09 November 2023
EMA/xxxxxxx/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): valproate

Procedure No. EMEA/H/N/PSR/J/0045

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Annex I – Aurobindo Pharma B.V.

Specific Information for PASS107 Submissions

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Natriumvalproaat Aurobindo 150 mg, maagsspresistente tabletten	Not applicable	RVG 55564	Aurobindo Pharma B.V.	Netherlands	Not applicable
Natriumvalproaat Aurobindo 300 mg, maagsapresistente tabletten	Not applicable	RVG 55565	Aurobindo Pharma B.V.	Netherlands	Not applicable
Natriumvalproaat Aurobindo 600 mg, maagsapresistente tabletten	Not applicable	RVG 55566	Aurobindo Pharma B.V.	Netherlands	Not applicable
Natriumvalproaat Aurobindo 300 mg/5ml, drank	Not applicable	RVG 55567	Aurobindo Pharma B.V.	Netherlands	Not applicable

Annex I - Aristo Pharma GmbH

Specific Information for PASS107 Submissions

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Valproat Aristo® 300 mg, magensaftresistente Filmtabletten	Not applicable (national)	48771.01.00	Aristo Pharma GmbH	Germany	Not applicable
Valproat Aristo® 600 mg, magensaftresistente Filmtabletten	Not applicable (national)	48771.02.00	Aristo Pharma GmbH	Germany	Not applicable
Valproat Aristo® 300 mg/g Tropfen zum Einnehmen	Not applicable (national)	3000102.00.00	Aristo Pharma GmbH	Germany	Not applicable

Annex I - Arrow generiques

Specific Information for PASS107 Submissions

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
VALPROATE DE SODIUM ARROW LP 500 mg, comprimé pelliculé sécable à liberation prolongée	Not applicable	NL30697	ARROW GENERIQUES	France	Not applicable
VALPROATE DE SODIUM ARROW 200 mg/ml, solution buvable	Not applicable	NL39636	ARROW GENERIQUES	France	Not applicable
VALPROATE DE SODIUM ARROW LAB 200 mg/ml, solution buvable	Not applicable	NL51137	ARROW GENERIQUES	France	Not applicable

Annex I - Betapharm Arzneimittel GmbH / Dr Reddy's

Specific Information for PASS107 Submissions

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Valpro beta 150, Filmtabletten	Not applicable	47335.00.01	betapharm Arzneimittel GmbH	Germany	Not applicable
Valpro beta 300, Filmtabletten	Not applicable	46584.00.00	betapharm Arzneimittel GmbH	Germany	Not applicable
Valpro beta 600, Filmtabletten	Not applicable	46584.01.00	betapharm Arzneimittel GmbH	Germany	Not applicable
Valpro beta chrono 300 mg Retardtabletten	Not applicable	59589.00.00	betapharm Arzneimittel GmbH	Germany	Not applicable
Valpro beta chrono 500 mg Retardtabletten	Not applicable	59589.01.00	betapharm Arzneimittel GmbH	Germany	Not applicable

Annex I - Consilient Health

Specific Information for PASS107 Submissions

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Belvo 250 mg gastro-resistant tablets	DCP	PL 24837/0108	Consilient Health Ltd	United Kingdom	Not applicable
Belvo 500 mg gastro-resistant tablets	DCP	PL 24837/0109	Consilient Health Ltd	United Kingdom	Not applicable

Annex I – CRESCENT PHARMA Limited

Specific Information for PASS107 Submissions

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Sodium Valproate Crescent Oral Solution BP 200mg/5ml or Kentlim (for Kent/OPD) or Valpal (for Ashbourne)	Not applicable	PL20416/0575	Crescent Pharma Limited	United Kingdom	Not applicable

Annex I - Desitin Arzneimittel GmbH

Specific Information for PASS107 Submissions

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Orfiril 150	Not applicable	1691.02.00	Desitin Arzneimittel GmbH	Germany	Not applicable
Orfiril 200 mg	Not applicable	43630.00.00	Desitin Arzneimittel GmbH	Germany	Not applicable
Orfiril 300	Not applicable	1691.01.00	Desitin Arzneimittel GmbH	Germany	Not applicable
Orfiril 600	Not applicable	1691.00.00	Desitin Arzneimittel GmbH	Germany	Not applicable
Orfiril long 1000 mg	Not applicable	57471.01.01	Desitin Arzneimittel GmbH	Germany	Not applicable
Orfiril long 150 mg	Not applicable	57471.00.00	Desitin Arzneimittel GmbH	Germany	Not applicable
Orfiril long 300 mg	Not applicable	57471.01.00	Desitin Arzneimittel GmbH	Germany	Not applicable
Orfiril long 500 mg	Not applicable	57471.00.01	Desitin Arzneimittel GmbH	Germany	Not applicable
Orfiril Saft	Not applicable	1691.00.02	Desitin Arzneimittel GmbH	Germany	Not applicable
Orfiril chrono Desitin 300 mg Retardtabletten	Not applicable	63963.00.00	Desitin Arzneimittel GmbH	Germany	Not applicable
Orfiril chrono Desitin 500 mg Retardtabletten	Not applicable	63964.00.00	Desitin Arzneimittel GmbH	Germany	Not applicable
Episenta 1000 mg prolonged-release granules	Not applicable	PL 14040/0027	Desitin Arzneimittel GmbH	Great Britain	Not applicable
Episenta 150 mg prolonged-release capsule	Not applicable	PL 14040/0024	Desitin Arzneimittel GmbH	Great Britain	Not applicable
Episenta 300 mg prolonged-release capsule	Not applicable	PL 14040/0025	Desitin Arzneimittel GmbH	Great Britain	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Episenta 500 mg prolonged-release granules	Not applicable	PL 14040/0026	Desitin Arzneimittel GmbH	Great Britain	Not applicable
Orfiril 150 mg enterotabletter	Not applicable	9648	Desitin Arzneimittel GmbH	Sweden	Not applicable
Orfiril 300 mg enterotabletter	Not applicable	9649	Desitin Arzneimittel GmbH	Sweden	Not applicable
Orfiril long 150 mg	Not applicable	13188	Desitin Arzneimittel GmbH	Sweden	Not applicable
Orfiril long 300 mg	Not applicable	13189	Desitin Arzneimittel GmbH	Sweden	Not applicable
Orfiril long 500 mg	Not applicable	14577	Desitin Arzneimittel GmbH	Sweden	Not applicable
Orfiril 300	Not applicable	21/142/92-B/C	Desitin Arzneimittel GmbH	Czech Republic	Not applicable
Orfiril 600	Not applicable	21/142/92-C/C	Desitin Arzneimittel GmbH	Czech Republic	Not applicable
Orfiril long 1000 mg	Not applicable	21/086/00-C	Desitin Arzneimittel GmbH	Czech Republic	Not applicable
Orfiril long 150 mg	Not applicable	21/083/00-C	Desitin Arzneimittel GmbH	Czech Republic	Not applicable
Orfiril long 300 mg	Not applicable	21/084/00-C	Desitin Arzneimittel GmbH	Czech Republic	Not applicable
Orfiril long 500 mg	Not applicable	21/085/00-C	Desitin Arzneimittel GmbH	Czech Republic	Not applicable
Orfiril 300 mg	Not applicable	9918	Desitin Arzneimittel GmbH	Denmark	Not applicable
Orfiril, Oral opløsning	Not applicable	9919	Desitin Arzneimittel GmbH	Denmark	Not applicable
Orfiril 600 mg	Not applicable	10635	Desitin Arzneimittel GmbH	Denmark	Not applicable
Orfiril long 1000 mg	Not applicable	19056	Desitin Arzneimittel GmbH	Denmark	Not applicable
Orfiril long 150 mg	Not applicable	18324	Desitin Arzneimittel GmbH	Denmark	Not applicable
Orfiril long 300 mg	Not applicable	18325	Desitin Arzneimittel GmbH	Denmark	Not applicable
Orfiril long 500 mg	Not applicable	19055	Desitin Arzneimittel GmbH	Denmark	Not applicable
Orfiril retard	Not applicable	14700	Desitin Arzneimittel GmbH	Denmark	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Orfiril 300	Not applicable	209098	Desitin Arzneimittel GmbH	Estonia	Not applicable
Orfiril 600	Not applicable	209198	Desitin Arzneimittel GmbH	Estonia	Not applicable
Orfiril 150	Not applicable	208998	Desitin Arzneimittel GmbH	Estonia	Not applicable
Orfiril long 150 mg	Not applicable	326200	Desitin Arzneimittel GmbH	Estonia	Not applicable
Orfiril long 300 mg	EE/H/0104/001/MR	326300	Desitin Arzneimittel GmbH	Estonia	Not applicable
Orfiril long 500 mg	EE/H/0104/002/MR	326400	Desitin Arzneimittel GmbH	Estonia	Not applicable
Orfiril Saft	Not applicable	178797	Desitin Arzneimittel GmbH	Estonia	Not applicable
Orfiril long 150 mg	Not applicable	13214	Desitin Arzneimittel GmbH	Finland	Not applicable
Orfiril long 300 mg	Not applicable	13215	Desitin Arzneimittel GmbH	Finland	Not applicable
Orfiril long 500 mg	Not applicable	13216	Desitin Arzneimittel GmbH	Finland	Not applicable
Orfiril 150 mg	Not applicable	792388	Desitin Arzneimittel GmbH	Iceland	Not applicable
Orfiril 60 mg/ml mixtúra, lausn	Not applicable	812671	Desitin Arzneimittel GmbH	Iceland	Not applicable
Orfiril 600 mg	Not applicable	812672	Desitin Arzneimittel GmbH	Iceland	Not applicable
Orfiril retard 300 mg fordatöflur	Not applicable	920075	Desitin Arzneimittel GmbH	Iceland	Not applicable
Orfiril 150 mg enterotablett	Not applicable	6564	Desitin Arzneimittel GmbH	Norway	Not applicable
Orfiril 300 mg enterotablett	Not applicable	6565	Desitin Arzneimittel GmbH	Norway	Not applicable
Orfiril 60 mg/ml mikstur, oppløsning	Not applicable	6563	Desitin Arzneimittel GmbH	Norway	Not applicable
Orfiril 600 mg enterotablett	Not applicable	6635	Desitin Arzneimittel GmbH	Norway	Not applicable
Orfiril long 1000 mg	Not applicable	98-2477	Desitin Arzneimittel GmbH	Norway	Not applicable
Orfiril long 150 mg	Not applicable	96-1965	Desitin Arzneimittel GmbH	Norway	Not applicable
Orfiril long 300 mg	Not applicable	96-1966	Desitin Arzneimittel GmbH	Norway	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Orfiril long 500 mg	Not applicable	98-2476	Desitin Arzneimittel GmbH	Norway	Not applicable
Orfiril retard 300 mg depottablett	Not applicable	7866	Desitin Arzneimittel GmbH	Norway	Not applicable
Orfiril long 1000 mg	Not applicable	8680/2016/01-06	Desitin Arzneimittel GmbH	Romania	Not applicable
Orfiril long 150 mg	Not applicable	8677/2016/01-03	Desitin Arzneimittel GmbH	Romania	Not applicable
Orfiril long 300 mg	Not applicable	8678/2016/01-06	Desitin Arzneimittel GmbH	Romania	Not applicable
Orfiril long 500 mg	Not applicable	8679/2016/01-06	Desitin Arzneimittel GmbH	Romania	Not applicable
Orfiri 300	Not applicable	21/0142/92-S	Desitin Arzneimittel GmbH	Slovakia	Not applicable
Orfiri 600	Not applicable	21/0142/92-S	Desitin Arzneimittel GmbH	Slovakia	Not applicable
Orfiri 150	Not applicable	21/0142/92-S	Desitin Arzneimittel GmbH	Slovakia	Not applicable
Orfiril long 1000 mg	Not applicable	21/0077/01-S	Desitin Arzneimittel GmbH	Slovakia	Not applicable
Orfiril long 150 mg	Not applicable	21/0298/00-S	Desitin Arzneimittel GmbH	Slovakia	Not applicable
Orfiril long 300 mg	Not applicable	21/0299/00-S	Desitin Arzneimittel GmbH	Slovakia	Not applicable
Orfiril long 500 mg	Not applicable	21/0076/01-S	Desitin Arzneimittel GmbH	Slovakia	Not applicable

