



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

23 March 2017  
EMA/203466/2017 Corr. 1<sup>1</sup>  
Procedure Management and Business Support

## Products for which the marketing authorisations are recommended for suspension and marketing authorisation applications which do not satisfy the criteria for authorisation as adopted by the CHMP on 23 March 2017

Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1450  
EMEA/H/A31/1450/C/003787/0005

Some of these medicinal products may be considered critical by the individual EU Member States. The suspension of the concerned marketing authorisation(s) may be deferred by the period for which the medicinal product is considered critical.

---

<sup>1</sup> 12 April 2017



Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Austria	Sandoz GmbH		Bupropion Sandoz 300 mg - Tablette mit veränderter Wirkstofffreisetzung	bupropion	300 mg	Modified-release tablet	Oral use
Austria	1A Pharma GmbH		Bupropion 1A Pharma 300 mg - Tablette mit veränderter Wirkstofffreisetzung	bupropion	300 mg	Modified-release tablet	Oral use
Belgium	Aurobindo Pharma BV		Amlodipine-Valsartan AB	amlodipine / valsartan	5 mg/80 mg	Film-coated tablet	Oral use
Belgium	Aurobindo Pharma BV		Amlodipine-Valsartan AB	amlodipine / valsartan	5 mg/160 mg	Film-coated tablet	Oral use
Belgium	Aurobindo Pharma BV		Amlodipine-Valsartan AB	amlodipine / valsartan	10 mg/160 mg	Film-coated tablet	Oral use
Belgium	Sandoz n.v./s.a.		Betados 8 mg	betahistine	8 mg	Tablet	Oral use
Belgium	Sandoz n.v./s.a.		Betados 16 mg	betahistine	16 mg	Tablet	Oral use
Belgium	Sandoz n.v./s.a.		Betahistine Sandoz 24 mg	betahistine	24 mg	Tablet	Oral use
Belgium	Aurobindo Pharma BV		Voriconazole AB	voriconazol	50 mg	Tablet	Oral use
Belgium	Aurobindo Pharma BV		Voriconazole AB	voriconazol	200 mg	Tablet	Oral use
Belgium	Aurobindo Pharma BV		Tadalafil AB	tadalafil	5 mg	Film-coated tablet	Oral use
Belgium	Aurobindo Pharma BV		Tadalafil AB	tadalafil	10 mg	Film-coated tablet	Oral use
Belgium	Aurobindo Pharma BV		Tadalafil AB	tadalafil	20 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Belgium	Aurobindo Pharma BV		Naproxen Aurobindo	naproxen	250 mg	Tablet	Oral use
Belgium	Sandoz n.v./s.a.		Bupropion HCl Sandoz	bupropion	300 mg	Modified-release tablet	Oral use
Belgium	Aurobindo Pharma BV		Naproxen Aurobindo	naproxen	500 mg	Tablet	Oral use
Bulgaria		Sandoz B.V.	Betahistin HEXAL 16 mg Tabletten	betahistine	16 mg	Tablet	Oral use
Bulgaria		Sandoz B.V.	Betahistin HEXAL 24 mg Tabletten	betahistine	24 mg	Tablet	Oral use
Bulgaria		Sandoz B.V.	Betahistin HEXAL 8 mg Tabletten	betahistine	8 mg	Tablet	Oral use
Bulgaria	Proenzi s.r.o.		Etrixenal	naproxen	250 mg	Tablet	Oral use
Czech Republic		Famy Care Europe Ltd.	LARCIA 125 MIKROGRAMŮ/30 MIKROGRAMŮ	ethinylestradiol / levonorgestrel	0.03 mg / 0.125 mg	Tablet	Oral use
Czech Republic		Famy Care Europe Ltd.	Levonorgestrel/Ethinylestradiol Famy Care 125 mikrogramů/30 mikrogramů	ethinylestradiol / levonorgestrel	0.03 mg / 0.125 mg	Tablet	Oral use
Czech Republic		Sandoz B.V.	BETAHISTIN SANDOZ 8 MG	betahistine dihydrochloride	8 mg	Tablet	Oral use
Czech Republic		Sandoz B.V.	BETAHISTIN SANDOZ 16 MG	betahistine dihydrochloride	16 mg	Tablet	Oral use
Czech Republic		Sandoz B.V.	BETAHISTIN SANDOZ 24 MG	betahistine dihydrochloride	24 mg	Tablet	Oral use

<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
Czech Republic	Proenzi s.r.o.		ETRIXENAL 250 MG TABLETY	naproxen	250 mg	Tablet	Oral use
Denmark	EQL Pharma AB		Hydroxyzinhydrochlorid EQL Pharma	hydroxyzine	25 mg	Film-coated tablet	Oral use
Denmark	Alternova A/S		Dicloxacillin Alternova	dicloxacillin	250 mg	Capsule, hard	Oral use
Denmark	Alternova A/S		Dicloxacillin Alternova	dicloxacillin	500 mg	Capsule, hard	Oral use
Denmark	2care4 Aps		Betahistin 2care4	betahistine	8 mg	Tablet	Oral use
Denmark	2care4 Aps		Betahistin 2care4	betahistine	16 mg	Tablet	Oral use
Denmark	2care4 Aps		Betahistin 2care4	betahistine	24 mg	Tablet	Oral use
Denmark	Alternova A/S		Novertigo	betahistine	8 mg	Tablet	Oral use
Denmark	Alternova A/S		Novertigo	betahistine	16 mg	Tablet	Oral use
Denmark		Orifarm Generics A/S	Loperamid Orifarm	loperamide	2 mg	Tablet	Oral use
Denmark		Alternova A/S	Baklofen Alternova	baclofen	10 mg	Tablet	Oral use
Denmark	Orion Corporation, Finland		Tadalafil Orion	tadalafil	5 mg	Film-coated tablet	Oral use
Denmark	Orion Corporation, Finland		Tadalafil Orion	tadalafil	10 mg	Film-coated tablet	Oral use
Denmark	Orion Corporation, Finland		Tadalafil Orion	tadalafil	20 mg	Film-coated tablet	Oral use
Denmark		Alternova A/S	Etodolac Alternova	etodolac	300 mg	Film-coated tablet	Oral use
Denmark	Aurobindo Pharma (Malta) Limited		Naproxen Orion	naproxen	250 mg	Tablet	Oral use
Denmark	Aurobindo Pharma (Malta) Limited		Naproxen Orion	naproxen	500 mg	Tablet	Oral use

