/006	OGYI-T-21638/06		
Palexias 200 mg retard tableta	DE/H/2020/007	OGYI-T-21638/07		
Palexias 250 mg retard tableta	DE/H/2020/008	OGYI-T-21638/08		
Palexia SR 25 mg prolonged-release tablets	DE/H/2020/009	PA1189/007/009	Grünenthal Ltd. Regus Lakeside House 1 Furzeground Way Stockley Park East Uxbridge, Middlesex	IE
Palexia SR 50 mg prolonged-release tablets	DE/H/2020/004	PA1189/007/004		

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
Palexia SR 100 mg prolonged-release tablets	DE/H/2020/005	PA1189/007/005	UB11 1BD United Kingdom	
Palexia SR 150 mg prolonged-release tablets	DE/H/2020/006	PA1189/007/006		
Palexia SR 200 mg prolonged-release tablets	DE/H/2020/007	PA1189/007/007		
Palexia SR 250 mg prolonged-release tablets	DE/H/2020/008	PA1189/007/008		
Palexia Depot	DE/H/2020/009	IS/1/12/050/01	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	IS
Palexia Depot	DE/H/2020/004	IS/1/10/009/04		
Palexia Depot	DE/H/2020/005	IS/1/10/009/05		
Palexia Depot	DE/H/2020/006	IS/1/10/009/06		
Palexia Depot	DE/H/2020/007	IS/1/10/009/07		
Palexia Depot	DE/H/2020/008	IS/1/10/009/08		
Palexia 25 mg compresse a rilascio prolungato	DE/H/2020/009	040423788/040423991 040423903/040423992 041571100/041571112	Grünenthal Italia S.r.l. Via Carlo Bo n. 11 20143 Milano Italy	IT
Palexia 50 mg compresse a rilascio prolungato	DE/H/2020/004	040422370/040422483 040423283/040423372 041571224/041571136		
Palexia 100 mg compresse a rilascio prolungato	DE/H/2020/005	040422495/040422608 040423384/040423473 041571148/041571151		
Palexia 150 mg compresse a rilascio prolungato	DE/H/2020/006	040422610/040422723 040423485/040423574 041571163/041571175		

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
Palexia 200 mg comprese a rilascio prolungato	DE/H/2020/007	040422735/040422848 040423586/040423675 041571187/041571199		
Palexia 250 mg comprese a rilascio prolungato	DE/H/2020/008	040422851/040422964 040423687/040423776 041571201/041571213		
Palexia retard 25 mg pailginto atpalaidavimo tabletės	DE/H/2020/009	LT/1/10/2342/111-132	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	LT
Palexia retard 50 mg pailginto atpalaidavimo tabletės	DE/H/2020/004	LT/1/10/2342/001-022		
Palexia retard 100 mg pailginto atpalaidavimo tabletės	DE/H/2020/005	LT/1/10/2342/023-044		
Palexia retard 150 mg pailginto atpalaidavimo tabletės	DE/H/2020/006	LT/1/10/2342/045-066		
Palexia retard 200 mg pailginto atpalaidavimo tabletės	DE/H/2020/007	LT/1/10/2342/067-088		
Palexia retard 250 mg pailginto atpalaidavimo tabletės	DE/H/2020/008	LT/1/10/2342/089-110		
Palexia retard 25 mg tabletten met verlengde afgifte	DE/H/2020/009	2012090063		
Palexia retard 50 mg tabletten met verlengde afgifte	DE/H/2020/004	2010110042		
Palexia retard 100 mg tabletten met verlengde afgifte	DE/H/2020/005	2010110043		



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
Palexia retard 150 mg tabletten met verlengde afgifte	DE/H/2020/006	2010110044		
Palexia retard 200 mg tabletten met verlengde afgifte	DE/H/2020/007	2010110045		
Palexia retard 250 mg tabletten met verlengde afgifte	DE/H/2020/008	2010110046		
Palexia retard 25 mg prolonged-release tablets	DE/H/2020/009	12-0156	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	LV
Palexia retard 50 mg prolonged-release tablets	DE/H/2020/004	10-0615		
Palexia retard 100 mg prolonged-release tablets	DE/H/2020/005	10-0616		
Palexia retard 150 mg prolonged-release tablets	DE/H/2020/006	10-0617		
Palexia retard 200 mg prolonged-release tablets	DE/H/2020/007	10-0618		
Palexia retard 250 mg prolonged-release tablets	DE/H/2020/008	10-0619		
Palexia retard 25 mg prolonged-release tablets	DE/H/2020/009	MA840/00109		
Palexia retard 50 mg prolonged-release tablets	DE/H/2020/004	MA840/00104		
Palexia retard 100 mg prolonged-release tablets	DE/H/2020/005	MA840/00105		