Annex I - Generis Farmaceutica S.A.

Specific Information for PASS107 Submissions

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Ácido Valpróico Generis 300 mg comprimido de libertação prolongada	Not applicable	04/H/0076/001	Generis Farmacêutica S.A.	Portugal	Not applicable
Ácido Valpróico Generis 500 mg comprimido de libertação prolongada	Not applicable	04/H/0076/002	Generis Farmacêutica S.A.	Portugal	Not applicable

Annex I - G.L. Pharma GmbH

Specific Information for PASS107 Submissions

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Natriumvalproat G.L. 300 mg – Retardtabletten	Not applicable	1-25766	G.L. Pharma GmbH	Austria	Not applicable
Natriumvalproat G.L. 500 mg – Retardtabletten (generic)	Not applicable	1-25767	G.L. Pharma GmbH	Austria	Not applicable
Convulex 100 mg/ml - Injektionslösung	Not applicable	1-25002	G.L. Pharma GmbH	Austria	Not applicable
Convulex 300 mg - Retardtabletten	AT/H/0820/001 /MR	1-24546	G.L. Pharma GmbH	Austria	Not applicable
Convulex 500 mg - Retardtabletten	AT/H/0820/002 /MR	1-24547	G.L. Pharma GmbH	Austria	Not applicable
Convulex 50 mg/ml - Sirup für Kinder	Not applicable	17.127	G.L. Pharma GmbH	Austria	Not applicable
Convulex 300 mg/ml Lösung zum Einnehmen	Not applicable	15.864	G.L. Pharma GmbH	Austria	Not applicable
Convulex 150 mg - Kapseln	Not applicable	16.058	G.L. Pharma GmbH	Austria	Not applicable
Convulex 300 mg - Kapseln	Not applicable	16.057	G.L. Pharma GmbH	Austria	Not applicable
Convulex 500 mg - Kapseln	Not applicable	17.044	G.L. Pharma GmbH	Austria	Not applicable
Convulex 50 mg/ml syrup	Not applicable	20000205	G.L. Pharma GmbH	Bulgaria	Not applicable
Convulex chrono 300 mg prolonged-release tablets	Not applicable	20030189	G.L. Pharma GmbH	Bulgaria	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Convulex chrono 500 mg prolonged-release tablets	Not applicable	20030190	G.L. Pharma GmbH	Bulgaria	Not applicable
Convulex 100 mg/ml solution for injection/infusion	Not applicable	20110203	G.L. Pharma GmbH	Bulgaria	Not applicable
Convulex 300 mg gastro-resistant capsules, soft	Not applicable	20000210	G.L. Pharma GmbH	Bulgaria	Not applicable
Convulex 500 mg gastro-resistant capsules, soft	Not applicable	20000206	G.L. Pharma GmbH	Bulgaria	Not applicable
Convulex	Not applicable	21/037/82-S/C	G.L. Pharma GmbH	Czech Republic	Not applicable
Convulex	Not applicable	21/033/77-S/C	G.L. Pharma GmbH	Czech Republic	Not applicable
Convulex CR 300 mg	Not applicable	21/173/01-C	G.L. Pharma GmbH	Czech Republic	Not applicable
Convulex CR 500 mg	Not applicable	21/184/01-C	G.L. Pharma GmbH	Czech Republic	Not applicable
Convulex 150 mg	Not applicable	21/032/77-A/C	G.L. Pharma GmbH	Czech Republic	Not applicable
Convulex 300 mg	Not applicable	21/032/77-B/C	G.L. Pharma GmbH	Czech Republic	Not applicable
Convulex 500 mg	Not applicable	21/032/77-C/C	G.L. Pharma GmbH	Czech Republic	Not applicable
CONVULEX, 50 mg/ml siirup	Not applicable	450804	G.L. Pharma GmbH	Estonia	Not applicable
CONVULEX 300 MG/ML, 300 mg/ml suukaudne lahus, tilgad	Not applicable	450904	G.L. Pharma GmbH	Estonia	Not applicable
Convulex, 100 mg/ml süstelahus/infusiooni lahuse kontsentraat	Not applicable	515406	G.L. Pharma GmbH	Estonia	Not applicable
CONVULEX RETARD 300 mg, toimeainet prolongeeritult vabastavad tabletid	Not applicable	513806	G.L. Pharma GmbH	Estonia	Not applicable
CONVULEX RETARD 500 mg, toimeainet prolongeeritult vabastavad tabletid	Not applicable	513706	G.L. Pharma GmbH	Estonia	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
CONVULEX 150 mg, gastroresistentsed pehmekapslid	Not applicable	443204	G.L. Pharma GmbH	Estonia	Not applicable
CONVULEX 300 mg, gastroresistentsed pehmekapslid	Not applicable	443304	G.L. Pharma GmbH	Estonia	Not applicable
CONVULEX 500 mg, gastroresistentsed pehmekapslid	Not applicable	443404	G.L. Pharma GmbH	Estonia	Not applicable
Convulex 300	Not applicable	2241.02.00	G.L. Pharma GmbH	Germany	Not applicable
Convulex 500	Not applicable	2241.00.00	G.L. Pharma GmbH	Germany	Not applicable
Valproat G.L. Pharma 300 mg Retardtabletten	AT/H/0820/001	54240.00.00	G.L. Pharma GmbH	Germany	Not applicable
Valproat G.L. Pharma 500 mg Retardtabletten	AT/H/0820/002	54240.01.00	G.L. Pharma GmbH	Germany	Not applicable
Convulex 300 mg retard filmtabletta	Not applicable	OGYI-T-8893/01-02	G.L. Pharma GmbH	Hungary	Not applicable
Convulex 500 mg retard filmtabletta	Not applicable	OGYI-T-8893/03-04	G.L. Pharma GmbH	Hungary	Not applicable
Convulex 50 mg/ml szirup gyermekeknek	Not applicable	OGYI-T-1114/01	G.L. Pharma GmbH	Hungary	Not applicable
Convulex 100 mg/ml oldatos injekció	Not applicable	OGYI-T-1112/13	G.L. Pharma GmbH	Hungary	Not applicable
Convulex 150 mg gyomornedv-ellenálló lágy kapszula	Not applicable	OGYI-T-1112/01-04	G.L. Pharma GmbH	Hungary	Not applicable
Convulex 300 mg gyomornedv-ellenálló lágy kapszula	Not applicable	OGYI-T-1112/05-08	G.L. Pharma GmbH	Hungary	Not applicable
Convulex 500 mg gyomornedv-ellenálló lágy kapszula	Not applicable	OGYI-T-1112/09-12	G.L. Pharma GmbH	Hungary	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Convulex 100 mg/ml šķīdums injekcijām/ koncentrāts infūziju šķīduma pagatavošanai	Not applicable	05-0261	G.L. Pharma GmbH	Latvia	Not applicable
Convulex® retard 300 mg ilgstošās darbības tabletes	Not applicable	03-0393	G.L. Pharma GmbH	Latvia	Not applicable
Convulex® retard 500 mg ilgstošās darbības tabletes	Not applicable	03-0394	G.L. Pharma GmbH	Latvia	Not applicable
Convulex® 50 mg/ml sīrups	Not applicable	99-0607	G.L. Pharma GmbH	Latvia	Not applicable
CONVULEX® 300 mg/ml šķīdums iekšķīgai lietošanai	Not applicable	99-0608	G.L. Pharma GmbH	Latvia	Not applicable
Convulex® 150 mg zarnās šķīstošās mīkstās kapsulas	Not applicable	99-0604	G.L. Pharma GmbH	Latvia	Not applicable
Convulex® 300 mg zarnās šķīstošās mīkstās kapsulas	Not applicable	99-0605	G.L. Pharma GmbH	Latvia	Not applicable
Convulex® 500 mg zarnās šķīstošās mīkstās kapsulas	Not applicable	99-0606	G.L. Pharma GmbH	Latvia	Not applicable
Convulex retard 300 mg pailginto atpalaidavimo tabletės	Not applicable	LT/1/03/3653/001-006	G.L. Pharma GmbH	Lithuania	Not applicable
Convulex retard 500 mg pailginto atpalaidavimo tabletės	Not applicable	LT/1/03/3653/007-012	G.L. Pharma GmbH	Lithuania	Not applicable
Convulex 50 mg/ml sirupas	Not applicable	LT/1/99/0115/002	G.L. Pharma GmbH	Lithuania	Not applicable
Convulex 300 mg/ml geriamasis tirpalas	Not applicable	LT/1/99/0115/001	G.L. Pharma GmbH	Lithuania	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Convulex 100 mg/ml injekcinis ar infuzinis tirpalas	Not applicable	LT/1/99/0115/006	G.L. Pharma GmbH	Lithuania	Not applicable
Convulex 150 mg skrandyje neirios minkštosios kapsulės	Not applicable	LT/1/99/0115/003,007	G.L. Pharma GmbH	Lithuania	Not applicable
Convulex 300 mg skrandyje neirios minkštosios kapsulės	Not applicable	LT/1/99/0115/004,008	G.L. Pharma GmbH	Lithuania	Not applicable
Convulex 500 mg skrandyje neirios minkštosios kapsulės	Not applicable	LT/1/99/0115/005,009	G.L. Pharma GmbH	Lithuania	Not applicable
Convulex syrup for children 50 mg/ml	Not applicable	R/0239	G.L. Pharma GmbH	Poland	Not applicable
Convival Chrono 300 mg	Not applicable	26335	G.L. Pharma GmbH	Poland	Not applicable
Convival Chrono 500 mg	Not applicable	19521	G.L. Pharma GmbH	Poland	Not applicable
Convulex capsules 150 mg	Not applicable	R/2443	G.L. Pharma GmbH	Poland	Not applicable
Convulex capsules 300 mg	Not applicable	R/2444	G.L. Pharma GmbH	Poland	Not applicable
Convulex capsules 500 mg	Not applicable	R/0238	G.L. Pharma GmbH	Poland	Not applicable
Convulex 150 mg, capsule moi gastrorezistente	Not applicable	5919/2013/01-02	Lannacher Heilmittel Ges.m.b.H.	Romania	Not applicable
Convulex 300 mg, capsule moi gastroreszistente	Not applicable	5920/2013/01-02	Lannacher Heilmittel Ges.m.b.H.	Romania	Not applicable
Convulex	Not applicable	21/0037/82-S	G.L. Pharma GmbH	Slovakia	Not applicable
CONVULEX 300 mg/ml kvapky	Not applicable	21/0033/77-S	G.L. Pharma GmbH	Slovakia	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Convulex prolonged-release tablets 500 mg	Not applicable	21/0418/10-S	G.L. Pharma GmbH	Slovakia	Not applicable
Convulex 150 mg kapsuly	Not applicable	21/0032/77-S	G.L. Pharma GmbH	Slovakia	Not applicable
Convulex 300 mg kapsuly	Not applicable	021/0481/13-S	G.L. Pharma GmbH	Slovakia	Not applicable
Convulex 500 mg kapsuly	Not applicable	21/0482/13-S	G.L. Pharma GmbH	Slovakia	Not applicable
Epival CR prolonged-release tablets 300 mg	AT/H/0820/001 /MR	PL 21597/0005	G.L. Pharma GmbH	United Kingdom	Not applicable
Epival CR prolonged-release tablets 500 mg	AT/H/0820/002 /MR	PL 21597/0006	G.L. Pharma GmbH	United Kingdom	Not applicable
Convulex capsules 150 mg	Not applicable	PL 21597/0004	G.L. Pharma GmbH	United Kingdom	Not applicable
Convulex capsules 300 mg	Not applicable	PL 21597/0002	G.L. Pharma GmbH	United Kingdom	Not applicable
Convulex capsules 500 mg	Not applicable	PL 21597/0003	G.L. Pharma GmbH	United Kingdom	Not applicable