<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
Estonia		Sandoz B.V.	Betahistidine Sandoz	betahistine	8 mg	Tablet	Oral use
Estonia		Sandoz B.V.	Betahistidine Sandoz	betahistine	16 mg	Tablet	Oral use
Estonia		Sandoz B.V.	Betahistidine Sandoz	betahistine	24 mg	Tablet	Oral use
Estonia	Proenzi s.r.o.		Etrixenal	naproxen	250 mg	Tablet	Oral use
Finland	Orion Corporation		Bupropion Orion	bupropion	300 mg	modified-release tablet	Oral use
Finland	Sandoz A/S, Denmark		Hydroxyzine Sandoz	hydroxyzine	25 mg	Film-coated tablet	Oral use
Finland	Orion Corporation Orion Pharma, Finland		Tadalafil Orion	tadalafil	5 mg	Film-coated tablet	Oral use
Finland	Orion Corporation Orion Pharma, Finland		Tadalafil Orion	tadalafil	10 mg	Film-coated tablet	Oral use
Finland	Orion Corporation Orion Pharma, Finland		Tadalafil Orion	tadalafil	20 mg	Film-coated tablet	Oral use
Finland	Aurobindo Pharma Ltd, Malta		Naproxen Orion	naproxen	250 mg	Tablet	Oral use
Finland	Sandoz A/S, Denmark		Bupropion Sandoz	bupropion	300 mg	Modified-release tablet	Oral use
Finland	Aurobindo Pharma Ltd, Malta		Naproxen Orion	naproxen	500 mg	Tablet	Oral use
Finland	Alternova A/S		Prednisolon Alternova	prednisolone	20 mg		
France		Arrow Génériques	amlodipine / valsartan Arrow	amlodipine / valsartan	5 mg/80 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
France		Arrow Génériques	amlodipine / valsartan Arrow	amlodipine / valsartan	5 mg/160 mg	Film-coated tablet	Oral use
France		Arrow Génériques	amlodipine / valsartan Arrow	amlodipine / valsartan	10 mg/160 mg	Film-coated tablet	Oral use
France		Sandoz B.V.	BETAHISTINE GNR	betahistine	8 mg	Tablet	Oral use
France		Sandoz B.V.	BETAHISTINE GNR	betahistine	24 mg	Tablet	Oral use
France	Sanofi Aventis France		Hydroxyzine ZENTIVA	hydroxyzine	25 mg	Film-coated tablet	Oral use
France	Mylan SAS		Hydroxyzine MYLAN	hydroxyzine	25 mg	Film-coated tablet	Oral use
France	Sandoz		Hydroxyzine SANDOZ	hydroxyzine	25 mg	Film-coated tablet	Oral use
France	Biogaran		hydroxyzine BIOGARAN	hydroxyzine	25 mg	Film-coated tablet	Oral use
France	Arrow Génériques		Hydroxyzine ARROW	hydroxyzine	25 mg	Film-coated tablet	Oral use
France	Cristers		Hydroxyzine CRISTERS	hydroxyzine	25 mg	Film-coated tablet	Oral use
France	EG LABO - Laboratoires Eurogenerics		Hydroxyzine EG	hydroxyzine	25 mg	Film-coated tablet	Oral use
France	Teva Sante		Hydroxyzine TEVA	hydroxyzine	25 mg	Film-coated tablet	Oral use
France		Special Concept Development (UK) Ltd	Metformine Almus	metformin hydrochloride	500 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
France		Special Concept Development (UK) Ltd	Metformine Almus	metformin hydrochloride	850 mg	Tablet	Oral use
France		Special Concept Development (UK) Ltd	Metformine Almus	metformin hydrochloride	1000 mg	Tablet	Oral use
France		ELC Group s.r.o.	Esters ethyliques d'acides omega-3 Strides	omega-3-acid-ethyl esters 90	1 g	Capsule, soft	Oral use
France		ARROW GENERIQUES	tadalafil Arrow	tadalafil	2.5 mg	Film-coated tablet	Oral use
France		ARROW GENERIQUES	tadalafil Arrow	tadalafil	5 mg	Film-coated tablet	Oral use
France		ARROW GENERIQUES	tadalafil Arrow	tadalafil	10 mg	Film-coated tablet	Oral use
France		ARROW GENERIQUES	tadalafil Arrow	tadalafil	20 mg	Film-coated tablet	Oral use
France		AUROVITAS UNIPESOAL Lda	Tadalafil Quiver	tadalafil	20 mg	Film-coated tablet	Oral use
France	ZYDUS France		TIANEPTINE ZYDUS	tianeptine	12.5 mg	Tablet	Oral use
France		SUBSTIPHARM DEVELOPPEMENT	PERURCIL	ursodeoxycholic acid	500 mg	Film-coated tablet	Oral use
France		SUBSTIPHARM DEVELOPPEMENT	acide ursodesoxycholique Inopharm	ursodeoxycholic acid	500 mg	Film-coated tablet	Oral use
France		SUBSTIPHARM DEVELOPPEMENT	VALDINE	ursodeoxycholic acid	500 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
France		ARROW GENERIQUES	voriconazole Arrow	voriconazol	50 mg	Film-coated tablet	Oral use
France		ARROW GENERIQUES	voriconazole Arrow	voriconazol	200 mg	Film-coated tablet	Oral use
France		Special Concept Development (UK) Limited	Paracetamol Almus Pharma	paracetamol	500 mg	Tablet	Oral use
France		Special Concept Development (UK) Limited	Paracetamol Almus Pharma	paracetamol	1000 mg	Tablet	Oral use
France	ZYDUS France		perindopril/Indapamide Zydus France	perindopril/indapamide	2 mg/ 0.625 mg	Tablet	Oral use
France	ZYDUS France		perindopril/Indapamide Zydus France	perindopril/indapamide	4 mg / 1.25 mg	Tablet	Oral use
France	ZYDUS France		perindopril/Indapamide Zydus France	perindopril/indapamide	8 mg / 2.5 mg	Tablet	Oral use
Germany	Hormosan Pharma GmbH		Maexeni 30 0,03 mg/0,15 mg Filmtabletten	ethinylestradiol / levonorgestrel	0.03 mg/0.15 mg	Film-coated tablet	Oral use
Germany	neuraxpharm Arzneimittel GmbH		Bupropion-neuraxpharm 300 mg Tabletten mit veränderter Wirkstofffreisetzung	bupropion	300 mg	Modified-release tablet	Oral use
Germany	HEC Pharm GmbH		Irbesartan HEC Pharm 75 mg Filmtabletten	irbesartan	75 mg	Film-coated tablet	Oral use
Germany	HEC Pharm GmbH		Irbesartan HEC Pharm 150 mg Filmtabletten	irbesartan	150 mg	Film-coated tablet	Oral use



