



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 February 2016
EMA/244934/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: aciclovir

Procedure no.: PSUSA 00000048/201506



Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Aciclovir		30306/0282 \$ 30306/0283	Actavis Group Ptc Ehf.	United Kingdom
Aciclovir		PL 29831/0517 \$ PL 29831/0518 \$ PL 29831/0519	Wockhardt Uk Ltd	United Kingdom
Aciclovir 200 - 1 A Pharma		AA939/01801	1 A Pharma GmbH	Malta
Aciclovir 400 - 1 A Pharma		AA939/01802	1 A Pharma GmbH	Malta
Aciclovir 800 - 1 A Pharma		AA939/01803	1 A Pharma GmbH	Malta
Aciclovir akut Creme - 1 A Pharma		AA939/01804	1 A Pharma GmbH	Malta
Aciclovir Alonga Gel		56.675	Sanofi-Aventis, S.A.	Spain
Aciclovir Biogaran		NL28177	Laboratoire Glaxosmithkline	France
Aciclovir dura	DE/H/2713/001/DC	80997.00.00 ENR 2180997	Mylan S.A.S	Germany
Aciclovir Generics	DE/H/2713/001/DC	43442/24-06-2015	Generics Pharma Hellas Ltd	Greece

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Aciclovir Koortslipcrème Sandoz	NL/H/0148	RVG 20659	Sandoz B.V.	Netherlands
Aciclovir Mylan		NL 38 582	Mylan S.A.S	France
Aciclovir Mylan	DE/H/2713/001/DC	BE396453 \$ BE396462	Mylan Bvba/Sprl	Belgium
Aciclovir Mylan	DE/H/2713/001/DC	RVG 106953	Mylan B.V.	Netherlands
Aciclovir Pensa		62.739	Pensa Pharma S.A.U.	Spain
Aciclovir Pharmagenus		63450	Pharmagenus, S.A.	Spain
Aciclovir Ratiopharm		27480.01.00	Ratiopharm Gmbh	Germany
Aciclovir Ratiopharm		27480.02.00 \$ 27482.00.00	Ratiopharm Gmbh	Germany
Aciclovir Ratiopharm		28080.00.00	Ratiopharm Gmbh	Germany

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Aciclovir Ratiopharm		28082.00.00	Ratiopharm Gmbh	Germany
Aciclovir Sandoz		RVG 22569	Sandoz B.V.	Netherlands
Aciclovir Tedec		5913082 \$ 5913181	Decomed Farmacêutica, S.A.	Portugal
Aciclovir Terapia		4096/2011/01	Terapia S.A.	Romania
Acivision		24567.00.00	Omnivision Gmbh	Germany
Activir		NL 20390	Glaxosmithkline Sante Grand Public	France
Alovexlabiale		042187	Recordati Industria Chimica E Farmaceutica S.P.A.	Italy
AMODIVYR 5 % cream tube 10 g			RO-FARM DI SALVATORE DE MAIO & C. S.A.S.	Italy
AMODYVIR 400 mg/ 5 ml oral suspension		33471020	RO-FARM DI SALVATORE DE MAIO & C. S.A.S.	Italy

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
AMODYVIR 800 mg 35 tablets		33471018	RO-FARM DI SALVATORE DE MAIO & C. S.A.S.	Italy
Anti		15649	Meda Otc Ab	Sweden
Antix		03-1910	Meda Otc Ab	Norway
AVIX 800 MG Tablets 35		28619031	I.BIR.N-Istituto Bioterapico Nazionale S.r.l.	Italy
Bel Labial		64138	Angelini Farmaceutica, S.A.	Spain
Contra	SE/H/0326/001	17841	Meda Otc Ab	Sweden
Cycloviran		025299049	Sigma-Tau Industrie Farmaceutiche Riunite S.P.A.	Italy
Cycloviran		025299064	Sigma-Tau Industrie Farmaceutiche Riunite S.P.A.	Italy
Cycloviran		025299138 \$ 025299140	Sigma-Tau Industrie Farmaceutiche Riunite S.P.A.	Italy

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Cycloviran		038902019	Sigma-Tau Industrie Farmaceutiche Riunite S.P.A.	Italy
Cycloviran		025299052	Sigma-Tau Industrie Farmaceutiche Riunite S.P.A.	Italy
Cycloviran		025299076	Sigma-Tau Industrie Farmaceutiche Riunite S.P.A.	Italy
Cycloviran		025299126	Sigma-Tau Industrie Farmaceutiche Riunite S.P.A.	Italy
Cycloviran		025299088	Sigma-Tau Industrie Farmaceutiche Riunite S.P.A.	Italy
Efriviral		027534078	Aesculapius Farmaceutici S.R.L.	Italy
Efriviral		027534116	Aesculapius Farmaceutici S.R.L.	Italy
Efriviral		027534128	Aesculapius Farmaceutici S.R.L.	Italy
Efrivirallabiale		038942025	Aesculapius Farmaceutici S.R.L.	Italy