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
Palexia retard 150 mg prolonged-release tablets	DE/H/2020/006	MA840/00106		
Palexia retard 200 mg prolonged-release tablets	DE/H/2020/007	MA840/00107		
Palexia retard 250 mg prolonged-release tablets	DE/H/2020/008	MA840/00108		
Palexia retard	DE/H/2020/004	RVG 110724	Grünenthal B.V. De Corridor 21K 3621 ZA Breukelen The Netherlands	NL
Palexia retard	DE/H/2020/005	RVG 110728		
Palexia retard	DE/H/2020/006	RVG 110729		
Palexia retard	DE/H/2020/007	RVG 110730		
Palexia retard	DE/H/2020/008	RVG 110731		
Palexia depot 25 mg depottablett	DE/H/2020/009	11-8344	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	NO
Palexia depot 50 mg depottablett	DE/H/2020/004	09-6806		
Palexia depot 100 mg depottablett	DE/H/2020/005	09-6807		
Palexia depot 150 mg depottablett	DE/H/2020/006	09-6808		
Palexia depot 200 mg depottablett	DE/H/2020/007	09-6809		
Palexia depot 250 mg depottablett	DE/H/2020/008	09-6810		
Palexia retard	DE/H/2020/009	20417	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	PL
Palexia retard	DE/H/2020/004	18192		
Palexia retard	DE/H/2020/005	18193		
Palexia retard	DE/H/2020/006	18194		
Palexia retard	DE/H/2020/007	18195		

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
Palexia retard	DE/H/2020/008	18196		
Palexia retard	DE/H/2020/009	5462957 (20) 5462965 (30)	Grünenthal, S.A. Rua Alfredo da Silva,16 2610-016 Amadora Portugal	PT
Palexia retard	DE/H/2020/004	5334420 (20) 5334438 (30) 5334446 (60)		
Palexia retard	DE/H/2020/005	5334453 (20) 5334461 (30) 5334479 (60)		
Palexia retard	DE/H/2020/006	5334503 (20) 5334511 (30) 5334529 (60)		
Palexia retard	DE/H/2020/007	5334537 (20) 5334545 (30) 5334552 (60)		
Palexia retard	DE/H/2020/008	5334560 (20) 5334578 (30) 5334602 (60)		
Palexia retard 25 mg comprimate cu eliberare prelungita	DE/H/2020/009	4905/2012/01-22		
Palexia retard 50 mg comprimate cu eliberare prelungita	DE/H/2020/004	3282/2011/01-22		
Palexia retard 100 mg comprimate cu eliberare prelungita	DE/H/2020/005	3283/2011/01-22		
Palexia retard 150 mg comprimate cu eliberare prelungita	DE/H/2020/006	3284/2011/01-22		
Palexia retard 200 mg comprimate cu eliberare prelungita	DE/H/2020/007	3285/2011/01-22		

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		
Palexia retard 250 mg comprimate cu eliberare prelungita	DE/H/2020/008	3286/2011/01-22				
Palexia Depot, 25 mg depottablett	DE/H/2020/009	46138	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	SE		
Palexia Depot, 50 mg depottablett	DE/H/2020/004	42624				
Palexia Depot, 100 mg depottablett	DE/H/2020/005	42625				
Palexia Depot, 150 mg depottablett	DE/H/2020/006	42626				
Palexia Depot, 200 mg depottablett	DE/H/2020/007	42627				
Palexia Depot, 250 mg depottablett	DE/H/2020/008	42628				
Palexia SR 25 mg tablete s podaljšanim sproščanjem	DE/H/2020/009	5363-I-1495/12	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	SI		
Palexia SR 50 mg tablete s podaljšanim sproščanjem	DE/H/2020/004	5363-I-2339/12				
Palexia SR 100 mg tablete s podaljšanim sproščanjem	DE/H/2020/005	5363-I-2340/12				
Palexia SR 150 mg tablete s podaljšanim sproščanjem	DE/H/2020/006	5363-I-2341/12				
Palexia SR 200 mg tablete s podaljšanim sproščanjem	DE/H/2020/007	5363-I-2342/12				
Palexia SR 250 mg tablete s podaljšanim sproščanjem	DE/H/2020/008	5363-I-2343/12				
Palexia retard 25 mg tablety s predĺženým uvoľňovaním tbl plg	DE/H/2020/009	65/0225/12-S			Grünenthal GmbH Zieglerstraße 6	SK

