5 September 2019
EMA/517429/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: bupropion

Procedure no.: PSUSA/00000461/201812

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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
ELONTRIL 150 mg compresse a rilascio modificato	NL/H/786/001	037697012	GLAXOSMITHKLINE S.P.A.	IT
ELONTRIL 150 mg compresse a rilascio modificato	NL/H/786/001	037697024	GLAXOSMITHKLINE S.P.A.	IT
ELONTRIL 150 mg compresse a rilascio modificato	NL/H/786/001	037697036	GLAXOSMITHKLINE S.P.A.	IT
ELONTRIL 150 mg comprimate cu eliberare modificata	NL/H/786/001	4430/2012/01	GLAXOSMITHKLINE (GSK) S.R.L.	RO
ELONTRIL 150 mg comprimate cu eliberare modificată	NL/H/786/001	4430/2012/02	GLAXOSMITHKLINE (GSK) S.R.L.	RO
ELONTRIL 150 mg comprimate cu eliberare modificată	NL/H/786/001	4430/2012/03	GLAXOSMITHKLINE (GSK) S.R.L.	RO
Elontril 150 mg comprimidos de liberación modificada	NL/H/0786/001	68.615	GLAXOSMITHKLINE S.A.	ES
ELONTRIL 150 mg comprimidos de libertação modificada	NL/H/0786/001	5015649	BIAL - PORTELA & Cª , SA	PT
ELONTRIL 150 mg comprimidos de libertação modificada	NL/H/0786/001	5015656	BIAL - PORTELA & Cª , SA	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
ELONTRIL 150 mg comprimidos de libertação modificada	NL/H/0786/001	5015631	BIAL - PORTELA & Cª , SA	PT
ELONTRIL 150 mg comprimidos de libertação modificada	NL/H/0786/001	5015649	BIAL - PORTELA & Cª , SA	PT
ELONTRIL 150 mg comprimidos de libertação modificada	NL/H/0786/001	5015656	BIAL - PORTELA & Cª , SA	PT
ELONTRIL 150 mg comprimidos de libertação modificada	NL/H/0786/001	5015631	BIAL - PORTELA & Cª , SA	PT
Elontril 150 mg modifikuoto atpalaidavimo tabletes	NL/H/0786/001	LT/1/07/0705/001	GLAXOSMITHKLINE LIETUVA UAB	LT
Elontril 150 mg modifikuoto atpalaidavimo tabletes	NL/H/0786/001	LT/1/07/0705/003	GLAXOSMITHKLINE LIETUVA UAB	LT
Elontril 150 mg modifikuoto atpalaidavimo tabletės	NL/H/0786/001	LT/1/07/0705/002	GLAXOSMITHKLINE LIETUVA UAB	LT
Elontril 150 mg módosított hatóanyagleadású tabletta	NL/H/0786/001	OGYI-T-20351/01	GLAXOSMITHKLINE KFT.	HU
ELONTRIL 150 mg tabletten met gereguleerde afgifte	NL/H/786/001	RVG 33670	GLAXOSMITHKLINE B.V.	NL

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
Elontril 150 mg Tabletten mit veränderter Wirkstofffreisetzung	NL/H/0786/001	65630.00.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Elontril 150 mg tablety s riadeným uvoľňovaním	NL/H/0786/001	30/0041/07-S	GLAXOSMITHKLINE SLOVAKIA S.R.O.	SK
Elontril 150 mg tablety s řízeným uvolňováním	NL/H/0786/001	30/206/07-C	GLAXOSMITHKLINE (IRELAND) LIMITED	CZ
ELONTRIL 300 mg compresse a rilascio modificato	NL/H/786/002	037697048	GLAXOSMITHKLINE S.P.A.	IT
ELONTRIL 300 mg compresse a rilascio modificato	NL/H/786/002	037697051	GLAXOSMITHKLINE S.P.A.	IT
ELONTRIL 300 mg compresse a rilascio modificato	NL/H/786/002	037697063	GLAXOSMITHKLINE S.P.A.	IT
Elontril 300 mg comprimidos de liberación modificada	NL/H/0786/002	68.616	GLAXOSMITHKLINE S.A.	ES
ELONTRIL 300 mg comprimidos de libertação modificada	NL/H/0786/002	5015672	BIAL - PORTELA & Cª , SA	PT
ELONTRIL 300 mg comprimidos de libertação modificada	NL/H/0786/002	5015706	BIAL - PORTELA & Cª , SA	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
ELONTRIL 300 mg comprimidos de libertação modificada	NL/H/0786/002	5015664	BIAL - PORTELA & Cª , SA	PT
ELONTRIL 300 mg comprimidos de libertação modificada	NL/H/0786/002	5015672	BIAL - PORTELA & Cª , SA	PT
ELONTRIL 300 mg comprimidos de libertação modificada	NL/H/0786/002	5015706	BIAL - PORTELA & Cª , SA	PT
ELONTRIL 300 mg comprimidos de libertação modificada	NL/H/0786/002	5015664	BIAL - PORTELA & Cª , SA	PT
Elontril 300 mg modifikuoto atpalaidavimo tabletes	NL/H/0786/002	LT/1/07/0705/005	GLAXOSMITHKLINE LIETUVA UAB	LT
Elontril 300 mg modifikuoto atpalaidavimo tablets	NL/H/0786/002	LT/1/07/0705/006	GLAXOSMITHKLINE LIETUVA UAB	LT
Elontril 300 mg modifikuoto atpalaidavimo tabletės	NL/H/0786/002	LT/1/07/0705/004	GLAXOSMITHKLINE LIETUVA UAB	LT
Elontril 300 mg módosított hatóanyagleadású tabletta	NL/H/0786/002	OGYI-T-20351/02	GLAXOSMITHKLINE KFT.	HU
ELONTRIL 300 mg tabletten met gereguleerde afgifte	NL/H/786/002	RVG 33671	GLAXOSMITHKLINE B.V.	NL