<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
Germany	HEC Pharm GmbH		Irbesartan HEC Pharm 300 mg Filmtabletten	irbesartan	300 mg	Film-coated tablet	Oral use
Germany	Famy Care Europe Ltd.		Ethinylestradiol / Levonorgeshel Famy Care 30 mikrogramm 125 mikrogramm tablette	ethinylestradiol / levonorgestrel	0.03 mg / 0.125 mg	Film-coated tablet	Oral use
Germany	Mylan Dura GmbH		Oralcon 30 Microgramm/125 Microgramm Tabletten	ethinylestradiol / levonorgestrel	0.03 mg / 0.125 mg	Film-coated tablet	Oral use
Germany	HEC Pharm GmbH		Olanzapin HEC Pharm 5 mg Schmelztabletten	olanzapin	5 mg	Oro-dispersible tablet	Oral use
Germany	HEC Pharm GmbH		Olanzapin HEC Pharm 10 mg Schmelztabletten	olanzapin	10 mg	Oro-dispersible tablet	Oral use
Germany	HEC Pharm GmbH		Olanzapin HEC Pharm 15 mg Schmelztabletten	olanzapin	15 mg	Oro-dispersible tablet	Oral use
Germany	HEC Pharm GmbH		Olanzapin HEC Pharm 20 mg Schmelztabletten	olanzapin	20 mg	Oro-dispersible tablet	Oral use
Germany		Sandoz B.V.	Betahistin HEXAL 8 mg Tabletten	betahistine	8 mg	Tablet	Oral use
Germany		Sandoz B.V.	Betahistin HEXAL 16 mg Tabletten	betahistine	16 mg	Tablet	Oral use
Germany		Sandoz B.V.	Betahistin HEXAL 24 mg Tabletten	betahistine	24 mg	Tablet	Oral use
Germany		Sandoz B.V.	Betahistin HEXAL bei Schwindel 8 mg Tabletten	betahistine	8 mg	Tablet	Oral use

<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
Germany		Sandoz B.V.	Betahistin HEXAL bei Schwindel 16 mg Tabletten	betahistine	16 mg	Tablet	Oral use
Germany		Sandoz B.V.	Betahistin HEXAL bei Schwindel 24 mg Tabletten	betahistine	24 mg	Tablet	Oral use
Germany		Sandoz B.V.	Betahistin - 1 A Pharma 8 mg Tabletten	betahistine	8 mg	Tablet	Oral use
Germany		Sandoz B.V.	Betahistin - 1 A Pharma 16 mg Tabletten	betahistine	16 mg	Tablet	Oral use
Germany		Sandoz B.V.	Betahistin - 1 A Pharma 24 mg Tabletten	betahistine	24 mg	Tablet	Oral use
Germany	PUREN Pharma GmbH & Co. KG (in Germany)		Tadalafil Aurovitas	tadalafil	5 mg	Film-coated tablet	Oral use
Germany	PUREN Pharma GmbH & Co. KG (in Germany)		Tadalafil Aurovitas	tadalafil	10 mg	Film-coated tablet	Oral use
Germany	PUREN Pharma GmbH & Co. KG (in Germany)		Tadalafil Aurovitas	tadalafil	20 mg	Film-coated tablet	Oral use
Germany	PUREN Pharma GmbH & Co. KG (in Germany)		Amlodipina + Valsartan Aurovitas, Amlodipin/Valsartan PUREN (in Germany)	amlodipine / valsartan	5 mg/80 mg	Film-coated tablet	Oral use

<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
Germany	PUREN Pharma GmbH & Co. KG (in Germany)		Amlodipina + Valsartan Aurovitas, Amlodipin/Valsartan PUREN (in Germany)	amlodipine / valsartan	5 mg/160 mg	Film-coated tablet	Oral use
Germany	PUREN Pharma GmbH & Co. KG (in Germany)		Amlodipina + Valsartan Aurovitas, Amlodipin/Valsartan PUREN (in Germany)	amlodipine / valsartan	10 mg/160 mg	Film-coated tablet	Oral use
Germany		Aurovitas Unipessoal, Lda.	Tadalafil Ritista	tadalafil	20 mg	Film-coated tablet	Oral use
Germany	PUREN Pharma GmbH & Co. KG		Voriconazol PUREN 50 mg Filmtabletten	voriconazol	50 mg	Film-coated tablet	Oral use
Germany	PUREN Pharma GmbH & Co. KG		Voriconazol PUREN 200 mg Filmtabletten	voriconazol	200 mg	Film-coated tablet	Oral use
Germany	Hexal AG, Germany		Bupropionhydrochlorid Hexal 300 mg	bupropion	300 mg	Modified-release tablet	Oral use
Germany	1 A Pharma GmbH, Germany		Bupropion 1 A Pharma 300 mg	bupropion	300 mg	Modified-release tablet	Oral use
Greece	Pharmanel Commercial Pharmaceutical S.A.		PRABEX	ibuprofen	200 mg	Film-coated tablet	Oral use
Greece		Pharmanel Commercial Pharmaceutical S.A.	DUARIDE	dutasteride	0.5 mg	Capsule, soft	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Greece		ΦΑΡΜΑΖΑΚ ΑΝΩΝΥΜΗ ΦΑΡΜΑΚΕΥΤΙΚΗ ΕΜΠΟΡΙΚΗ ΒΙΟΜΗΧΑΝΙΚΗ ΕΤΑΙΡΕΙΑ Δ.Τ. PHARMAZAC AE	AMLODIPINE+ VALSARTAN/ PHARMAZAC	amlodipine / valsartan	5 mg / 80 mg	Film-coated tablet	Oral use
Greece		ΦΑΡΜΑΖΑΚ ΑΝΩΝΥΜΗ ΦΑΡΜΑΚΕΥΤΙΚΗ ΕΜΠΟΡΙΚΗ ΒΙΟΜΗΧΑΝΙΚΗ ΕΤΑΙΡΕΙΑ Δ.Τ. PHARMAZAC AE	AMLODIPINE+ VALSARTAN/ PHARMAZAC	amlodipine / valsartan	5 mg / 160 mg	Film-coated tablet	Oral use
Greece		ΦΑΡΜΑΖΑΚ ΑΝΩΝΥΜΗ ΦΑΡΜΑΚΕΥΤΙΚΗ ΕΜΠΟΡΙΚΗ ΒΙΟΜΗΧΑΝΙΚΗ ΕΤΑΙΡΕΙΑ Δ.Τ. PHARMAZAC AE	AMLODIPINE+ VALSARTAN/ PHARMAZAC	amlodipine / valsartan	10 mg / 160 mg	Film-coated tablet	Oral use
Greece		BRADEx AEBE	DUTASTERIDE/BRADEx	dutasteride	0.5 mg	Capsule, soft	Oral use
Greece	Pharmanel Commercial Pharmaceutical S.A.		PRABEX	ibuprofen	400 mg	Film-coated tablet	Oral use