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
Palexia retard 50 mg tablety s predĺženým uvoľňovaním tbl plg	DE/H/2020/004	65/0670/10-S	52078 Aachen Germany	
Palexia retard 100 mg tablety s predĺženým uvoľňovaním tbl plg	DE/H/2020/005	65/0671/10-S		
Palexia retard 150 mg tablety s predĺženým uvoľňovaním tbl plg	DE/H/2020/006	65/0672/10-S		
Palexia retard 200 mg tablety s predĺženým uvoľňovaním tbl plg	DE/H/2020/007	65/0673/10-S		
Palexia retard 250 mg tablety s predĺženým uvoľňovaním tbl plg	DE/H/2020/008	65/0674/10-S		
Palexia SR 25 mg prolonged-release tablets	DE/H/2020/009	PL 21727/0051	Grünenthal Ltd. Regus Lakeside House 1 Furzeground Way Stockley Park East Uxbridge, Middlesex UB11 1BD United Kingdom	UK
Palexia SR 50 mg prolonged-release tablets	DE/H/2020/004	PL 21727/0041		
Palexia SR 100 mg prolonged-release tablets	DE/H/2020/005	PL 21727/0042		
Palexia SR 150 mg prolonged-release tablets	DE/H/2020/006	PL 21727/0043		
Palexia SR 200 mg prolonged-release tablets	DE/H/2020/007	PL 21727/0044		
Palexia SR 250 mg prolonged-release tablets	DE/H/2020/008	PL 21727/0045		
Yantil	DE/H/2021/001	75046.00.00 ENR: 2175046		

Yantil	DE/H/2021/002	75047.00.00 ENR: 2175047	52078 Aachen Germany	
Yantil	DE/H/2021/003	75048.00.00 ENR: 2175048		
Yantil	DE/H/2021/010	85578.00.00 ENR: 2185578		
Yantil	DE/H/2021/011	85579.00.00 ENR: 2185579		
Yantil 50 mg filmomhulde tabletten	DE/H/2021/001	BE383083	S.A. Grünenthal N.V. Lenneke Marelaan 8 1932 Sint-Stevens-Woluwe Belgium	BE
Yantil 75 mg filmomhulde tabletten	DE/H/2021/002	BE383092		
Yantil 100 mg filmomhulde tabletten	DE/H/2021/003	BE383101		
Yantil 4 mg/ml drank	DE/H/2021/010	BE430263		
Yantil 20 mg/ml drank	DE/H/2021/011	BE430272		
Yantil 50 mg comprimidos recubiertos con película	DE/H/2021/001	73601	Grünenthal Pharma S.A C/ Doctor Zamenhof No. 36 28027 Madrid Spain	ES
Yantil 75 mg comprimidos recubiertos con película	DE/H/2021/002	73616		
Yantil 100 mg comprimidos recubiertos con película	DE/H/2021/003	73613		
Yantil 4 mg/ml solucion oral	DE/H/2021/010	76794		
Yantil 20 mg/ml solucion oral	DE/H/2021/011	76795		
Yantil 50 mg compresse rivestite con film	DE/H/2021/001	040425011/040425124 040425973/040428070		
Yantil 75 mg compresse rivestite con film	DE/H/2021/002	040425136/040425249 040428082/040428171		
Yantil 100 mg compresse rivestite con film	DE/H/2021/003	040425252/040425365 040428183/040428272		
Yantil	DE/H/2021/010	*		
Yantil	DE/H/2021/011	*		