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Galpharm Aciclovir 5%w/w Cream		PL 1602810136	Galpharm Healthcare Limited	United Kingdom
Galpharm Cold Sore 5%w/w Cream		PL 1602810135	Galpharm Healthcare Limited	United Kingdom
Labiriad	SE/H/1123/01/DC	041535016	ONXEO	Italy
Labiriad	SE/H/1123/01/DC	77449	ONXEO	Spain
Sitavig	SE/H/1123/01/DC	21151	ONXEO	Poland
Sitavig	SE/H/1123/01/DC	11-8663	ONXEO	Norway
Sitavig	SE/H/1123/01/DC	30235	ONXEO	Finland
Sitavig	SE/H/1123/01/DC	46953	ONXEO	Sweden
Sitavig	SE/H/1123/01/DC	49660	ONXEO	Denmark

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Sitavig	SE/H/1123/01/DC	PL31030/0004	ONXEO	United Kingdom
Sitavig	SE/H/1123/01/DC	90765.00.00	ONXEO	Germany
Sitavig	SE/H/1123/01/DC	NL43885	ONXEO	France
Tuclor		035005014	A.T.F. Farmaceutici S.r.l.	Italy
Viranti	SE/H/1123/01/DC	5640255	Alvogen Ipco S.Ar.L	Portugal
Viranti	SE/H/1123/01/DC	OGYI-T-22790/01	Alvogen Ipco S.Ar.L	Hungary
Viranti	PT/H/1216/01/DC	HR-H-511720383	Alvogen Ipco S.Ar.L	Croatia
Viranti	PT/H/1216/01/DC	IS/1/15/017/01	Alvogen Ipco S.Ar.L	Iceland
Viranti	PT/H/1216/01/DC	20150035	Alvogen Ipco S.Ar.L	Bulgaria

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Viruderm		56.804	Laboratorios Cinfa, S.A.	Spain
Voraclor		033943010	General Services Spain Italy SI	Italy
Zov		4642088	Laboratorios Wellcome De Portugal Limitada	Portugal
Zov 800		8583948 \$ 8583955	Laboratorios Wellcome De Portugal Limitada	Portugal
Zovir		15191	Glaxosmithkline Pharma A/S	Denmark
Zovir		15192	Glaxosmithkline Pharma A/S	Denmark
Zovir		15193 \$ 15194 \$ 15195	Glaxosmithkline Pharma A/S	Denmark
Zovir		15419	Glaxosmithkline Pharma A/S	Denmark
Zovir		870008	Glaxosmithkline Ehf.	Iceland

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Zovir		870009	Glaxosmithkline Consumer Healthcare A/S	Iceland
Zovir		870252 \$ 930150	Glaxosmithkline Ehf.	Iceland
Zovir		870253	Glaxosmithkline Ehf.	Iceland
Zovir		930297 \$ 930298	Glaxosmithkline Ehf.	Iceland
Zovir 10 G		15415	Glaxosmithkline Pharma A/S	Denmark
Zovirax		025298047	Glaxosmithkline S.P.A.	Italy
Zovirax		025298050	Glaxosmithkline S.P.A.	Italy
Zovirax		025298062	Glaxosmithkline S.P.A.	Italy
Zovirax		025298074	Glaxosmithkline S.P.A.	Italy

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Zovirax		025298086	Glaxosmithkline S.P.A.	Italy
Zovirax		025298124	Glaxosmithkline S.P.A.	Italy
Zovirax		025298136	Glaxosmithkline S.P.A.	Italy
Zovirax		025298148	Glaxosmithkline S.P.A.	Italy
Zovirax		0260/03/06/7406	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Zovirax		0260/03/06/7406	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Zovirax		0260/07/11/9546	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Zovirax		0260/07/11/9547	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Zovirax		0260/07/11/9547	Glaxosmithkline Pharmaceuticals Sa	Luxembourg

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Zovirax		0260/07/11/9547	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Zovirax		091794	Glaxosmithkline Export Ltd	Estonia
Zovirax		092294	Glaxo Wellcome Ltd	Estonia
Zovirax		10130	The Wellcome Foundation Ltd	Finland
Zovirax		10130	The Wellcome Foundation Ltd	Finland
Zovirax		10242	Glaxosmithkline Ab	Sweden
Zovirax		10431	Glaxosmithkline (Cyprus) Limited	Cyprus
Zovirax		10472	The Wellcome Foundation Ltd	Finland
Zovirax		10472 \$ 8983	The Wellcome Foundation Ltd	Finland

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Zovirax		10625	Glaxosmithkline Ab	Sweden
Zovirax		10762	The Wellcome Foundation Ltd	Finland
Zovirax		10762	The Wellcome Foundation Ltd	Finland
Zovirax		11093	Glaxosmithkline Ab	Sweden
Zovirax		11199	Glaxosmithkline Ab	Sweden
Zovirax		11374.00.01	Glaxosmithkline Gmbh & Co. Kg	Germany
Zovirax		11377.00.00	Glaxosmithkline Gmbh & Co. Kg	Germany
Zovirax		188020302	Glaxosmithkline Aebe	Greece
Zovirax		19407	Glaxosmithkline Consumer Healthcare A/S	Sweden