<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
Greece	Pharmanel Commercial Pharmaceutical S.A.		PRABEX	ibuprofen	600 mg	Film-coated tablet	Oral use
Hungary	Proenzi s.r.o.		ETRIXENAL	naproxen	250 mg	Tablet	Oral use
Ireland	Stasisport Pharma N.V.		Miofen	ibuprofen	200 mg	Film-coated tablet	Oral use
Ireland	Stasisport Pharma N.V.		Miofen	ibuprofen	400 mg	Film-coated tablet	Oral use
Ireland	Stasisport Pharma N.V.		Miofen	ibuprofen	600 mg	Film-coated tablet	Oral use
Ireland		Alissa Healthcare Research Limited	Carbocisteine 375 mg Capsules, Hard	carbocisteine	375 mg	Capsule, hard	Oral use
Italy	Aurobindo Pharma (Italia), srl		Tadalafil Aurobindo	tadalafil	5 mg	Film-coated tablet	Oral use
Italy	Aurobindo Pharma (Italia) srl		Voriconazolo Aurobindo	voriconazol	50 mg	Film-coated tablet	Oral use
Italy	Sandoz SpA		Bupropione Sandoz	bupropion	300 mg	Modified-release tablet	Oral use
Italy	Strides Arcolab International Limited		Omega 3 Strides Arcolab International	omega-3-acid-ethyl esters 90	1000 mg	Capsule, soft	Oral use
Italy		Special Concept Development (UK) Ltd	Metformina Almus	metformin hydrochloride	850 mg	Film-coated tablet	Oral use

<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
Italy		Special Concept Development (UK) Ltd	Metformina Almus	metformin hydrochloride	1000 mg	Film-coated tablet	Oral use
Italy	Aurobindo Pharma (Italia), srl		Tadalafil Aurobindo	tadalafil	10 mg	Film-coated tablet	Oral use
Italy	Aurobindo Pharma (Italia), srl		Tadalafil Aurobindo	tadalafil	20 mg	Film-coated tablet	Oral use
Italy	Aurobindo Pharma (Italia) srl		Voriconazolo Aurobindo	voriconazol	200 mg	Film-coated tablet	Oral use
Italy	Strides Arcolab International Limited		Omega 3 Strides Arcolab International	omega-3-acid-ethyl esters 90	1000 mg	Capsule, soft	Oral use
Italy		Special Concept Development (UK) Ltd	Metformina Almus	metformin hydrochloride	500 mg	Film-coated tablet	Oral use
Latvia		Sandoz B.V.	Betahistin Sandoz 8 mg tabletes	betahistine	8 mg	Tablet	Oral use
Latvia		Sandoz B.V.	Betahistin Sandoz 16 mg tabletes	betahistine	16 mg	Tablet	Oral use
Latvia		Sandoz B.V.	Betahistin Sandoz 24 mg tabletes	betahistine	24 mg	Tablet	Oral use
Latvia	Proenzi s.r.o		Etrixenal 250 mg tabletes	naproxen	250 mg	Tablet	Oral use
Lithuania	Proenzi s.r.o		Etrixenal	naproxen	250 mg	Tablet	Oral use
Lithuania		Sandoz B. V.	Betahistine Sandoz	betahistine	8 mg	Tablet	Oral use
Lithuania		Sandoz B. V.	Betahistine Sandoz	betahistine	16 mg	Tablet	Oral use
Lithuania		Sandoz B. V.	Betahistine Sandoz	betahistine	24 mg	Tablet	Oral use

<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
Luxembourg		Aurobindo Pharma B.V.	Naproxen Aurobindo	naproxen	250 mg	Tablet	Oral use
Luxembourg		Sandoz B.V.	Bupropion HCl Sandoz	bupropion	300 mg	Modified-release tablet	Oral use
Luxembourg		Aurobindo Pharma B.V.	Naproxen Aurobindo	naproxen	500 mg	Tablet	Oral use
Norway	EQL Pharma AB		Hydroxyzine EQL Pharma	hydroxyzine	25 mg	Film-coated tablet	Oral use
Norway	Alternova A/S		Dicloxacillin Alternova	dicloxacillin	250 mg	Capsule, hard	Oral use
Norway	Alternova A/S		Dicloxacillin Alternova	dicloxacillin	500 mg	Capsule, hard	Oral use
Norway	Orion Corporation		Tadalafil Orion	tadalafil	5 mg	Film-coated tablet	Oral use
Norway	Orion Corporation		Tadalafil Orion	tadalafil	10 mg	Film-coated tablet	Oral use
Norway	Orion Corporation		Tadalafil Orion	tadalafil	20 mg	Film-coated tablet	Oral use
Norway	Aurobindo Pharma Limited		Naproxen Orion	naproxen	250 mg	Tablet	Oral use
Norway	Aurobindo Pharma Limited		Naproxen Orion	naproxen	500 mg	Tablet	Oral use
Poland	Bluefish Pharmaceuticals AB		Betahistyna Bluefish	betahistine dihydrochloride	8 mg	Tablet	Oral use
Poland	VITAMA S.A.		Sarpin	amlodipine / valsartan	10 mg /160 mg	Film-coated tablet	Oral use