Annex I - Hexal A.G.

Specific Information for PASS107 Submissions

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Valproat - 1 A Pharma 300 mg Retardtabletten	NL/H/0736/001	64971.00.00	1 A PHARMA GMBH	Germany	Not applicable
Valproat - 1 A Pharma 500 mg Retardtabletten	NL/H/0736/002	64972.00.00	1 A PHARMA GMBH	Germany	Not applicable
Valproat HEXAL®chrono 300 mg Retardtabletten	Not applicable	59587.00.00	HEXAL AG	Germany	Not applicable
Valproat HEXAL®chrono 500 mg Retardtabletten	Not applicable	59587.01.00	HEXAL AG	Germany	Not applicable
Valproate Sandoz 300 mg tabletten met verlengde afgifte	NL/H/0736/001	BE285993	SANDOZ N.V.	Belgium	Not applicable
Valproat Chrono Sandoz	NL/H/0736/001	21/195/06-C	SANDOZ GMBH	Czech Republic	Not applicable
Valproat Sandoz 300 mg depottabletti	NL/H/0736/001	21855	SANDOZ A/S	Finland	Not applicable
VALPROLEK 300, 300 MG, TABLETKI O PRZEDLUZONYM UWALNIANIU	NL/H/0736/001	12375	SANDOZ GMBH	Poland	Not applicable
Natriumvalproaat Sandoz Chrono 300, tabletten met verlengde afgifte 300 mg	NL/H/0736/001	RVG 33299	SANDOZ B.V.	Netherlands	Not applicable
Natriumvalproaat Sandoz Chrono500, tabletten met verlengde afgifte 500 mg	NL/H/0736/002	RVG 33300	SANDOZ B.V.	Netherlands	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Valproate Sandoz 500 mg tabletten met verlengde afgifte	NL/H/0736/002	BE286002	SANDOZ N.V.	Belgium	Not applicable
Valproat Chrono Sandoz	NL/H/0736/002	21/196/06-C	SANDOZ GMBH	Czech Republic	Not applicable
Valproate sodium Sandoz 500 mg	NL/H/0736/002	517306	SANDOZ PHARMACEUTICALS D.D.	Estonia	Not applicable
Valproat Sandoz 500 mg depottabletti	NL/H/0736/002	21856	SANDOZ A/S	Finland	Not applicable
Valproate sodium Sandoz 500 mg pailginto atpalaidavimo tabletės	NL/H/0736/002	LT/1/06/0550/008-014	SANDOZ PHARMACEUTICALS D.D.	Lithuania	Not applicable
VALPROLEK 500, 500 MG, TABLETKI O PRZEDŁUŻONYM UWALNIANIU	NL/H/0736/002	12376	SANDOZ GMBH	Poland	Not applicable
ACIDO VALPROICO SANDOZ	Not applicable	036334011	SANDOZ S.P.A.	Italia	Not applicable
ACIDO VALPROICO SANDOZ	Not applicable	036334023	SANDOZ S.P.A.	Italia	Not applicable
Natriumvalproaat chrono 1A Pharma 300 mg, tabletten met verlengde afgifte	NL/H/0737/001	RVG 33301	1 A PHARMA GMBH	Netherlands	Not applicable
Natriumvalproaat chrono 1A Pharma 500 mg, tabletten met verlengde afgifte	NL/H/0737/002	RVG 33302	1 A PHARMA GMBH	Netherlands	Not applicable

Annex I - LUPIN

Specific Information for PASS107 Submissions

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Syonell 250 mg Gastro-Resistant tablets	UK-H-6533-001-002-DC	PL 35507/0191	Lupin Healthcare (UK) Limited	United Kingdom	Not applicable
Syonell 500 mg Gastro-Resistant tablets	UK-H-6533-001-002-DC	PL 35507/0192	Lupin Healthcare (UK) Limited	United Kingdom	Not applicable

Annex I - Viatris Sante / Mylan bvba/sprl

Specific Information for PASS107 Submissions

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state *	Member State where product is authorised	Legal Basis
Valproate de sodium Viatris L.P. 500 mg, comprimé pelliculé sécable à libération prolongée	Not applicable	NL 30448	Viatris Sante (Lyon): FR	France	
DIVALCOTE 250 mg, comprimé gastro-résistant	Not applicable	NL 48878	Viatris Sante (Lyon): FR	France	
DIVALCOTE 500 mg, comprimé gastro-résistant	Not applicable	NL 48879	Viatris Sante (Lyon): FR	France	
Valproate Mylan 100 mg/ml oplossing voor injectie	FI/H/0127	BE229144	Mylan bvba/sprl : BE	Belgium	
Valproate Mylan 100 mg/ml oplossing voor injectie	FI/H/0127	BE229153	Mylan bvba/sprl : BE	Belgium	

Annex I - Neuraxpharm Arzneimittel GmbH

Specific Information for PASS107 Submissions

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Valproat-neuraxpharm 150 mg	Not applicable	47334.00.01	Neuraxpharm Arzneimittel GmbH	Germany	Not applicable
Valproat-neuraxpharm 300 mg	Not applicable	46588.00.00	Neuraxpharm Arzneimittel GmbH	Germany	Not applicable
Valproat-neuraxpharm 600 mg	Not applicable	46588.01.00	Neuraxpharm Arzneimittel GmbH	Germany	Not applicable
Valproat-neuraxpharm 300 mg/ml Lösung zum Einnehmen	Not applicable	46475.00.0	Neuraxpharm Arzneimittel GmbH	Germany	Not applicable
Valproat-neuraxpharm chrono 300 mg	Not applicable	67176.00.00	Neuraxpharm Arzneimittel GmbH	Germany	Not applicable
Valproat-neuraxpharm chrono 500 mg	Not applicable	67177.00.00	Neuraxpharm Arzneimittel GmbH	Germany	Not applicable
Valproat-neuraxpharm chrono 300 mg	Not applicable	59585.00.00	Neuraxpharm Arzneimittel GmbH	Germany	Not applicable
Valproat-neuraxpharm chrono 500 mg	Not applicable	59585.01.00	Neuraxpharm Arzneimittel GmbH	Germany	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Valproat-neuraxpharm 60 mg/ml Lösung zum Einnehmen	DE/H/3620/001/DC	87742.00.00	Neuraxpharm Arzneimittel GmbH	Germany	Not applicable