Yantil 50 mg filmomhulde tabletten	DE/H/2021/001	2010110062	S.A. Grünenthal N.V. Lenneke Marelaan 8 1932 Sint-Stevens Woluwe Belgium	LU
Yantil 75 mg filmomhulde tabletten	DE/H/2021/002	2010110063		
Yantil 100 mg filmomhulde tabletten	DE/H/2021/003	2010110064		
Yantil	DE/H/2021/010	2013040139		
Yantil	DE/H/2021/011	2013040140		
Yantil	DE/H/2021/001	RVG 110690	Grünenthal B.V. De Corridor 21K 3621 ZA Breukelen The Netherlands	NL
Yantil	DE/H/2021/002	RVG 110691		
Yantil	DE/H/2021/003	RVG 110697		
Yantil retard	DE/H/2021/009	84739.00.00 ENR: 2184739	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany	DE
Yantil retard	DE/H/2021/004	76266.00.00 ENR: 2176266		
Yantil retard	DE/H/2021/005	76267.00.00 ENR: 2176267		
Yantil retard	DE/H/2021/006	76268.00.00 ENR: 2176268		
Yantil retard	DE/H/2021/007	76269.00.00 ENR: 2176269		
Yantil retard	DE/H/2021/008	76270.00.00 ENR: 2176270		
Yantil retard 25 mg tabletten met verlengde afgifte	DE/H/2021/009	BE425257		
Yantil retard 50 mg tabletten met verlengde afgifte	DE/H/2021/004	BE383117		
Yantil retard 100 mg tabletten met verlengde afgifte	DE/H/2021/005	BE383126		
Yantil retard 150 mg tabletten met verlengde afgifte	DE/H/2021/006	BE383135		

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	
Yantil retard 200 mg tabletten met verlengde afgifte	DE/H/2021/007	BE383144			
Yantil retard 250 mg tabletten met verlengde afgifte	DE/H/2021/008	BE383153			
Yantil retard 25 mg comprimidos de liberación prolongada	DE/H/2021/009	75921	Grünenthal Pharma S.A C/ Doctor Zamenhof No. 36 28027 Madrid Spain	ES	
Yantil retard 50 mg comprimidos de liberación prolongada	DE/H/2021/004	73624			
Yantil retard 100 mg comprimidos de liberación prolongada	DE/H/2021/005	73641			
Yantil retard 150 mg comprimidos de liberación prolongada	DE/H/2021/006	73629			
Yantil retard 200 mg comprimidos de liberación prolongada	DE/H/2021/007	73639			
Yantil retard 250 mg comprimidos de liberación prolongada	DE/H/2021/008	73630			
Yantil 25 mg compresse a rilascio prolungato	DE/H/2021/009	040428789/040428892 040428904/040428993 041572102/041572114		Grünenthal Italia S.r.l. Via Carlo Bo n. 11 20143 Milano Italy	IT
Yantil 50 mg compresse a rilascio prolungato	DE/H/2021/004	040425377/040425480 040428284/040428373 041572126/041572138			



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
Yantil 100 mg compresse a rilascio prolungato	DE/H/2021/005	040425492/040425605 040428385/040428474 041572140/041572153		
Yantil 150 mg compresse a rilascio prolungato	DE/H/2021/006	040425617/040425720 040428486/040428575 041572165/041572177		
Yantil 200 mg compresse a rilascio prolungato	DE/H/2021/007	040425732/040425845 040428587/040428676 041572189/041572191		
Yantil 250 mg compresse a rilascio prolungato	DE/H/2021/008	040425858/040425961 040428688/040428777 041572203/041572215		
Yantil retard 25 mg tabletten met verlengde afgifte	DE/H/2021/009	2012090080	S.A. Grünenthal N.V. Lenneke Marelaan 8 1932 Sint-Stevens Woluwe Belgium	LU
Yantil retard 50 mg tabletten met verlengde afgifte	DE/H/2021/004	2010110065		
Yantil retard 100 mg tabletten met verlengde afgifte	DE/H/2021/005	2010110066		
Yantil retard 150 mg tabletten met verlengde afgifte	DE/H/2021/006	2010110067		
Yantil retard 200 mg tabletten met verlengde afgifte	DE/H/2021/007	2010110068		
Yantil retard 250 mg tabletten met verlengde afgifte	DE/H/2021/008	2010110069		
Yantil retard	DE/H/2021/004	RVG 110698	Grünenthal B.V. De Corridor 21K	NL
Yantil retard	DE/H/2021/005	RVG 110702		

<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member state where product is authorised</b>
Yantil retard	DE/H/2021/006	RVG 110704	3621 ZA Breukelen	
Yantil retard	DE/H/2021/007	RVG 110705	The Netherlands	
Yantil retard	DE/H/2021/008	RVG 110706		