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
Elontril 300 mg Tabletten mit veränderter Wirkstofffreisetzung	NL/H/0786/002	65631.00.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Elontril 300 mg tablety s riadeným uvoľňovaním	NL/H/786/002	30/0042/07-S	GLAXOSMITHKLINE SLOVAKIA S.R.O.	SK
Elontril 300 mg tablety s řízeným uvolňováním	NL/H/786/002	30/207/07-C	GLAXOSMITHKLINE (IRELAND) LIMITED	CZ
Elontril, 150 mg toimeainet modifitseeritult vabastavad tabletid	NL/H/786/001	534007	GLAXOSMITHKLINE (IRELAND) LIMITED	EE
Elontril, 300 mg toimeainet modifitseeritult vabastavad tabletid	NL/H/786/002	533907	GLAXOSMITHKLINE (IRELAND) LIMITED	EE
Voxra 150 mg säädellysti vapauttava tabletti	NL/H/786/001	27987	GLAXOSMITHKLINE OY	FI
Voxra 150 mg tablett med modifierad frisättning	NL/H/0786/001	23491	GLAXOSMITHKLINE AB	SE
Voxra 300 mg säädellysti vapauttava tabletti	NL/H/786/002	27988	GLAXOSMITHKLINE OY	FI
Voxra 300 mg tablett med modifierad frisättning	NL/H/0786/002	23492	GLAXOSMITHKLINE AB	SE

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
WELLBUTRIN 150 mg compresse a rilascio modificato	NL/H/785/001	037685017	GLAXOSMITHKLINE S.P.A.	IT
WELLBUTRIN 150 mg compresse a rilascio modificato.	NL/H/785/001	037685029	GLAXOSMITHKLINE S.P.A.	IT
WELLBUTRIN 150 mg compresse a rilascio modificato.	NL/H/785/001	037685031	GLAXOSMITHKLINE S.P.A.	IT
WELLBUTRIN 300 mg compresse a rilascio modificato	NL/H/785/002	037685043	GLAXOSMITHKLINE S.P.A.	IT
WELLBUTRIN 300 mg compresse a rilascio modificato.	NL/H/785/002	037685056	GLAXOSMITHKLINE S.P.A.	IT
WELLBUTRIN 300 mg compresse a rilascio modificato.	NL/H/785/002	037685068	GLAXOSMITHKLINE S.P.A.	IT
WELLBUTRIN RETARD 150 mg tablett med modifisert frisetting	NL/H/0786/001	06-3990	GLAXOSMITHKLINE AS	NO
Wellbutrin Retard 150 mg töflur með breyttan losunarhraða	NL/H/0786/001	IS/1/06/016/01	GLAXOSMITHKLINE PHARMA A/S	IS
WELLBUTRIN RETARD 300 mg tablett med modifisert frisetting	NL/H/0786/002	06-3991	GLAXOSMITHKLINE AS	NO