Annex I - Orion Corporation

Specific Information for PASS107 Submissions

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Valproat Orion 300 mg Prolonged-release Tablets	DE/H/1910/001/MR	67033.00.00	Orion Corporation	Germany	Not applicable
Valproat Orion 500 mg Prolonged-release Tablets	DE/H/1910/002/MR	67034.00.00	Orion Corporation	Germany	Not applicable
Absenor 300 mg Prolonged-release Tablets	DE/H/1910/001/MR	12748	Orion Corporation	Poland	Not applicable
Absenor 500 mg Prolonged-release Tablets	DE/H/1910/002/MR	12747	Orion Corporation	Poland	Not applicable
Delepsine 60mg/ml Oral solution	Not applicable	10329	Orion Corporation	Denmark	Not applicable
Delepsine 200mg/ml Oral drops solution	Not applicable	10655	Orion Corporation	Denmark	Not applicable
Delepsine 100mg Gastro-resistant tablet	Not applicable	10293	Orion Corporation	Denmark	Not applicable
Delepsine 300mg Gastro-resistant tablet	Not applicable	10294	Orion Corporation	Denmark	Not applicable
Delepsine 500mg Gastro-resistant tablet	Not applicable	10295	Orion Corporation	Denmark	Not applicable
Delepsine Retard 300mg Prolonged-release tablet	Not applicable	17605	Orion Corporation	Denmark	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Delepsine Retard 500mg Prolonged-release tablet	Not applicable	17606	Orion Corporation	Denmark	Not applicable
Absenor 60mg/ml Oral solution	Not applicable	8163	Orion Corporation	Finland	Not applicable
Absenor 200mg/ml Oral drops solution	Not applicable	6377	Orion Corporation	Finland	Not applicable
Absenor 100mg Gastro resistant tablet	Not applicable	8161	Orion Corporation	Finland	Not applicable
Absenor 300mg Gastro resistant tablet	Not applicable	6376	Orion Corporation	Finland	Not applicable
Absenor 500mg Gastro resistant tablet	Not applicable	8162	Orion Corporation	Finland	Not applicable
Absenor 300mg Prolonged release tablet	Not applicable	12147	Orion Corporation	Finland	Not applicable
Absenor 500mg Prolonged release tablet	Not applicable	12148	Orion Corporation	Finland	Not applicable
Absenor 60mg/ml Oral solution	Not applicable	9686	Orion Corporation	Sweden	Not applicable
Absenor 200mg/ml Oral drops solution	Not applicable	9507	Orion Corporation	Sweden	Not applicable
Absenor 100mg Gastro resistant tablet	Not applicable	9683	Orion Corporation	Sweden	Not applicable
Absenor 300mg Gastro resistant tablet	Not applicable	9684	Orion Corporation	Sweden	Not applicable
Absenor 500mg Gastro resistant tablet	Not applicable	9685	Orion Corporation	Sweden	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Absenor Depot 300mg Prolonged release tablet	Not applicable	15698	Orion Corporation	Sweden	Not applicable
Absenor Depot 500mg Prolonged release tablet	Not applicable	15699	Orion Corporation	Sweden	Not applicable

Annex I - Sanofi Aventis Groupe

Specific Information for PASS107 Submissions

SODIUM VALPROATE					
Product Name (in authorisation country)	**MRP/DCP Authorisation number**	**Authorisation Number of product in the member state**	**MAH of product in the member state**	**Member State where product is authorised**	**Legal Basis**
DEPAKINE 300 MG/ML-TROPFEN	Not applicable	15.699	SANOFI-AVENTIS GMBH	Austria	Not applicable
DEPAKINE-TROCKENSTECHAMPULLEN MIT LOSUNGSMITTEL	Not applicable	1-24529	SANOFI-AVENTIS GMBH	Austria	Not applicable
DEPAKINE 300 MG/5ML, SIROOP	Not applicable	BE110923	SANOFI BELGIUM	Belgium	Not applicable
DEPAKINE 300 mg/ml DRANK	Not applicable	BE048316	SANOFI BELGIUM	Belgium	Not applicable
DEPAKINE ENTERIC 300 MG, MAAGSAPRESISTENTE TABLETTEN	Not applicable	BE092775	SANOFI BELGIUM	Belgium	Not applicable
DEPAKINE ENTERIC 500 MG, MAAGSAPRESISTENTE TABLETTEN	Not applicable	BE110932	SANOFI BELGIUM	Belgium	Not applicable
DEPAKINE I.V. 400 MG/4ML, POEDER EN OPLOSMIDDEL VOOR OPLOSSING VOOR INJECTIE	Not applicable	BE163134	SANOFI BELGIUM	Belgium	Not applicable
DEPAKINE	Not applicable	20010250	SANOFI-AVENTIS GROUPE	Bulgaria	Not applicable
DEPAKINE	Not applicable	20010272	SANOFI-AVENTIS GROUPE	Bulgaria	Not applicable
DEPAKINE	Not applicable	9600303	SANOFI-AVENTIS GROUPE	Bulgaria	Not applicable
DEPAKINE	Not applicable	21/312/99-C	SANOFI-AVENTIS S.R.O.	Czech Republic	Not applicable
DEPAKINE	Not applicable	21/265/96-C	SANOFI-AVENTIS S.R.O.	Czech Republic	Not applicable
DEPAKINE 200 MG, COMPRIME GASTRO RESISTANT	Not applicable	VNL7528	SANOFI-AVENTIS FRANCE	France	Not applicable
DEPAKINE 200 MG/ML, SOLUTION BUVABLE	Not applicable	VNL7534	SANOFI-AVENTIS FRANCE	France	Not applicable

SODIUM VALPROATE					
Product Name (in authorisation country)	**MRP/DCP Authorisation number**	**Authorisation Number of product in the member state**	**MAH of product in the member state**	**Member State where product is authorised**	**Legal Basis**
DEPAKINE 400 MG/4 ML, PREPARATION INJECTABLE POUR VOIE I.V.	Not applicable	NL 12796	SANOFI-AVENTIS FRANCE	France	Not applicable
DEPAKINE 500 MG, COMPRIME GASTRO RESISTANT	Not applicable	VNL 10477	SANOFI-AVENTIS FRANCE	France	Not applicable
DEPAKINE 57,64 MG/ML, SIROP	Not applicable	NL 13075	SANOFI-AVENTIS FRANCE	France	Not applicable
ERGENYL 150 MG	Not applicable	378.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	Germany	Not applicable
ERGENYL 300 MG	Not applicable	6020971.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	Germany	Not applicable
Ergenyl 300 mg/ml Lösung, Lösung zum Einnehmen	Not applicable	6020801.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	Germany	Not applicable
ERGENYL 500 MG	Not applicable	378.01.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	Germany	Not applicable
Ergenyl intravenös 100 mg/ml Injektionslösung	Not applicable	32555.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	Germany	Not applicable
Ergenyl vial 400 mg Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	Not applicable	32556.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	Germany	Not applicable
DEPAKINE	Not applicable	41430/07/27-5-2008	SANOFI-AVENTIS AEBE	Greece	Not applicable
DEPAKINE	Not applicable	41428/07/27-5-2008	SANOFI-AVENTIS AEBE	Greece	Not applicable
DEPAKINE	Not applicable	41432/07/27-5-2008	SANOFI-AVENTIS AEBE	Greece	Not applicable
EPILIM 100MG CRUSHABLE TABLETS	Not applicable	PA 540/150/1	SANOFI-AVENTIS IRELAND Ltd. T/A SANOFI	Ireland	Not applicable
EPILIM ENTERIC 200MG GASTRO-RESISTANT COATED TABLETS	Not applicable	PA 540/150/2	SANOFI-AVENTIS IRELAND Ltd. T/A SANOFI	Ireland	Not applicable
EPILIM ENTERIC 500MG GASTRO-RESISTANT COATED TABLETS	Not applicable	PA 540/150/3	SANOFI-AVENTIS IRELAND Ltd. T/A SANOFI	Ireland	Not applicable
EPILIM INTRAVENOUS	Not applicable	PA 540/150/13	SANOFI-AVENTIS IRELAND Ltd. T/A SANOFI	Ireland	Not applicable
Epilim Liquid 200 mg/5ml Oral Solution	Not applicable	PA 540/150/14	SANOFI-AVENTIS IRELAND Ltd. T/A SANOFI	Ireland	Not applicable
Epilim Syrup 200mg/5ml Oral Solution	Not applicable	PA 540/150/15	SANOFI-AVENTIS IRELAND Ltd. T/A SANOFI	Ireland	Not applicable

