



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 September 2022
EMA/842375/2022
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): bupropion

Procedure No. PSUSA/00000461/202112



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/0786/001	037697012	GLAXOSMITHKLINE S.P.A.	IT
ELONTRIL 150 mg compresse a rilascio modificato	NL/H/0786/001	037697024	GLAXOSMITHKLINE S.P.A.	IT
ELONTRIL 150 mg compresse a rilascio modificato	NL/H/0786/001	037697036	GLAXOSMITHKLINE S.P.A.	IT
ELONTRIL 150 mg comprimate cu eliberare modificata	NL/H/0786/001	4430/2012/01	GLAXOSMITHKLINE TRADING SERVICES LIMITED	RO
ELONTRIL 150 mg comprimate cu eliberare modificata	NL/H/0786/001	4430/2012/03	GLAXOSMITHKLINE TRADING SERVICES LIMITED	RO
ELONTRIL 150 mg comprimate cu eliberare modificată	NL/H/0786/001	4430/2012/02	GLAXOSMITHKLINE TRADING SERVICES LIMITED	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 & C ^a , SA	PT
ELONTRIL 150 mg comprimidos de libertação modificada.	NL/H/0786/001	5015656	BIAL - PORTELA & C ^a , SA	PT
ELONTRIL 150 mg comprimidos de libertação modificada.	NL/H/0786/001	5015631	BIAL - PORTELA & C ^a , SA	PT
Elontril 150 mg modifikuoto atpalaidavimo tabletes	NL/H/0786/001	LT/1/07/0705/001	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LT
Elontril 150 mg modifikuoto	NL/H/0786/001	LT/1/07/0705/003	GLAXOSMITHKLINE TRADING SERVICES	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
atpalaidavimo tabletės			LIMITED	
Elontril 150 mg modifikuoto atpalaidavimo tabletės	NL/H/0786/001	LT/1/07/0705/002	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LT
Elontril 150 mg módosított hatóanyagleadású tabletta	NL/H/0786/001	OGYI-T-20351/01	GLAXOSMITHKLINE TRADING SERVICES LIMITED	HU
ELONTRIL 150 mg tabletten met gereguleerde afgifte.	NL/H/0786/001	RVG 33670	GLAXOSMITHKLINE B.V.	NL
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 TRADING SERVICES LIMITED	SK
Elontril 150 mg tablety s řízeným uvoľňovaním	NL/H/0786/001	30/206/07-C	GLAXOSMITHKLINE (IRELAND) LIMITED	CZ
ELONTRIL 300 mg compresse a rilascio modificato	NL/H/0786/002	037697048	GLAXOSMITHKLINE S.P.A.	IT
ELONTRIL 300 mg compresse a rilascio modificato	NL/H/0786/002	037697051	GLAXOSMITHKLINE S.P.A.	IT
ELONTRIL 300 mg compresse a rilascio modificato	NL/H/0786/002	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 & C ^a , SA	PT
ELONTRIL 300 mg comprimidos de libertação modificada.	NL/H/0786/002	5015706	BIAL - PORTELA & C ^a , 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 modifikuoto atpalaidavimo tabletės	NL/H/0786/002	LT/1/07/0705/004	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LT
Elontril 300 mg modifikuoto atpalaidavimo tabletės	NL/H/0786/002	LT/1/07/0705/005	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LT
Elontril 300 mg modifikuoto atpalaidavimo tabletės	NL/H/0786/002	LT/1/07/0705/006	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LT
Elontril 300 mg módosított hatóanyagleadású tableta	NL/H/0786/002	OGYI-T-20351/02	GLAXOSMITHKLINE TRADING SERVICES LIMITED	HU
ELONTRIL 300 mg tabletten met gereguleerde afgifte.	NL/H/0786/002	RVG 33671	GLAXOSMITHKLINE B.V.	NL
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 TRADING SERVICES LIMITED	SK
Elontril 300 mg tablety s řízeným uvoľňovaním	NL/H/786/002	30/207/07-C	GLAXOSMITHKLINE (IRELAND) LIMITED	CZ
Elontril, 150 mg toimeainet modifitseeritult vabastavad tabletid	NL/H/0786/001	534007	GLAXOSMITHKLINE (IRELAND) LIMITED	EE
Elontril, 300 mg toimeainet modifitseeritult vabastavad tabletid	NL/H/0786/002	533907	GLAXOSMITHKLINE (IRELAND) LIMITED	EE
Voxra 150 mg säädellysti vapauttava tabletti	NL/H/0786/001	27987	GLAXOSMITHKLINE OY	FI