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
Wellbutrin Retard 300 mg töflur með breyttan losunarhraða.	NL/H/0786/002	IS/1/06/016/02	GLAXOSMITHKLINE PHARMA A/S	IS
WELLBUTRIN SR 150 mg ilgstošās darbības tabletes	not available	99-1047	GLAXOSMITHKLINE LATVIA SIA	LV
Wellbutrin SR 150 mg retard tabletta	not available	OGYI-T-7363/01	GLAXOSMITHKLINE KFT.	HU
Wellbutrin SR 150 mg tablety s predĺženým uvoľňovaním	not available	30/0309/00-S	GLAXOSMITHKLINE SLOVAKIA S.R.O.	SK
Wellbutrin SR 150 mg tablety s prodlouženým uvolnováním	not available	30/067/01-C	GLAXOSMITHKLINE (IRELAND) LIMITED	CZ
WELLBUTRIN XR 150 mg comprimés à libération modifiée	NL/H/0785/001	2007 09 0029	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
WELLBUTRIN XR 150 mg comprimidos de libertação modificada	NL/H/785/001	5015565	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LDA	PT
WELLBUTRIN XR 150 mg comprimidos de libertação modificada	NL/H/785/001	5015573	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LDA	PT
WELLBUTRIN XR 150 mg comprimidos de libertação modificada.	NL/H/0785/001	5015557	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LDA	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
WELLBUTRIN XR 150 mg modified release tablets	NL/H/0785/001	MA192/02301	GLAXOSMITHKLINE (IRELAND) LIMITED	MT
Wellbutrin XR 150 mg tablete s prilagođenim oslobađanjem	not available	HR-H-157768861	GLAXOSMITHKLINE D.O.O.	HR
WELLBUTRIN XR 150 mg tablete s prirejenim sproščanjem	NL/H/785/001	H/07/01664/001	GLAXOSMITHKLINE D.O.O.	SI
WELLBUTRIN XR 150 mg tablete s prirejenim sproščanjem	NL/H/785/001	H/07/01664/002	GLAXOSMITHKLINE D.O.O.	SI
WELLBUTRIN XR 150 mg tablete s prirejenim sproščanjem	NL/H/785/001	H/07/01664/003	GLAXOSMITHKLINE D.O.O.	SI
WELLBUTRIN XR 150 mg tabletten met gereguleerde afgifte	NL/H/785/001	RVG 33668	GLAXOSMITHKLINE B.V.	NL
WELLBUTRIN XR 150 mg Tabletten mit veränderter Wirkstofffreisetzung	NL/H/0785/001	BE294226	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
WELLBUTRIN XR 150 mg δισκία ελεγχόμενης αποδέσμευσης	NL/H/0785/001	20248	GLAXOSMITHKLINE (IRELAND) LIMITED	CY
WELLBUTRIN XR 150 mg δισκία ελεγχόμενης αποδέσμευσης.	NL/H/0785/001	2718801	GLAXOSMITHKLINE AEBE	GR