SODIUM VALPROATE					
Product Name (in authorisation country)	**MRP/DCP Authorisation number**	**Authorisation Number of product in the member state**	**MAH of product in the member state**	**Member State where product is authorised**	**Legal Basis**
DEPAKIN	Not applicable	022483061	Sanofi S.r.l.	Italy	Not applicable
DEPAKIN	Not applicable	022483248	Sanofi S.r.l.	Italy	Not applicable
DEPAKIN	Not applicable	022483251	Sanofi S.r.l.	Italy	Not applicable
DEPAKIN	Not applicable	022483034	Sanofi S.r.l.	Italy	Not applicable
DEPAKINE 57.64 MG/ML SYRUP	Not applicable	96-0149	SANOFI-AVENTIS GROUPE	Latvia	Not applicable
Depakine 57,64 mg/ml sirupas	Not applicable	LT/1/94/0973/001	SANOFI-AVENTIS GROUPE	Lithuania	Not applicable
DEPAKINE 300 MG/5 ML SIROP	Not applicable	2009030237	SANOFI BELGIUM	Luxembourg	Not applicable
DEPAKINE 300 MG/ML SOLUTION BUVABLE	Not applicable	2009030236	SANOFI BELGIUM	Luxembourg	Not applicable
DEPAKINE ENTERIC 300 MG COMPRIMÉS GASTRO-RÉSISTANTS	Not applicable	2009030232	SANOFI BELGIUM	Luxembourg	Not applicable
Depakine Enteric 500 mg comprimés gastro-résistants	Not applicable	2009030233	SANOFI BELGIUM	Luxembourg	Not applicable
DEPAKINE I.V. 400 MG/ML POUDRE ET SOLVANT POUR SOLUTION INJECTABLE	Not applicable	2009030238	SANOFI BELGIUM	Luxembourg	Not applicable
EPILIM 400MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION	Not applicable	MA1359/01903	Sanofi S.r.l.	Malta	Not applicable
EPILIM LIQUID	Not applicable	MA1359/01904	Sanofi S.r.l.	Malta	Not applicable
DEPAKINE ENTERIC 150 MG, MAAGSAPRESISTENTE TABLETTEN	Not applicable	RVG 07405	GENZYME EUROPE B.V.	Netherlands	Not applicable
DEPAKINE ENTERIC 300 MG, MAAGSAPRESISTENTE TABLETTEN	Not applicable	RVG 07055	GENZYME EUROPE B.V.	Netherlands	Not applicable
DEPAKINE ENTERIC 500 MG, MAAGSAPRESISTENTE TABLETTEN	Not applicable	RVG 07476	GENZYME EUROPE B.V.	Netherlands	Not applicable
Depakine i.v. 400, poeder voor injectievloeistof 400 mg	Not applicable	RVG 14996	GENZYME EUROPE B.V.	Netherlands	Not applicable
Depakine suikervrije stroop, drank 200 mg/ 5ml	Not applicable	RVG 18153	GENZYME EUROPE B.V.	Netherlands	Not applicable
Depakine vloeistof voor kinderen, vloeistof voor oraal gebruik 300 mg/ ml	Not applicable	RVG 17569	GENZYME EUROPE B.V.	Netherlands	Not applicable

SODIUM VALPROATE					
Product Name (in authorisation country)	**MRP/DCP Authorisation number**	**Authorisation Number of product in the member state**	**MAH of product in the member state**	**Member State where product is authorised**	**Legal Basis**
DEPAKINE	Not applicable	R/3074	SANOFI-AVENTIS FRANCE	Poland	Not applicable
DEPAKINE	Not applicable	R/7170	SANOFI-AVENTIS FRANCE	Poland	Not applicable
Depakine 200 mg/ml solução oral	Not applicable	9729400	SANOFI - PRODUTOS FARMACEUTICOS LDA	Portugal	Not applicable
Depakine 40 mg/ml xarope	Not applicable	6/84/94	SANOFI - PRODUTOS FARMACEUTICOS LDA	Portugal	Not applicable
Depakine 400 mg/4 ml pó e solvente para solução injetável	Not applicable	6/44/93	SANOFI - PRODUTOS FARMACEUTICOS LDA	Portugal	Not applicable
Depakine 200 mg comprimate gastrorezistente	Not applicable	11542/2019	Sanofi Romania SRL	Romania	Not applicable
Depakine 57,64 mg/ml sirop	Not applicable	11541/2019	Sanofi Romania SRL	Romania	Not applicable
DEPAKINE	Not applicable	21/0322/94-S	SANOFI-AVENTIS GROUPE	Slovakia	Not applicable
Depakine 400 mg/4 ml	Not applicable	21/0674/96-S	SANOFI-AVENTIS GROUPE	Slovakia	Not applicable
DEPAKINE 100 MG/ML POLVO Y DISOLVENTE PARA SOLUCION INYECTABLE	Not applicable	60352	SANOFI-AVENTIS, S.A.	Spain	Not applicable
DEPAKINE 200 MG COMPRIMIDOS GASTRORRESISTENTES	Not applicable	48827	SANOFI-AVENTIS, S.A.	Spain	Not applicable
DEPAKINE 200 MG/ML SOLUCION ORAL	Not applicable	48828	SANOFI-AVENTIS, S.A.	Spain	Not applicable
DEPAKINE 500 MG COMPRIMIDOS GASTRORRESISTENTES	Not applicable	54470	SANOFI-AVENTIS, S.A.	Spain	Not applicable
ERGENYL PULVER OCH VATSKA TILL INJEKTIONSVATSKA, LOSNING	Not applicable	14282	SANOFI AB	Sweden	Not applicable
EPILIM 200 GASTRO-RESISTANT TABLETS	Not Applicable	PL 04425/0302	AVENTIS PHARMA LTD	United Kingdom	Not applicable
EPILIM 500 GASTRO-RESISTANT TABLETS	Not Applicable	PL 04425/0303	AVENTIS PHARMA LTD	United Kingdom	Not applicable
EPILIM SYRUP	Not Applicable	PL 04425/0301	AVENTIS PHARMA LTD	United Kingdom	Not applicable
EPILIM LIQUID	Not Applicable	PL 04425/0300	AVENTIS PHARMA LTD	United Kingdom	Not applicable
EPILIM 100MG CRUSHABLE TABLETS	Not Applicable	PL 04425/0317	AVENTIS PHARMA LTD	United Kingdom	Not applicable

SODIUM VALPROATE					
Product Name (in authorisation country)	**MRP/DCP Authorisation number**	**Authorisation Number of product in the member state**	**MAH of product in the member state**	**Member State where product is authorised**	**Legal Basis**
EPILIM 400MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION	Not Applicable	PL 04425/0685	AVENTIS PHARMA LTD	United Kingdom	Not applicable

SODIUM VALPROATE + VALPROIC ACID					
Product Name (in authorisation country)	**MRP/DCP Authorisation number**	**Authorisation Number of product in the member state**	**MAH of product in the member state**	**Member State where product is authorised**	**Legal Basis**
DEPAKINE CHRONO RETARD 300 MG-FILMTABLETTEN	Not applicable	1-19787	SANOFI-AVENTIS GMBH	Austria	Not applicable
DEPAKINE CHRONO RETARD 500 MG-FILMTABLETTEN	Not applicable	1-19786	SANOFI-AVENTIS GMBH	Austria	Not applicable
DEPAKINE CHRONOSPHERE 250 MG-RETARDGRANULAT IN BEUTELN	Not applicable	1-25371	SANOFI-AVENTIS GMBH	Austria	Not applicable
DEPAKINE CHRONOSPHERE 50 MG-RETARDGRANULAT IN BEUTELN	Not applicable	1-25369	SANOFI-AVENTIS GMBH	Austria	Not applicable
DEPAKINE CHRONOSPHERE 500 MG-RETARDGRANULAT IN BEUTELN	Not applicable	1-25372	SANOFI-AVENTIS GMBH	Austria	Not applicable
DEPAKINE CHRONO 300 MG, TABLETTEN MET VERLENGDE AFGIFTE	Not applicable	BE166512	SANOFI BELGIUM	Belgium	Not applicable
DEPAKINE CHRONO 300 MG, TABLETTEN MET VERLENGDE AFGIFTE	Not applicable	BE532551	SANOFI BELGIUM	Belgium	Not applicable
DEPAKINE CHRONO 500 MG, TABLETTEN MET VERLENGDE AFGIFTE	Not applicable	BE166521	SANOFI BELGIUM	Belgium	Not applicable
DEPAKINE CHRONO 500 MG, TABLETTEN MET VERLENGDE AFGIFTE	Not applicable	BE532560	SANOFI BELGIUM	Belgium	Not applicable
DEPAKINE CHRONO	Not applicable	9900385	SANOFI-AVENTIS GROUPE	Bulgaria	Not applicable
DEPAKINE CHRONO	Not applicable	20010812	SANOFI-AVENTIS GROUPE	Bulgaria	Not applicable
Depakine Chrono 300 mg tablete s prilagođenim oslobađanjem	Not applicable	HR-H-132091526	SANOFI-AVENTIS GROUPE	Croatia	Not applicable
Depakine Chrono 500 mg tablete s prilagođenim oslobađanjem	Not applicable	HR-H-202764510	SANOFI-AVENTIS GROUPE	Croatia	Not applicable
DEPAKINE CHRONO 500 mg, prolonged-release tablets	Not applicable	19172	SANOFI-AVENTIS GROUPE	Cyprus	Not applicable

SODIUM VALPROATE + VALPROIC ACID					
Product Name (in authorisation country)	**MRP/DCP Authorisation number**	**Authorisation Number of product in the member state**	**MAH of product in the member state**	**Member State where product is authorised**	**Legal Basis**
DEPAKINE CHRONO 300MG SECABLE	Not applicable	21/056/91-A/C	SANOFI-AVENTIS S.R.O.	Czech Republic	Not applicable
DEPAKINE CHRONO 500MG SECABLE	Not applicable	21/056/91-B/C	SANOFI-AVENTIS S.R.O.	Czech Republic	Not applicable
DEPRAKINE RETARD	Not applicable	13148	Sanofi A/S	Denmark	Not applicable
DEPRAKINE RETARD	Not applicable	13230	Sanofi A/S	Denmark	Not applicable
DEPAKINE CHRONO 300 MG, TOIMEAINET PROLONGEERITULT VABASTAVAD TABLETID	Not applicable	151096	SANOFI-AVENTIS GROUPE	Estonia	Not applicable
DEPAKINE CHRONO 500 MG, TOIMEAINET PROLONGEERITULT VABASTAVAD TABLETID	Not applicable	151196	SANOFI-AVENTIS GROUPE	Estonia	Not applicable
DEPRAKINE 300 MG DEPOTTABLETTI	Not applicable	10266	SANOFI OY	Finland	Not applicable
DEPRAKINE 500 MG DEPOTTABLETTI	Not applicable	10267	SANOFI OY	Finland	Not applicable
DEPAKINE CHRONO 500 MG, COMPRIME PELLICULE SECABLE A LIBERATION PROLONGEE	Not applicable	NL 14877	SANOFI-AVENTIS FRANCE	France	Not applicable
MICROPAKINE L.P. 250 MG, GRANULES A LIBERATION PROLONGEE	Not applicable	NL 29915	SANOFI-AVENTIS FRANCE	France	Not applicable
MICROPAKINE L.P. 100 MG, GRANULES À LIBERATION PROLONGEE EN SACHET-DOSE	Not applicable	NL 29914	SANOFI-AVENTIS FRANCE	France	Not applicable
MICROPAKINE L.P. 1000 MG, GRANULES A LIBERATION PROLONGEE EN SACHET-DOSE	Not applicable	NL 29918	SANOFI-AVENTIS FRANCE	France	Not applicable
MICROPAKINE L.P. 500 MG, GRANULES A LIBERATION PROLONGEE EN SACHET-DOSE	Not applicable	NL 29916	SANOFI-AVENTIS FRANCE	France	Not applicable