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
Voxra 150 mg tablett med modifierad frisättning	NL/H/0786/001	27987	GLAXOSMITHKLINE OY	FI
Voxra 150 mg tablett med modifierad frisättning.	NL/H/0786/001	23491	GLAXOSMITHKLINE AB	SE
Voxra 300 mg säadellysti vapauttava tabletti	NL/H/786/002	27988	GLAXOSMITHKLINE OY	FI
Voxra 300 mg tablett med modifierad frisättning	NL/H/0786/002	27988	GLAXOSMITHKLINE OY	FI
Voxra 300 mg tablett med modifierad frisättning.	NL/H/0786/002	23492	GLAXOSMITHKLINE AB	SE
WELLBUTRIN 150 mg compresse a rilascio modificato	NL/H/0785/001	037685017	GLAXOSMITHKLINE S.P.A.	IT
WELLBUTRIN 150 mg compresse a rilascio modificato.	NL/H/0785/001	037685029	GLAXOSMITHKLINE S.P.A.	IT
WELLBUTRIN 150 mg compresse a rilascio modificato.	NL/H/0785/001	037685031	GLAXOSMITHKLINE S.P.A.	IT
WELLBUTRIN 300 mg compresse a rilascio modificato	NL/H/0785/002	037685043	GLAXOSMITHKLINE S.P.A.	IT
WELLBUTRIN 300 mg compresse a rilascio modificato.	NL/H/0785/002	037685056	GLAXOSMITHKLINE S.P.A.	IT
WELLBUTRIN 300 mg compresse a rilascio modificato.	NL/H/0785/002	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 breytta losunarhraða.	NL/H/0786/001	IS/1/06/016/01	GLAXOSMITHKLINE PHARMA A/S	IS

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 tablett med modifisert frisetting	NL/H/0786/002	06-3991	GLAXOSMITHKLINE AS	NO
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 ilgstošas darbības tabletes	not available	99-1047	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LV
Wellbutrin SR 150 mg tablety s riadeným uvoľňovaním	not available	30/0309/00-S	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SK
WELLBUTRIN XR 150 mg comprimés à libération modifiée	NL/H/0785/001	BE294226	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
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/0785/001	5015557	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LDA	PT
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/0785/001	5015573	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LDA	PT
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 TRADING SERVICES LIMITED	HR
WELLBUTRIN XR 150 mg tablete s prirejenim sproščanjem	NL/H/0785/001	H/07/01664/001	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SI
WELLBUTRIN XR 150 mg tablete s prirejenim sproščanjem	NL/H/0785/001	H/07/01664/002	GLAXOSMITHKLINE TRADING SERVICES LIMITED	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 150 mg tablete s prirejenim sproščanjem	NL/H/0785/001	H/07/01664/003	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SI
WELLBUTRIN XR 150 mg tabletten met gereguleerde afgifte	NL/H/0785/001	BE294226	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
WELLBUTRIN XR 150 mg tabletten met gereguleerde afgifte.	NL/H/0785/001	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 Tabletten mit veränderter Wirkstofffreisetzung	NL/H/0785/001	2007 09 0029	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
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 SINGLE MEMBER A.E.B.E.	GR
Wellbutrin XR 150 mg-Retardtabletten	NL/H/0785/001	1-26840	GLAXOSMITHKLINE PHARMA GMBH.	AT
WELLBUTRIN XR 300 mg comprimés à libération modifiée	NL/H/0785/002	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/0785/002	5015607	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LDA	PT
WELLBUTRIN XR 300 mg comprimidos de libertação modificada.	NL/H/0785/002	5015615	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LDA	PT
WELLBUTRIN XR 300 mg	NL/H/0785/002	5015623	GLAXOSMITHKLINE -	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 de libertação modificada.			PRODUTOS FARMACEUTICOS, LDA	
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 TRADING SERVICES LIMITED	HR
WELLBUTRIN XR 300 mg tablete s prirejenim sproščanjem	NL/H/0785/002	H/07/01664/005	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SI
WELLBUTRIN XR 300 mg tablete s prirejenim sproščanjem	NL/H/0785/002	H/07/01664/006	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SI
WELLBUTRIN XR 300 mg tablete s prirejenim sproščanjem	NL/H/0785/002	H/07/01664/004	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SI
WELLBUTRIN XR 300 mg tabletten met gereguleerde afgifte.	NL/H/0785/002	BE294235	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
WELLBUTRIN XR 300 mg tabletten met gereguleerde afgifte.	NL/H/0785/002	RVG 33669	GLAXOSMITHKLINE B.V.	NL
WELLBUTRIN XR 300 mg Tabletten mit veränderter Wirkstofffreisetzung	NL/H/0785/002	BE294235	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
WELLBUTRIN XR 300 mg Tabletten mit veränderter Wirkstofffreisetzung	NL/H/0785/002	2007 09 0030	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
WELLBUTRIN XR 300 mg δισκία ελεγχόμενης αποδέσμευσης	NL/H/0785/002	20249	GLAXOSMITHKLINE (IRELAND) LIMITED	CY
WELLBUTRIN XR 300 mg δισκία ελεγχόμενης αποδέσμευσης.	NL/H/0785/002	2718802	GLAXOSMITHKLINE SINGLE MEMBER A.E.B.E.	GR
Wellbutrin XR 300 mg-Retardtabletten	NL/H/785/002	1-26841	GLAXOSMITHKLINE PHARMA GMBH.	AT

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, 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
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	12478/2019/02	GLAXOSMITHKLINE (IRELAND) LIMITED	RO
Zyban 150 mg comprimate cu eliberare prelungită	not available	12478/2019/01	GLAXOSMITHKLINE (IRELAND) LIMITED	RO
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	0260/10050796	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Zyban 150 mg comprimidos de libertação prolongada	NL/H/191/001	3198884	GLAXO WELLCOME FARMACÉUTICA, 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	3199080	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	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/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	XI
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 tabletten met verlengde afgifte.	NL/H/0191/001	BE212843	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
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/0191/001	2479701	GLAXOSMITHKLINE SINGLE MEMBER A.E.B.E.	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/0194/001	RVG 25041	GLAXOSMITHKLINE B.V.	NL