<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
Poland	VITAMA S.A.		Napritum	naproxen	250 mg	Tablet	Oral use
Poland	VITAMA S.A.		Napritum	naproxen	500 mg	Tablet	Oral use
Poland	Bluefish Pharmaceuticals AB		Betahistyna Bluefish	betahistine dihydrochloride	16 mg	Tablet	Oral use
Poland	Bluefish Pharmaceuticals AB		Betahistyna Bluefish	betahistine dihydrochloride	24 mg	Tablet	Oral use
Poland	Orion Corporation		Bupropion Orion	bupropion	300 mg	Modified-release tablet	Oral use
Poland	Proenzi s.r.o.		Etrixenal	naproxen	250 mg	Tablet	Oral use
Portugal		Sandoz B.V.	Beta-histina Sandoz	betahistine	16 mg	Tablet	Oral use
Portugal		Sandoz B.V.	Beta-histina Sandoz	betahistine	24 mg	Tablet	Oral use
Portugal		Special Concept Development (UK) Ltd	Metformina Almus	metformin hydrochloride	850 mg	Film-coated tablet	Oral use
Portugal		Special Concept Development (UK) Ltd	Metformina Almus	metformin hydrochloride	1000 mg	Film-coated tablet	Oral use
Portugal	Aurobindo Pharma (Portugal), Unipessoal Lda.		Tadalafil Aurobindo	tadalafil	5 mg	Film-coated tablet	Oral use
Portugal	Aurovitas Unipessoal, Lda.		Tadalafil Aurovitas	tadalafil	2.5 mg	Film-coated tablet	Oral use
Portugal	Aurovitas Unipessoal, Lda.		Amlodipina + Valsartan Aurovitas	amlodipine / valsartan	5 mg /80 mg	Film-coated tablet	Oral use



<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
Portugal	Bluefish Pharmaceuticals AB		Beta-histina Bluefish	betahistine	8 mg	Tablet	Oral use
Portugal	Farmoz - Sociedade Técnico Medicinal, S.A.		Beta-histina Farmoz	betahistine	16 mg	Tablet	Oral use
Portugal	Farmoz - Sociedade Técnico Medicinal, S.A.		Beta-histina Farmoz	betahistine	24 mg	Tablet	Oral use
Portugal		Pharma Bavaria International (PBI) Portugal, Unip. Lda.	Vasobex	betahistine	8 mg	Tablet	Oral use
Portugal		Pharma Bavaria International (PBI) Portugal, Unip. Lda.	Vasobex	betahistine	16 mg	Tablet	Oral use
Portugal		Pharma Bavaria International (PBI) Portugal, Unip. Lda.	Vasobex	betahistine	24 mg	Tablet	Oral use
Portugal		Generic Speciality Pharma Limited	Histabal	betahistine	8 mg	Tablet	Oral use
Portugal		Generic Speciality Pharma Limited	Histabal	betahistine	16 mg	Tablet	Oral use

<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
Portugal		Generic Speciality Pharma Limited	Histabal	betahistine	24 mg	Tablet	Oral use
Portugal		Aurovitas Unipessoal, Lda.	Tadalafil Aurobindo	tadalafil	20 mg	Film-coated tablet	Oral use
Portugal	Laboratórios Basi - Indústria Farm		Beta-histina Basi	betahistine	8 mg	Tablet	Oral use
Portugal	Generis Farmacêutica, S.A.		Baclofeno Generis	baclofen	10 mg	Tablet	Oral use
Portugal	Aurovitas Unipessoal, Lda.		Voriconazol Aurovitas	voriconazol	50 mg	Film-coated tablet	Oral use
Portugal	Glob Ltd.		Voriconazol Glob	voriconazol	50 mg	Film-coated tablet	Oral use
Portugal	Aurobindo Pharma (Portugal), Unipessoal Lda.		Naproxen Aurobindo	naproxen	250 mg	Tablet	Oral use
Portugal	Sandoz Farmacêutica, Lda.		Bupropion HCl Sandoz	bupropion	300 mg	Modified-release tablet	Oral use
Portugal	Aurobindo Pharma (Portugal), Unipessoal Lda.		Naproxeno Aurobindo	naproxen	500 mg	Tablet	Oral use
Portugal	Aurobindo Pharma (Portugal), Unipessoal Lda.		Tadalafil Aurobindo	tadalafil	10 mg	Film-coated tablet	Oral use