SODIUM VALPROATE + VALPROIC ACID					
Product Name (in authorisation country)	**MRP/DCP Authorisation number**	**Authorisation Number of product in the member state**	**MAH of product in the member state**	**Member State where product is authorised**	**Legal Basis**
MICROPAKINE L.P. 750 MG, GRANULES A LIBERATION PROLONGEE EN SACHET-DOSE	Not applicable	NL 29917	SANOFI-AVENTIS FRANCE	France	Not applicable
ERGENYL CHRONO 300 MG, RETARDTABLETTEN	Not applicable	55390.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	Germany	Not applicable
ERGENYL CHRONO 500 MG, RETARDTABLETTEN	Not applicable	55391.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	Germany	Not applicable
VALPROAT CHRONO WINTHROP 300 MG RETARDTABLETTEN	Not applicable	55392.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	Germany	Not applicable
VALPROAT CHRONO WINTHROP 500 MG RETARDTABLETTEN	Not applicable	55393.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	Germany	Not applicable
DEPAKINE CHRONO	Not applicable	41972/10/21-06-2011	SANOFI-AVENTIS AEBE	Greece	Not applicable
DEPAKINE CHRONOSPHERE 100 MG MODIFIED RELEASE GRANULES	Not applicable	41979/10/21-06-2011	SANOFI-AVENTIS AEBE	Greece	Not applicable
DEPAKINE CHRONOSPHERE 1000 MG MODIFIED RELEASE GRANULES	Not applicable	41990/10/21-06-2011	SANOFI-AVENTIS AEBE	Greece	Not applicable
DEPAKINE CHRONOSPHERE 250 MG MODIFIED RELEASE GRANULES	Not applicable	41982/10/21-06-2011	SANOFI-AVENTIS AEBE	Greece	Not applicable
DEPAKINE CHRONO 300 MG FILMTABLETTA	Not applicable	OGYI-T-5527/03	SANOFI-AVENTIS ZRT	Hungary	Not applicable
DEPAKINE CHRONO 500 MG FILMTABLETTA	Not applicable	OGYI-T-5527/04	SANOFI-AVENTIS ZRT	Hungary	Not applicable
EPILIM CHRONO 200MG CONTROLLED RELEASE TABLETS	Not applicable	PA 540/150/10	SANOFI-AVENTIS IRELAND Ltd. T/A SANOFI	Ireland	Not applicable
EPILIM CHRONO 300 CONTROLLED RELEASE TABLETS	Not applicable	PA 540/150/11	SANOFI-AVENTIS IRELAND Ltd. T/A SANOFI	Ireland	Not applicable
EPILIM CHRONO 500MG CONTROLLED RELEASE TABLETS	Not applicable	PA 540/150/12	SANOFI-AVENTIS IRELAND Ltd. T/A SANOFI	Ireland	Not applicable
Epilim Chronosphere 100mg prolonged-release granules	Not applicable	PA 540/150/5	SANOFI-AVENTIS IRELAND Ltd. T/A SANOFI	Ireland	Not applicable
Epilim Chronosphere 250mg prolonged-release granules	Not applicable	PA 540/150/6	SANOFI-AVENTIS IRELAND Ltd. T/A SANOFI	Ireland	Not applicable
Epilim Chronosphere 500mg prolonged-release granules	Not applicable	PA 540/150/7	SANOFI-AVENTIS IRELAND Ltd. T/A SANOFI	Ireland	Not applicable

SODIUM VALPROATE + VALPROIC ACID					
Product Name (in authorisation country)	**MRP/DCP Authorisation number**	**Authorisation Number of product in the member state**	**MAH of product in the member state**	**Member State where product is authorised**	**Legal Basis**
DEPAKIN	Not applicable	022483186-198	Sanofi S.r.l.	Italy	Not applicable
DEPAKIN	Not applicable	022483200-212	Sanofi S.r.l.	Italy	Not applicable
DEPAKIN	Not applicable	022483224-236	Sanofi S.r.l.	Italy	Not applicable
DEPAKIN	Not applicable	022483147-150	Sanofi S.r.l.	Italy	Not applicable
DEPAKIN	Not applicable	022483162-174	Sanofi S.r.l.	Italy	Not applicable
DEPAKIN CHRONO	Not applicable	022483109	Sanofi S.r.l.	Italy	Not applicable
DEPAKIN CHRONO	Not applicable	022483111	Sanofi S.r.l.	Italy	Not applicable
Depakine Chrono 300 mg ilgstošās darbības tabletes	Not applicable	96-0286	SANOFI-AVENTIS GROUPE	Latvia	Not applicable
Depakine Chrono 500 mg ilgstošās darbības tabletes	Not applicable	96-0324	SANOFI-AVENTIS GROUPE	Latvia	Not applicable
DEPAKINE CHRONO 500 mg modifikuoto atpalaidavimo tabletės	Not applicable	LT/1/94/0818/002	SANOFI-AVENTIS GROUPE	Lithuania	Not applicable
DEPAKINE Chronosphere 1000 mg modifikuoto atpalaidavimo granulės	Not applicable	LT/1/07/0952/011-012	SANOFI-AVENTIS GROUPE	Lithuania	Not applicable
DEPAKINE Chronosphere 250 mg modifikuoto atpalaidavimo granulės	Not applicable	LT/1/94/0952/005-006	SANOFI-AVENTIS GROUPE	Lithuania	Not applicable
DEPAKINE Chronosphere 750 mg modifikuoto atpalaidavimo granulės	Not applicable	LT/1/07/0952/009-010	SANOFI-AVENTIS GROUPE	Lithuania	Not applicable
DEPAKINE CHRONO 300 MG COMPRIMÉS À LIBÉRATION PROLONGÉE	Not applicable	2009030234	SANOFI BELGIUM	Luxembourg	Not applicable
DEPAKINE CHRONO 500 MG COMPRIMÉS À LIBÉRATION PROLONGÉE	Not applicable	2009030235	SANOFI BELGIUM	Luxembourg	Not applicable
EPILIM CHRONO 200MG CONTROLLED RELEASE TABLETS	Not applicable	MA1359/01901	Sanofi S.r.l.	Malta	Not applicable
EPILIM CHRONO 500	Not applicable	MA1359/01902	Sanofi S.r.l.	Malta	Not applicable
DEPAKINE CHRONO 300	Not applicable	RVG 13157	GENZYME EUROPE B.V.	Netherlands	Not applicable
DEPAKINE CHRONO 500	Not applicable	RVG 11775	GENZYME EUROPE B.V.	Netherlands	Not applicable

SODIUM VALPROATE + VALPROIC ACID					
Product Name (in authorisation country)	**MRP/DCP Authorisation number**	**Authorisation Number of product in the member state**	**MAH of product in the member state**	**Member State where product is authorised**	**Legal Basis**
Depakine Chronosphere 100 mg, granulaat met gereguleerde afgifte	Not applicable	RVG 30759	GENZYME EUROPE B.V.	Netherlands	Not applicable
Depakine Chronosphere 1000 mg, granulaat met gereguleerde afgifte	Not applicable	RVG 30763	GENZYME EUROPE B.V.	Netherlands	Not applicable
Depakine Chronosphere 250 mg, granulaat met gereguleerde afgifte	Not applicable	RVG 30760	GENZYME EUROPE B.V.	Netherlands	Not applicable
Depakine Chronosphere 500 mg, granulaat met gereguleerde afgifte	Not applicable	RVG 30761	GENZYME EUROPE B.V.	Netherlands	Not applicable
Depakine Chronosphere 750 mg, granulaat met gereguleerde afgifte	Not applicable	RVG 30762	GENZYME EUROPE B.V.	Netherlands	Not applicable
DEPAKINE CHRONO 300	Not applicable	R/6943	SANOFI-AVENTIS SP Z.O.O.	Poland	Not applicable
DEPAKINE CHRONO 500	Not applicable	R/6944	SANOFI-AVENTIS SP Z.O.O.	Poland	Not applicable
DEPAKINE CHRONOSPHERE 500	Not applicable	11948	SANOFI-AVENTIS SP Z.O.O.	Poland	Not applicable
DEPAKINE CHRONOSPHERE 750	Not applicable	11947	SANOFI-AVENTIS SP Z.O.O.	Poland	Not applicable
DEPAKINE CHRONOSPHERE 100	Not applicable	11950	SANOFI-AVENTIS SP Z.O.O.	Poland	Not applicable
DEPAKINE CHRONOSPHERE 1000	Not applicable	11946	SANOFI-AVENTIS SP Z.O.O.	Poland	Not applicable
DEPAKINE CHRONOSPHERE 250	Not applicable	11949	SANOFI-AVENTIS SP Z.O.O.	Poland	Not applicable
Depakine Chrono 300 300 mg comprimidos de libertação prolongada	Not applicable	1/58/85	SANOFI - PRODUTOS FARMACEUTICOS LDA	Portugal	Not applicable
Depakine Chrono 500 500 mg comprimidos de libertação prolongada	Not applicable	1/58/85	SANOFI - PRODUTOS FARMACEUTICOS LDA	Portugal	Not applicable
Depakine Chronosphere 100 mg granulado de libertação modificada	Not applicable	03/H/0648/002	SANOFI - PRODUTOS FARMACEUTICOS LDA	Portugal	Not applicable
Depakine Chronosphere 1000 mg granulado de libertação modificada	Not applicable	03/H/0648/006	SANOFI - PRODUTOS FARMACEUTICOS LDA	Portugal	Not applicable
Depakine Chronosphere 250 mg granulado de libertação modificada	Not applicable	03/H/0648/003	SANOFI - PRODUTOS FARMACEUTICOS LDA	Portugal	Not applicable
Depakine Chronosphere 50 mg, granulado de libertação modificada	Not applicable	03/H/0648/001	SANOFI - PRODUTOS FARMACEUTICOS LDA	Portugal	Not applicable