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Wellbutrin XR 150 mg-Retardtabletten	NL/H/785/001	1-26840	GLAXOSMITHKLINE PHARMA GMBH.	AT
WELLBUTRIN XR 300 mg comprimés à libération modifiée	NL/H/785/002	BE294235	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
WELLBUTRIN XR 300 mg comprimés à libération modifiée	NL/H/0785/002	2007 09 0030	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
WELLBUTRIN XR 300 mg comprimidos de libertação modificada	NL/H/785/002	5015607	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LDA	PT
WELLBUTRIN XR 300 mg comprimidos de libertação modificada	NL/H/785/002	5015615	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LDA	PT
WELLBUTRIN XR 300 mg comprimidos de libertação modificada	NL/H/785/002	5015623	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LDA	PT
WELLBUTRIN XR 300 mg modified release tablets	NL/H/0785/002	MA192/02302	GLAXOSMITHKLINE (IRELAND) LIMITED	MT
Wellbutrin XR 300 mg tablete s prilagođenim oslobađanjem	not available	HR-H-345088727	GLAXOSMITHKLINE D.O.O.	HR
WELLBUTRIN XR 300 mg tablete s prirejenim sproščanjem	NL/H/785/002	H/07/01664/004	GLAXOSMITHKLINE D.O.O.	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
WELLBUTRIN XR 300 mg tablete s prirejenim sprošcanjem	NL/H/785/002	H/07/01664/005	GLAXOSMITHKLINE D.O.O.	SI
WELLBUTRIN XR 300 mg tablete s prirejenim sproščanjem	NL/H/785/002	H/07/01664/006	GLAXOSMITHKLINE D.O.O.	SI
WELLBUTRIN XR 300 mg tabletten met gereguleerde afgifte	NL/H/785/002	RVG 33669	GLAXOSMITHKLINE B.V.	NL
WELLBUTRIN XR 300 mg δισκία ελεγχόμενης αποδέσμευσης	NL/H/785/002	20249	GLAXOSMITHKLINE (IRELAND) LIMITED	CY
WELLBUTRIN XR 300 mg δισκία ελεγχόμενης αποδέσμευσης.	NL/H/0785/002	2718802	GLAXOSMITHKLINE AEBE	GR
Wellbutrin XR 300 mg-Retardtabletten	NL/H/785/002	1-26841	GLAXOSMITHKLINE PHARMA GMBH.	AT
Wellbutrin XR, 150 mg, tabletki o zmodyfikowanym uwalnianiu	NL/H/0785/001	12786	GLAXOSMITHKLINE (IRELAND) LIMITED	PL
Wellbutrin XR, 300 mg, tabletki o zmodyfikowanym uwalnianiu	NL/H/0785/002	12787	GLAXOSMITHKLINE (IRELAND) LIMITED	PL
Zyban 150 mg compresse a rilascio prolungato	NL/H/0191/001	034853010	GLAXOSMITHKLINE 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
Zyban 150 mg compresse a rilascio prolungato	NL/H/0191/001	034853022	GLAXOSMITHKLINE S.P.A.	IT
Zyban 150 mg compresse a rilascio prolungato	NL/H/0191/001	034853034	GLAXOSMITHKLINE S.P.A.	IT
Zyban 150 mg compresse a rilascio prolungato	NL/H/0191/001	034853046	GLAXOSMITHKLINE S.P.A.	IT
Zyban 150 mg compresse a rilascio prolungato	NL/H/0191/001	034853059	GLAXOSMITHKLINE S.P.A.	IT
Zyban 150 mg comprimate cu eliberare prelungita	not available	8027/2006/02	GLAXOSMITHKLINE (IRELAND) LIMITED	RO
Zyban 150 mg comprimate cu eliberare prelungita	not available	8027/2006/01	GLAXOSMITHKLINE (IRELAND) LIMITED	RO
Zyban 150 mg comprimidos de libertação prolongada	NL/H/191/001	3198884	GLAXO WELLCOME FARMACÊUTICA, LDA	PT
Zyban 150 mg comprimidos de libertação prolongada	NL/H/191/001	3198983	GLAXO WELLCOME FARMACÊUTICA, LDA	PT
Zyban 150 mg comprimidos de libertação prolongada	NL/H/191/001	3199080	GLAXO WELLCOME FARMACÊUTICA, LDA	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
Zyban 150 mg comprimidos de libertação prolongada	NL/H/191/001	3199189	GLAXO WELLCOME FARMACÊUTICA, LDA	PT
Zyban 150 mg comprimidos de libertação prolongada	NL/H/191/001	3199288	GLAXO WELLCOME FARMACÊUTICA, LDA	PT
Zyban 150 mg depottabletter	NL/H/0191/001	18057	GLAXOSMITHKLINE OY	FI
Zyban 150 mg depottabletter	NL/H/191/001	00-167	GLAXOSMITHKLINE AS	NO
Zyban 150 mg depottabletter	NL/H/0191/001	16117	GLAXOSMITHKLINE AB	SE
Zyban 150 mg depottabletti	NL/H/0191/001	18057	GLAXOSMITHKLINE OY	FI
Zyban 150 mg forðatöflur	NL/H/0191/001	IS/1/00/006/01	GLAXOSMITHKLINE PHARMA A/S	IS
Zyban 150 mg prolonged release tablets	NL/H/0191/001	PA1077/17/1	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Zyban 150 mg prolonged release tablets.	NL/H/0191/001	PL 10949/0340	GLAXO WELLCOME UK LTD TRADING AS GLAXOSMITHKLINE UK	UK

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
Zyban 150 mg Retardtabletten	NL/H/0191/001	BE212843	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Zyban 150 mg Retardtabletten	NL/H/0191/001	49008.00.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Zyban 150 mg Retardtabletten	NL/H/0191/001	260/10/05/0796	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Zyban 150 mg tablete s podaljšanim sproščanjem	not available	H/02/01726/001	GLAXOSMITHKLINE D.O.O.	SI
Zyban 150 mg tabletten met verlengde afgifte	NL/H/0191/001	BE212843	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Zyban 150 mg, comprimés à libération prolongée	NL/H/0191/001	BE212843	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Zyban 150 mg, comprimés à libération prolongée.	NL/H/0191/001	260/10/05/0796	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
ZYBAN L.P. 150 mg, comprimé à libération prolongée	NL/H/0191/001	NL26670	LABORATOIRE GLAXOSMITHKLINE	FR
Zyban, 150 mg δισκία. παρατεταμένης αποδέσμευσης	NL/H/191/001	2479701	GLAXOSMITHKLINE AEBE	GR

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
Zyban, 150 mg, tabletki powlekane o przedłużonym uwalnianiu	not available	4909	GLAXOSMITHKLINE (IRELAND) LIMITED	PL
Zyban, depottabletter	NL/H/0191/001	31347	GLAXOSMITHKLINE PHARMA A/S	DK
Zyban, tabletten met verlengde afgifte 150 mg.	NL/H/0191/001	RVG 24160	GLAXOSMITHKLINE B.V.	NL
Zyntabac 150 mg comprimidos de liberación prolongada.	NL/H/0194/001	63.265	GLAXOSMITHKLINE S.A.	ES
Zyntabac, tabletten met verlengde afgifte 150 mg	NL/H/194/001	RVG 25041	GLAXOSMITHKLINE B.V.	NL