<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
Portugal	Aurobindo Pharma (Portugal), Unipessoal Lda.		Tadalafil Aurobindo	tadalafil	20 mg	Film-coated tablet	Oral use
Portugal	Aurovitas Unipessoal, Lda.		Tadalafil Aurovitas	tadalafil	5 mg	Film-coated tablet	Oral use
Portugal	Aurovitas Unipessoal, Lda.		Tadalafil Aurovitas	tadalafil	10 mg	Film-coated tablet	Oral use
Portugal	Aurovitas Unipessoal, Lda.		Tadalafil Aurovitas	tadalafil	20 mg	Film-coated tablet	Oral use
Portugal	Aurovitas Unipessoal, Lda.		Amlodipina + Valsartan Aurovitas	amlodipine / valsartan	5 mg /160 mg	Film-coated tablet	Oral use
Portugal	Aurovitas Unipessoal, Lda.		Amlodipina + Valsartan Aurovitas	amlodipine / valsartan	10 mg/160 mg	Film-coated tablet	Oral use
Portugal	Aurovitas Unipessoal, Lda.		Voriconazol Aurovitas	voriconazol	200 mg	Film-coated tablet	Oral use
Portugal	Glob Ltd.		Voriconazol Glob	voriconazol	200 mg	Film-coated tablet	Oral use
Portugal	Bluefish Pharmaceuticals AB		Beta- histina Bluefish	betahistine dihydrochloride	16 mg	Tablet	Oral use
Portugal	Bluefish Pharmaceuticals AB		Beta- histina Bluefish	betahistine dihydrochloride	24 mg	Tablet	Oral use
Portugal		Special Concept Development (UK) Ltd	Metformina Almus	metformin hydrochloride	500 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Portugal		Almus, Lda.	Paracetamol 500mg Tablets	paracetamol	500 mg	Tablet	Oral use
Portugal		Almus, Lda.	Paracetamol 1000mg Tablets	paracetamol	1000 mg	Tablet	Oral use
Portugal	SVUS Pharma a.s.		Belfada	aripiprazole	10 mg	Tablet	Oral use
Portugal	SVUS Pharma a.s.		Belfada	aripiprazole	15 mg	Tablet	Oral use
Romania		Sandoz B.V.	Betahistin HEXAL 8 mg Tabletten	betahistine	8 mg	Tablet	Oral use
Romania		Sandoz B.V.	Betahistin HEXAL 16 mg Tabletten	betahistine	16 mg	Tablet	Oral use
Romania		Sandoz B.V.	Betahistin HEXAL 24 mg Tabletten	betahistine	24 mg	Tablet	Oral use
Romania	Aurobindo Pharma (Malta) Limited		Amlodipina/Valsartan Aurobindo 5 mg/80 mg comprimate filmate	amlodipine / valsartan	5 mg /80 mg	Film-coated tablet	Oral use
Romania	Aurobindo Pharma (Malta) Limited		Amlodipina/Valsartan Aurobindo 5 mg/160 mg comprimate filmate	amlodipine / valsartan	5 mg /160 mg	Film-coated tablet	Oral use
Romania	Aurobindo Pharma (Malta) Limited		Amlodipina/Valsartan Aurobindo 10 mg/160 mg comprimate filmate	amlodipine / valsartan	10 mg/160 mg	Film-coated tablet	Oral use
Romania	Aurobindo Pharma (Malta) Limited		Naproxen Aurobindo	naproxen	250 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Romania	Aurobindo Pharma (Malta) Limited		Naproxen Aurobindo	naproxen	500 mg	Tablet	Oral use
Romania	Proenzi s.r.o.		Etrixenal	naproxen	250 mg	Tablet	Oral use
Slovak Republic		Sandoz B.V.	Betahistin Sandoz 8 mg	betahistine	8 mg	Tablet	Oral use
Slovak Republic		Sandoz B.V.	Betahistin Sandoz 16 mg	betahistine	16 mg	Tablet	Oral use
Slovak Republic		Sandoz B.V.	Betahistin Sandoz 24 mg	betahistine	24 mg	Tablet	Oral use
Slovak Republic	Proenzi s.r.o.		Etrixenal	naproxen	250 mg	Tablet	Oral use
Slovenia		Sandoz B.V.	Betahistin Sandoz 8 mg tablete	betahistine	8 mg	Tablet	Oral use
Slovenia		Sandoz B.V.	Betahistin Sandoz 16 mg tablete	betahistine	16 mg	Tablet	Oral use
Slovenia		Sandoz B.V.	Betahistin Sandoz 24 mg tablete	betahistine	24 mg	Tablet	Oral use
Slovenia	Sandoz GmbH		Bupropion Sandoz 300 mg tablete s prirejenim sproščanjem	bupropion	300 mg	Modified-release tablet	Oral use
Spain	AUROVITAS SPAIN, SAU		Tadalafilo Aurovitas 5 mg comprimidos recubiertos con película EFG	tadalafil	5 mg	Film-coated tablet	Oral use
Spain	AUROVITAS SPAIN, SAU		Tadalafilo Aurovitas 10 mg comprimidos recubiertos con película EFG	tadalafil	10 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Spain	AUROVITAS SPAIN, SAU		Tadalafilo Aurovitas 20 mg comprimidos recubiertos con película	tadalafil	20 mg	Film-coated tablet	Oral use
Spain		AUROVITAS UNIPESONAL, LDA	Tadalafilo Aurovit 20 mg comprimidos recubiertos con película EFG	tadalafil	20 mg	Film-coated tablet	Oral use
Spain	Strides Arcolab International Limited		Ácidos Omega 3 Strides 1000 mg cápsulas blandas EFG	omega-3-acid-ethyl esters 90	1000 mg	Capsule, soft	Oral use
Spain		ALMUS FARMACEUTICA, SA	Metformina Almus Pharma 850 mg comprimdos recubiertos con película EFG	metformin hydrochloride	850 mg	Film-coated tablet	Oral use
Spain		ALMUS FARMACEUTICA, SA	Metformina Almus Pharma 1000 mg comprimdos recubiertos con película EFG	metformin hydrochloride	1000 mg	Film-coated tablet	Oral use
Spain	Bluefish Pharmaceuticals AB		Betahistina Bluefish	betahistine dihydrochloride	8 mg	Tablet	Oral use
Spain	Bluefish Pharmaceuticals AB		Betahistina Bluefish	betahistine dihydrochloride	16 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Spain	LABORATORIOS AUROBINDO, SLU		Amlodipino/Valsartán Aurobindo 5 mg/160 mg comprimidos recubiertos con película EFG	amlodipine / valsartan	5 mg/160 mg	Film-coated tablet	Oral use
Spain	LABORATORIOS AUROBINDO, SLU		Amlodipino/Valsartán Aurobindo 10 mg/160 mg comprimidos recubiertos con película EFG	amlodipine / valsartan	10 mg /160 mg	Film-coated tablet	Oral use
Spain	LABORATORIOS AUROBINDO, SLU		Naproxeno Aurobindo 250 mg comprimidos EFG	naproxen	250 mg	Tablet	Oral use
Spain	LABORATORIOS AUROBINDO, SLU		Naproxeno Aurobindo 500 mg comprimidos EFG	naproxen	500 mg	Tablet	Oral use
Spain		Aurovitas Spain	Voriconazol Aurovitas 50 mg comprimidos recubiertos con película EFG	voriconazol	50 mg	Tablet	Oral use
Spain		Aurovitas Spain SAU	Voriconazol Aurovitas 200 mg comprimidos recubiertos con película EFG	voriconazol	200 mg	Tablet	Oral use
Spain	AUROVITAS SPAIN, SAU		Amlodipino/Valsartan Aurovitas 5 mg/160 mg comprimidos recubiertos con película EFG	amlodipine / valsartan	5 mg /160 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Spain	AUROVITAS SPAIN, SAU		Amlodipino/Valsartan Aurovitas 10 mg/160 mg comprimidos recubiertos con película EFG	amlodipine / valsartan	10 mg/160 mg	Film-coated tablet	Oral use
Spain	QUALIGEN, SL		Hidroxizina Qualigen 25 mg comprimidos recubiertos con película EFG	hydroxyzine	25 mg	Film-coated tablet	Oral use
Spain	LABORATORIOS COMBIX, SLU		Perindopril/Indapamida Combix 2 mg/0,625 mg comprimidos EFG	perindopril / indapamide	2 mg /0.625 mg	Tablet	Oral use
Spain	LABORATORIOS COMBIX, SLU		Perindopril/Indapamida Combix 4 mg/1,25 mg comprimidos EFG	perindopril / indapamide	4 mg /1.25 mg	Tablet	Oral use
Spain	LABORATORIOS COMBIX, SLU		Perindopril/Indapamida Combix 8 mg/2,5 mg comprimidos EFG	perindopril / indapamide	8 mg/2.5 mg	Tablet	Oral use
Spain		LABORATORIOS CINFA, SA	Bupropion Cinfa 300 mg comprimidos de liberación modificada EFG	bupropion	300 mg	Modified-release tablet	Oral use
Spain	SANDOZ FARMACEUTICA, SA		Bupropion Sandoz 300 mg comprimidos de liberación modificada EFG	bupropion	300 mg	Modified-release tablet	Oral use
Spain		ALMUS FARMACEUTICA, SA	Paracetamol Almus 500 mg comprimidos EFG	paracetamol	500 mg	Tablet	Oral use



Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical Form	Route of Administration
Spain		ALMUS FARMACEUTICA, SA	Paracetamol Almus 1000 mg comprimidos EFG	paracetamol	1000 mg	Tablet	Oral use
Sweden	Orion Corporation		Bupropion Orion	bupropion	300 mg	modified-release tablet	Oral use
Sweden	EQL Pharma AB		Hydroxyzine EQL Pharma	hydroxyzine	25 mg	Film-coated tablet	Oral use
Sweden	2care4 Aps		Betahistin 2care4	betahistine	8 mg	Tablet	Oral use
Sweden	2care4 Aps		Betahistin 2care4	betahistine	16 mg	Tablet	Oral use
Sweden	2care4 Aps		Betahistin 2care4	betahistine	24 mg	Tablet	Oral use
Sweden	Orion Corporation		Tadalafil Orion	tadalafil	5 mg	Film-coated tablet	Oral use
Sweden	Orion Corporation		Tadalafil Orion	tadalafil	10 mg	Film-coated tablet	Oral use
Sweden	Orion Corporation		Tadalafil Orion	tadalafil	20 mg	Film-coated tablet	Oral use
Sweden	2care4 Generics ApS		Ibuprofen 2care4	ibuprofen	200 mg	Film-coated tablet	Oral use
Sweden	2care4 Generics ApS		Ibuprofen 2care4	ibuprofen	400 mg	Film-coated tablet	Oral use
Sweden	2care4 Generics ApS		Ibuprofen 2care4	ibuprofen	600 mg	Film-coated tablet	Oral use
Sweden	Alternova A/S		Metoklopramid Alternova	metoclopramide	10 mg	Film-coated tablet	Oral use
Sweden	EQL Pharma AB		Atyxine	hydroxyzine	25 mg	Film-coated tablet	Oral use

<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
Sweden	Alternova A/S		Clindamycin Alternova	clindamycin	150 mg	Capsule, hard	Oral use
Sweden		Apofri AB	Loperamid Apofri	loperamide	2 mg	Tablet	Oral use
Sweden		Evolan Pharma AB	Loperamid ABECE	loperamide	2 mg	Tablet	Oral use
Sweden		Evolan Pharma AB	Loperamid Evolan	loperamide	2 mg	Tablet	Oral use
Sweden		BBS Consult ApS	Loperamid BBS	loperamide	2 mg	Tablet	Oral use
Sweden	Aurobindo Pharma (Malta) Limited		Naproxen Orion	naproxen	250 mg	Tablet	Oral use
Sweden	Aurobindo Pharma (Malta) Limited		Naproxen Orion	naproxen	500 mg	Tablet	Oral use
Sweden	Sandoz A/S		Bupropion Sandoz	bupropion	300 mg	Modified-release tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Tadalafil Aurobindo 5 mg, filmomhulde tabletten	tadalafil	5 mg	Film-coated tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Tadalafil Aurobindo 10 mg, filmomhulde tabletten	tadalafil	10 mg	Film-coated tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Tadalafil Aurobindo 20 mg, filmomhulde tabletten	tadalafil	20 mg	Film-coated tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Amlodipine/ Valsartan Aurobindo 5/80 mg, filmomhulde tabletten	amlodipine / valsartan	5 mg /80 mg	Film-coated tablet	Oral use

<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
The Netherlands	Aurobindo Pharma B.V.		Amlodipine/ Valsartan Aurobindo 5/160 mg, filmomhulde tabletten	amlodipine / valsartan	5 mg /160 mg	Film-coated tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Amlodipine/ Valsartan Aurobindo 10/160 mg, filmomhulde tabletten	amlodipine / valsartan	10 mg /160 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Bupropion HCl Sandoz retard 300 mg, tabletten met geregleerde afgifte	bupropion	300 mg	Modified-release tablet	Oral use
The Netherlands	Sandoz B.V.		Bupropion HCl Sandoz retard 300 mg, tabletten met geregleerde afgifte	bupropion	300 mg	Modified-release tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Naproxen Aurobindo 250 mg, tabletten	naproxen	250 mg	Tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Naproxen Aurobindo 500 mg, tabletten	naproxen	500 mg	Tablet	Oral use
The Netherlands		Sandoz B.V.	Betahistine Sandoz 8 mg, tabletten	betahistine	8 mg	Tablet	Oral use
The Netherlands		Sandoz B.V.	Betahistine Sandoz 16 mg, tabletten	betahistine	16 mg	Tablet	Oral use
The Netherlands		Sandoz B.V.	Betahistine Sandoz 24 mg, tabletten	betahistine	24 mg	Tablet	Oral use
The Netherlands		Sandoz B.V.	Betahistine Sandoz 8 mg, tabletten	betahistine	8 mg	Tablet	Oral use
The Netherlands		Sandoz B.V.	Betahistine Sandoz 16 mg, tabletten	betahistine	16 mg	Tablet	Oral use