SODIUM VALPROATE + VALPROIC ACID					
Product Name (in authorisation country)	**MRP/DCP Authorisation number**	**Authorisation Number of product in the member state**	**MAH of product in the member state**	**Member State where product is authorised**	**Legal Basis**
Depakine Chronosphere 500 mg granulado de libertação modificada	Not applicable	03/H/0648/004	SANOFI - PRODUTOS FARMACEUTICOS LDA	Portugal	Not applicable
Depakine Chronosphere 750 mg granulado de libertação modificada	Not applicable	03/H/0648/005	SANOFI - PRODUTOS FARMACEUTICOS LDA	Portugal	Not applicable
Depakine Chrono 300 mg comprimate cu eliberare prelungita	Not applicable	11543/2019	Sanofi Romania SRL	Romania	Not applicable
Depakine Chrono 500 mg comprimate cu eliberare prelungita	Not applicable	1671/2009	Sanofi Romania SRL	Romania	Not applicable
DEPAKINE CHRONO 500 MG	Not applicable	21/0056/91-S	SANOFI-AVENTIS GROUPE	Slovakia	Not applicable
DEPAKINE CHRONO 300 MG FILMSKO OBLOZENE TABLETE S PODALJŠANIM SPROSCANJEM	Not applicable	H/00/00450/001	SANOFI-AVENTIS GROUPE	Slovenia	Not applicable
DEPAKINE CHRONO 500 MG FILMSKO OBLOZENE TABLETE S PODALJZANIM SPROSCANJEM	Not applicable	H/00/00450/002	SANOFI-AVENTIS GROUPE	Slovenia	Not applicable
Depakine Crono 300 mg comprimidos de liberación prolongada	Not applicable	60351	SANOFI-AVENTIS, S.A.	Spain	Not applicable
Depakine Crono 500 mg comprimidos de liberación prolongada	Not applicable	60350	SANOFI-AVENTIS, S.A.	Spain	Not applicable
ERGENYL RETARD 100 MG DEPOTGRANULAT, DOSPASE	Not applicable	20985	SANOFI AB	Sweden	Not applicable
ERGENYL RETARD 250 MG DEPOTGRANULAT, DOSPASE	Not applicable	20986	SANOFI AB	Sweden	Not applicable
ERGENYL RETARD 300 MG DEPOTTABLETTER	Not applicable	13043	SANOFI AB	Sweden	Not applicable
ERGENYL RETARD 500 MG DEPOTTABLETTER	Not applicable	13044	SANOFI AB	Sweden	Not applicable
ERGENYL RETARD 500 MG DEPOTGRANULAT, DOSPASE	Not applicable	20987	SANOFI AB	Sweden	Not applicable
EPILIM CHRONO 200MG CONTROLLED RELEASE TABLETS	Not Applicable	PL 04425/0307	AVENTIS PHARMA LTD	United Kingdom	Not applicable

SODIUM VALPROATE + VALPROIC ACID					
Product Name (in authorisation country)	**MRP/DCP Authorisation number**	**Authorisation Number of product in the member state**	**MAH of product in the member state**	**Member State where product is authorised**	**Legal Basis**
EPILIM CHRONO 300 CONTROLLED RELEASE TABLETS	Not Applicable	PL 04425/0308	AVENTIS PHARMA LTD	United Kingdom	Not applicable
EPILIM CHRONO 500MG CONTROLLED RELEASE TABLETS	Not Applicable	PL 04425/0309	AVENTIS PHARMA LTD	United Kingdom	Not applicable
EPILIM CHRONOSPHERE MR 50MG MODIFIED RELEASE GRANULES	Not Applicable	PL 04425/0310	AVENTIS PHARMA LTD	United Kingdom	Not applicable
EPILIM CHRONOSPHERE MR 100MG MODIFIED RELEASE GRANULES	Not Applicable	PL 04425/0312	AVENTIS PHARMA LTD	United Kingdom	Not applicable
EPILIM CHRONOSPHERE MR 250MG MODIFIED RELEASE GRANULES	Not Applicable	PL 04425/0313	AVENTIS PHARMA LTD	United Kingdom	Not applicable
EPILIM CHRONOSPHERE MR 500MG MODIFIED RELEASE GRANULES	Not Applicable	PL 04425/0314	AVENTIS PHARMA LTD	United Kingdom	Not applicable
EPILIM CHRONOSPHERE MR 750MG MODIFIED RELEASE GRANULES	Not Applicable	PL 04425/0315	AVENTIS PHARMA LTD	United Kingdom	Not applicable
EPILIM CHRONOSPHERE MR 1000MG MODIFIED RELEASE GRANULES	Not Applicable	PL 04425/0316	AVENTIS PHARMA LTD	United Kingdom	Not applicable

VALPROATE SEMISODIUM					
Product Name (in authorisation country)	**MRP/DCP Authorisation number**	**Authorisation Number of product in the member state**	**MAH of product in the member state**	**Member State where product is authorised**	**Legal Basis**
DEPAKOTE 250 MG, COMPRIME GASTRO-RESISTANT	Not Applicable	NL 13283	SANOFI-AVENTIS FRANCE	France	Not applicable
DEPAKOTE 500 MG, COMPRIME GASTRO-RESISTANT	Not Applicable	NL 13375	SANOFI-AVENTIS FRANCE	France	Not applicable
DEPAKOTE 250MG TABLETS	Not Applicable	PL 04425/0199	AVENTIS PHARMA LTD	United Kingdom	Not applicable
DEPAKOTE 500MG TABLETS	Not Applicable	PL 04425/0200	AVENTIS PHARMA LTD	United Kingdom	Not applicable

VALPROMIDE					
Product Name (in authorisation country)	**MRP/DCP Authorisation number**	**Authorisation Number of product in the member state**	**MAH of product in the member state**	**Member State where product is authorised**	**Legal Basis**
DEPAMIDE 300 MG, COMPRIME PELLICULE GASTRO-RESISTANT	Not Applicable	NL 10996	SANOFI-AVENTIS FRANCE	France	Not applicable
DEPAMIDE	Not Applicable	023105036-048	Sanofi S.r.l.	Italy	Not applicable

Annex I - Stada Arzneimittel AG

Specific Information for PASS107 Submissions

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Valproate Retard EG 500 mg tabletten met verlengde afgifte	DE/H/0811/002	BE300894 BE300885 BE300903	Eurogenerics N.V./S.A.	Belgium	Not applicable
Valproate Retard EG 300 mg tabletten met verlengde afgifte	DE/H/0811/001	BE300867 BE300851	Eurogenerics N.V./S.A.	Belgium	Not applicable
Valproate de Sodium EG L.P., 500 mg, comprimé pelliculé	Not applicable	NL 30239	EG LABO Laboratoires EuroGenerics	France	Not applicable
Valpro AL 500 mg Retardtabletten	Not applicable	59577.01.00	ALIUD PHARMA GmbH	Germany	Not applicable
Valproat STADA 300 mg Retardtabletten	DE/H/0811/001	59573.00.00	STADApharm GmbH	Germany	Not applicable
Valpro AL 300 mg Retardtabletten	Not applicable	59577.00.00	ALIUD PHARMA GmbH	Germany	Not applicable
Valproat STADA 500 mg Retardtabletten	DE/H/0811/002	59573.01.00	STADApharm GmbH	Germany	Not applicable
Valproat AL 300 mg/ml Lösung zum Einnehmen	DE/H/6803/001	7000774.00.00	ALIUD PHARMA GmbH	Germany	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
ACIDO VALPROICO E SODIO VALPROATO EG 300 mg compresse a rilascio prolungato	DE/H/0811/001	038036051/M 038036063/M 038036075/M 038036087/M 038036099/M 038036012/M 038036125/M 038036024/M 038036152/M 038036036/M 038036164/M 038036048/M 038036113/M 038036137/M 038036101/M 038036149/M	EG S.p.A.	Italy	Not applicable
ACIDO VALPROICO E SODIO VALPROATO EG 500 mg compresse a rilascio modificato	DE/H/0811/002	038036214/M 038036226/M 038036238/M 038036240/M 038036253/M 038036176/M 038036289/M 038036188/M 038036315/M 038036190/M 038036327/M 038036265/M 038036202/M 038036277/M 038036291/M 038036303/M 038036339/M 038036341/M 038036354/M 038036366/M 038036378/M	EG S.p.A.	Italy	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Valproate Retard EG 300 mg comprimés à libération prolongée	DE/H/0811/001	2008040008	Eurogenerics N.V./S.A.	Luxembourg	Not applicable
Valproate Retard EG 500 mg comprimés à libération prolongé	DE/H/0811/002	2008040009	Eurogenerics N.V./S.A.	Luxembourg	Not applicable
Natriumvalproaat Chrono CF 300 mg, tabletten met verlengde afgifte	DE/H/0811/001	RVG 35065	Centrafarm B.V.	Netherlands	Not applicable
Natriumvalproaat Chrono CF 500 mg, tabletten met verlengde afgifte	DE/H/0811/002	RVG 35066	Centrafarm B.V.	Netherlands	Not applicable

Annex I - Tecnifar

Specific Information for PASS107 Submissions

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
DIPLEXIL 200 mg comprimidos revestidos	Not applicable	1/191/72	Tecnifar Indústria Técnica Farmacêutica SA	Portugal	Not applicable
DIPLEXIL 500 mg comprimidos gastorresistentes	Not applicable	1/191/72	Tecnifar Indústria Técnica Farmacêutica SA	Portugal	Not applicable
DIPLEXIL 200 mg/ml solução oral	Not applicable	1/191/72	Tecnifar Indústria Técnica Farmacêutica SA	Portugal	Not applicable
DIPLEXIL 150, 150 mg, Cápsula dura de libertação prolongada	PT/H/1406/001	PT/H/1406/001	Tecnifar Indústria Técnica Farmacêutica SA	Portugal	Not applicable
DIPLEXIL 300, 300 mg, Cápsula dura de libertação prolongada	PT/H/1406/002	PT/H/1406/002	Tecnifar Indústria Técnica Farmacêutica SA	Portugal	Not applicable
DIPLEXIL 500, 500 mg, Granulado de libertação prolongada	PT/H/1406/003	PT/H/1406/003	Tecnifar Indústria Técnica Farmacêutica SA	Portugal	Not applicable
DIPLEXIL 1000, 1000 mg, Granulado de libertação prolongada	PT/H/1406/004	PT/H/1406/004	Tecnifar Indústria Técnica Farmacêutica SA	Portugal	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
DIPLEXIL-R 250 mg comprimidos gastorresistentes	Not applicable	6/15/93	Tecnifar Indústria Técnica Farmacêutica SA	Portugal	Not applicable
DIPLEXIL-R 500 mg comprimidos gastorresistentes	Not applicable	6/15/93	Tecnifar Indústria Técnica Farmacêutica SA	Portugal	Not applicable

Annex I - Teva Pharmaceuticals Europe BV

Specific Information for PASS107 Submissions

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Valproat-ratiopharm Chrono 500 mg	DE-H-0642-001-002-MR	21/432/06-C	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Czech Republic	Not applicable
Valproat-ratiopharm Chrono 300 mg	DE-H-0642-001-002-MR	21/431/06-C	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Czech Republic	Not applicable
Valproate de sodium Teva Santé LP 500 mg comprimé pelliculé sécable à libération prolongée	FR NL30238	NL30238	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	France	Not applicable
Valproat-CT 300 mg Filmtabletten	46596.00.00	46596.00.00	Abz-Pharma Gmbh Graf-Arco-Strasse. 3 Ulm, 89079 De	Germany	Not applicable
Valproat-CT 600 mg Filmtabletten	46596.01.00	46596.01.00	Abz-Pharma Gmbh Graf-Arco-Strasse. 3 Ulm, 89079 De	Germany	Not applicable
Valproinsäure-ratiopharm 600 Filmtabletten	46594.01.00	46594.01.00	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Germany	Not applicable
Valproinsäure-ratiopharm 300 Filmtabletten	46594.00.00	46594.00.00	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Germany	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Valproinsäure-ratiopharm 150 Filmtabletten	46594.02.00	46594.02.00	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Germany	Not applicable
Valproinsäure-ratiopharm 300 mg/ml Lösung	46594.00.01	46594.00.01	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Germany	Not applicable
Valproat chrono-CT 300 mg Retardtabletten	59571.00.00	59571.00.00	Abz-Pharma Gmbh Graf-Arco-Strasse. 3 Ulm, 89079 De	Germany	Not applicable
Valproat AbZ 300 mg Retardtabletten	59575.00.00	59575.00.00	Abz-Pharma Gmbh Graf-Arco-Strasse. 3 Ulm, 89079 De	Germany	Not applicable
Valproat chrono-CT 500 mg Retardtabletten	59571.01.00	59571.01.00	Abz-Pharma Gmbh Graf-Arco-Strasse. 3 Ulm, 89079 De	Germany	Not applicable
Valproat AbZ 500 mg Retardtabletten	59575.01.00	59575.01.00	Abz-Pharma Gmbh Graf-Arco-Strasse. 3 Ulm, 89079 De	Germany	Not applicable
Valproat-ratiopharm chrono 300 mg Retardtabletten	DE-H-0642-001-002-MR	59567.00.00	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Germany	Not applicable
Valproat-ratiopharm chrono 500 mg Retardtabletten	DE-H-0642-001-002-MR	59567.01.00	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Germany	Not applicable
Acido Valproico e Sodio Valproato ratiopharm 500 mg compresse a rilascio prolungato	DE-H-0642-001-002-MR	037839115	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Acido Valproico e Sodio Valproato ratiopharm 500 mg compresse a rilascio prolungato	DE-H-0642-001-002-MR	037839166	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable
Acido Valproico e Sodio Valproato ratiopharm 500 mg compresse a rilascio prolungato	DE-H-0642-001-002-MR	037839103	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable
Acido Valproico e Sodio Valproato ratiopharm 500 mg compresse a rilascio prolungato	DE-H-0642-001-002-MR	037839178	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable
Acido Valproico e Sodio Valproato ratiopharm 500 mg compresse a rilascio prolungato	DE-H-0642-001-002-MR	037839091	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable
Acido Valproico e Sodio Valproato ratiopharm 500 mg compresse a rilascio prolungato	DE-H-0642-001-002-MR	037839127	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable
Acido Valproico e Sodio Valproato ratiopharm 500 mg compresse a rilascio prolungato	DE-H-0642-001-002-MR	037839139	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Acido Valproico e Sodio Valproato ratiopharm 500 mg compresse a rilascio prolungato	DE-H-0642-001-002-MR	037839141	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable
Acido Valproico e Sodio Valproato ratiopharm 500 mg compresse a rilascio prolungato	DE-H-0642-001-002-MR	037839154	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable
Acido Valproico e Sodio Valproato ratiopharm 500 mg compresse a rilascio prolungato	DE-H-0642-001-002-MR	037839180	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable
Acido Valproico e Sodio Valproato ratiopharm 500 mg compresse a rilascio prolungato	DE-H-0642-001-002-MR	037839192	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable
Acido Valproico e Sodio Valproato ratiopharm 300 mg compresse a rilascio prolungato	DE-H-0642-001-002-MR	037839014	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable
Acido Valproico e Sodio Valproato ratiopharm 300 mg compresse a rilascio prolungato	DE-H-0642-001-002-MR	037839026	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Acido Valproico e Sodio Valproato ratiopharm 300 mg compresse a rilascio prolungato	DE-H-0642-001-002-MR	037839038	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable
Acido Valproico e Sodio Valproato ratiopharm 300 mg compresse a rilascio prolungato	DE-H-0642-001-002-MR	037839040	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable
Acido Valproico e Sodio Valproato ratiopharm 300 mg compresse a rilascio prolungato	DE-H-0642-001-002-MR	037839053	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable
Acido Valproico e Sodio Valproato ratiopharm 300 mg compresse a rilascio prolungato	DE-H-0642-001-002-MR	037839065	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable
Acido Valproico e Sodio Valproato ratiopharm 300 mg compresse a rilascio prolungato	DE-H-0642-001-002-MR	037839077	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable
Acido Valproico e Sodio Valproato ratiopharm 300 mg compresse a rilascio prolungato	DE-H-0642-001-002-MR	037839089	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable
Acido valproico e sodio valproato ratiopharm	DE-H-0642-001-002-MR	037839204	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Acido valproico e sodio valproato ratiopharm	DE-H-0642-001-002-MR	037839216	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Italy	Not applicable
Natriumvalproaat chrono 500 mg Teva, tabletten met gereguleerde afgifte	DE-H-0642-001-002-MR	RVG 33980	Teva Nederland B.V. Swensweg 5 Haarlem, 2031 Ga Nl	Netherlands	Not applicable
Natriumvalproaat chrono 300 mg Teva, tabletten met gereguleerde afgifte	DE-H-0642-001-002-MR	RVG 33979	Teva Nederland B.V. Swensweg 5 Haarlem, 2031 Ga Nl	Netherlands	Not applicable
Orfiril 100 mg/ml, oplossing voor injectie	RVG 24465	RVG 24465	Teva B.V Swensweg 5 Haarlem, 2031GA NL	Netherlands	Not applicable
Ácido Valpróico Ratiopharm 500 mg comprimidos de libertação prolongada	DE-H-0642-001-002-MR	5934989	Ratiopharm Comércio E Indústria De Produtos Farmacêuticos Lda. Lagoas Park 5-A, Piso 2 Porto Salvo, 2740-245 Pt	Portugal	Not applicable
Ácido Valpróico Ratiopharm 300 mg comprimidos de libertação prolongada	DE-H-0642-001-002-MR	5934781	Ratiopharm Comércio E Indústria De Produtos Farmacêuticos Lda. Lagoas Park 5-A, Piso 2 Porto Salvo, 2740-245 Pt	Portugal	Not applicable
Ácido Valpróico Ratiopharm 300 mg comprimidos de libertação prolongada	DE-H-0642-001-002-MR	5934880	Ratiopharm Comércio E Indústria De Produtos Farmacêuticos Lda. Lagoas Park 5-A, Piso 2 Porto Salvo, 2740-245 Pt	Portugal	Not applicable
Valpro-ratiopharm Chrono 500mg	DE-H-0642-001-002-MR	21/0429/06-S	Ratiopharm Gmbh Graf-Arco-Str. 3 Ulm, 89079 De	Slovakia	Not applicable

Annex I - Wockhardt UK Limited

Specific Information for PASS107 Submissions

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Sodium Valproate Wockhardt 200mg Gastro-Resistant Tablets or Orlept 200mg Gastro-Resistant Tablets	N/A (national MA)	PL 29831/0189	Wockhardt UK Limited	United Kingdom	Not applicable
Sodium Valproate 100mg/ml Solution for Injection or Infusion	N/A (national MA)	PL 29831/0506	Wockhardt UK Limited	United Kingdom	Not applicable
Sodium Valproate 40mg/ml Oral Solution (sugar free) or Orlept (SF) liquid	N/A (national MA)	PL 29831/0188	Wockhardt UK Limited	United Kingdom	Not applicable
Sodium Valproate Wockhardt 500mg Gastro-Resistant Tablets or Orlept 500mg Gastro-Resistant Tablets	N/A (national MA)	PL 29831/0190	Wockhardt UK Limited	United Kingdom	Not applicable