<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
The Netherlands		Sandoz B.V.	Betahistine Sandoz 24 mg, tabletten	betahistine	24 mg	Tablet	Oral use
The Netherlands		Sandoz B.V.	Betahistine Sandoz 8 mg, tabletten	betahistine	8 mg	Tablet	Oral use
The Netherlands		Sandoz B.V.	Betahistine Sandoz 16 mg, tabletten	betahistine	16 mg	Tablet	Oral use
The Netherlands		Sandoz B.V.	Betahistine Sandoz 24 mg, tabletten	betahistine	24 mg	Tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Voriconazol Aurobindo 50 mg, filmomhulde tabletten	voriconazol	50 mg	Film-coated tablet	Oral use
The Netherlands	Aurobindo Pharma B.V.		Voriconazol Aurobindo 200 mg, filmomhulde tabletten	voriconazol	200 mg	Film-coated tablet	Oral use
United Kingdom		Aurovitas Unipessoal, Lda.	Tadalafil Aurobindo	tadalafil	20 mg	Film-coated tablet	Oral use
United Kingdom	Milpharm Limited		Tadalafil Milpharm 2.5 mg film-coated tablets	tadalafil	2.5 mg	Film-coated tablet	Oral use
United Kingdom	Milpharm Limited		Tadalafil Milpharm 5 mg film-coated tablets	tadalafil	5 mg	Film-coated tablet	Oral use
United Kingdom	Milpharm Limited		Tadalafil Milpharm 10 mg film-coated tablets	tadalafil	10 mg	Film-coated tablet	Oral use
United Kingdom	Milpharm Limited		Tadalafil Milpharm 20 mg film-coated tablets	tadalafil	20 mg	Film-coated tablet	Oral use
United Kingdom	Milpharm Limited		Voriconazole Milpharm 50 mg film-coated tablets	voriconazol	50 mg	Film-coated tablet	Oral use
United Kingdom	Milpharm Limited		Voriconazole Milpharm 200 mg film-coated tablets	voriconazol	200 mg	Film-coated tablet	Oral use

<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
United Kingdom	Milpharm Limited		Naproxen 250 mg tablets	naproxen	250 mg	Tablet	Oral use
United Kingdom	Milpharm Limited		Naproxen 500 mg tablets	naproxen	500 mg	Tablet	Oral use
United Kingdom	HEC Pharm GmbH		Irbesartan 75 mg Film-coated Tablets	irbesartan	75 mg	Film-coated tablet	Oral use
United Kingdom	HEC Pharm GmbH		Irbesartan 150 mg Film-coated tablets	irbesartan	150 mg	Film-coated tablet	Oral use
United Kingdom	HEC Pharm GmbH		Irbesartan 300 mg Film-coated tablets	irbesartan	300 mg	Film-coated tablet	Oral use
United Kingdom	Strides Arcolab International Limited		Omega 3-acid-ethyl esters 1000mg soft capsules	omega-3-acid-ethyl esters 90	1000 mg	Capsule, soft	Oral use
United Kingdom	Dawa Limited		Paracetamol 500 mg Film Coated Tablets	paracetamol	500 mg	Film-coated tablet	Oral use
United Kingdom	Lupin (Europe) Limited		Maexeni 150/30 microgram Film Coated Tablets	ethinylestradiol / levonorgestrel	0.03 mg / 0.125 mg	Film-coated tablet	Oral use
United Kingdom	Kinedexe UK Limited (previously NRIM Limited)		Sodium Cromoglicate 100mg hard Capsules	sodium cromoglicate	100 mg	Capsule, hard	Oral use
United Kingdom	Milpharm Limited		Tadalafil Milpharm 20 mg film-coated tablets	tadalafil	20 mg	Film-coated tablet	Oral use
United Kingdom		Crescent Pharma Limited	Aripiprazole 5 mg tablets	aripiprazole	5 mg	Tablet	Oral use

<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
United Kingdom		Crescent Pharma Limited	Aripiprazole 10 mg tablets	aripiprazole	10 mg	Tablet	Oral use
United Kingdom		Crescent Pharma Limited	Aripiprazole 15 mg tablets	aripiprazole	15 mg	Tablet	Oral use
United Kingdom		Crescent Pharma Limited	Aripiprazole 30 mg tablets	aripiprazole	30 mg	Tablet	Oral use
United Kingdom		Medreich PLC	Gliclazide 40 mg tablets	gliclazide	40 mg	Tablet	Oral use
United Kingdom	Medreich PLC		Hydroxyzine hydrochloride 25mg film-coated tablets	hydroxyzine hydrochloride	25 mg	Film-coated tablet	Oral use
United Kingdom		Alissa Healthcare Research Limited	Carbocisteine 375 mg Capsules, Hard	carbocisteine	375 mg	Capsule, hard	Oral use
United Kingdom		Special Concept Development (UK) Limited	Metformin 500 mg Film-coated tablet	metformin hydrochloride	500 mg	Film-coated tablet	Oral use
United Kingdom		Special Concept Development (UK) Limited	Metformin 850 mg Film-coated tablet	metformin hydrochloride	850 mg	Film-coated tablet	Oral use
United Kingdom		Special Concept Development (UK) Limited	Metformin 1000 mg Film-coated tablet	metformin hydrochloride	1000 mg	Film-coated tablet	Oral use
United Kingdom		Special Concept Development (UK) Limited	Paracetamol 500mg Tablets	paracetamol	500 mg	Tablet	Oral use

<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
United Kingdom		Special Concept Development (UK) Limited	Paracetamol 1000mg Tablets	paracetamol	1000 mg	Tablet	Oral use
United Kingdom		Special Concept Development (UK) Limited	Paracetamol 500mg Tablets	paracetamol	500 mg	Tablet	Oral use
United Kingdom		Special Concept Development (UK) Limited	Paracetamol 1000mg Tablets	paracetamol	1000 mg	Tablet	Oral use
United Kingdom		Flamingo Pharma (UK) Limited	Gliclazide 80mg Tablets	gliclazide	80 mg	Tablet	Oral use
United Kingdom		Flamingo Pharma (UK) Limited	Gliclazide 40mg Tablets	gliclazide	40 mg	Tablet	Oral use
United Kingdom		HBS Healthcare Limited	Carbimazole 20 mg Tablets	carbimazole	20 mg	Tablet	Oral use
United Kingdom	Strides Arcolab International Limited		Omega 3-acid-ethyl esters 1000mg soft capsules	omega-3-acid-ethyl esters 90	1000 mg	Capsule, soft	Oral use
United Kingdom		Generic Partners UK Limited	Vzole 50 mg film-coated tablets	voriconazol	50 mg	Tablet	Oral use
United Kingdom		Generic Partners UK Limited	Vzole 200 mg film-coated tablets	voriconazol	200 mg	Tablet	Oral use
United Kingdom		Dawa Limited	Carbimazole 5mg Tablets	carbimazole	5 mg	Tablet	Oral use
United Kingdom		Dawa Limited	Carbimazole 20mg Tablets	carbimazole	20 mg	Tablet	Oral use

<b>Member State EU/EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Applicant</b>	<b>Invented name</b>	<b>Active Substance</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
United Kingdom		Essential-Healthcare Limited	Carbimazole 5mg Tablets	carbimazole	5 mg	Tablet	Oral use
United Kingdom		Essential-Healthcare Limited	Carbimazole 20mg Tablets	carbimazole	20 mg	Tablet	Oral use