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Zovirax		2009 01 0279	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Zovirax		2009 01 0279	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Zovirax		2009 01 0279	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Zovirax		2009 01 0280	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Zovirax		2009 01 0280	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Zovirax		2250587 \$ 2250686	Laboratorios Wellcome De Portugal Limitada	Portugal
Zovirax		2725.00.01	Glaxosmithkline Gmbh & Co. Kg	Germany
Zovirax		38287/20-5-2014	Glaxosmithkline Aebe	Greece
Zovirax		39882/28-5-13	Glaxosmithkline Aebe	Greece

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Zovirax		39883/28-05-13	Glaxosmithkline Aebe	Greece
Zovirax		39886/28-05-13	Glaxosmithkline Aebe	Greece
Zovirax		42/0190/87-C/S	Glaxosmithkline Slovakia S.R.O.	Slovakia
Zovirax		42/133/86-A/C \$ 42/133/86-B/C \$ 42/133/86-C/C	The Wellcome Foundation Ltd	Czech Republic
Zovirax		4486494 \$ 8624403 \$ 8624411	Glaxosmithkline Consumer Healthcare, Produtos Para A Saúde E Higiene, Lda	Portugal
Zovirax		46/0132/86-C/S	Glaxosmithkline Consumer Healthcare, Glaxosmithkline Export Ltd	Slovakia
Zovirax		46/132/86-C	Glaxosmithkline Consumer Healthcare, Glaxosmithkline Export Ltd	Czech Republic
Zovirax		4641981 \$ 8583906	Laboratorios Wellcome De Portugal Limitada	Portugal
Zovirax		56.663	Stiefel Farma, S.A.	Spain

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Zovirax		56.780	Glaxosmithkline S.A.	Spain
Zovirax		56779 \$ 58286	Stiefel Farma, S.A.	Spain
Zovirax		6257/2006/01	The Wellcome Foundation Ltd	Romania
Zovirax		64/120/84-C	The Wellcome Foundation Ltd	Czech Republic
Zovirax		6819	Glaxosmithkline As	Norway
Zovirax		7212	Glaxosmithkline As	Norway
Zovirax		7385/2006/01-02	The Wellcome Foundation Ltd	Romania
Zovirax		7645	Glaxosmithkline As	Norway
Zovirax		7646	Glaxosmithkline As	Norway

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Zovirax		7894	Glaxosmithkline As	Norway
Zovirax		8539	The Wellcome Foundation Ltd	Finland
Zovirax		8539	The Wellcome Foundation Ltd	Finland
Zovirax		8539	The Wellcome Foundation Ltd	Finland
Zovirax		8539	The Wellcome Foundation Ltd	Finland
Zovirax		8540	The Wellcome Foundation Ltd	Finland
Zovirax		8540	The Wellcome Foundation Ltd	Finland
Zovirax		8583807	Laboratorios Wellcome De Portugal Limitada	Portugal
Zovirax		85935/12/28-5-13	Glaxosmithkline Aebe	Greece

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Zovirax		8870	Glaxosmithkline Oy	Finland
Zovirax		8870	Glaxosmithkline Oy	Finland
Zovirax		89148/12/23-10-13	Glaxosmithkline Aebe	Greece
Zovirax		8983	The Wellcome Foundation Ltd	Finland
Zovirax		9376	Glaxo Group Limited	Cyprus
Zovirax		9463	The Wellcome Foundation Ltd	Finland
Zovirax		9463	The Wellcome Foundation Ltd	Finland
Zovirax		96-0131	Glaxosmithkline Latvia Sia	Latvia
Zovirax		98-5782	Glaxosmithkline As	Norway

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Zovirax		9834	Glaxosmithkline Ab	Sweden
Zovirax		BE119463	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zovirax		BE124442	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zovirax		BE124442	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zovirax		BE127285	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zovirax		BE143744	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zovirax		BE143744	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zovirax		BE143744	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zovirax		BE161533	Glaxosmithkline Pharmaceuticals Sa	Belgium

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Zovirax		BE161533	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zovirax		BE161533	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zovirax		MA 168/01306	The Wellcome Foundation Ltd	Malta
Zovirax		MA 192/01301	Glaxosmithkline (Ireland) Limited	Malta
Zovirax		MA168/01303	The Wellcome Foundation Ltd	Malta
Zovirax		NL12708	Laboratoire Glaxosmithkline	France
Zovirax		NL12936	Laboratoire Glaxosmithkline	France
Zovirax		NL13512	Laboratoire Glaxosmithkline	France
Zovirax		NL13908	Laboratoire Glaxosmithkline	France

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Zovirax		NL15624	Laboratoire Glaxosmithkline	France
Zovirax		NL16475	Laboratoire Glaxosmithkline	France
Zovirax		NL18007	Laboratoire Glaxosmithkline	France
Zovirax		NL18214	Laboratoire Glaxosmithkline	France
Zovirax		OGYI-T-1389/01	Glaxosmithkline Kft.	Hungary
Zovirax		PA 1077/084/3	Glaxosmithkline (Ireland) Limited	Ireland
Zovirax		PA 1077/084/5	Glaxosmithkline (Ireland) Limited	Ireland
Zovirax		PA 1077/084/6	Glaxosmithkline (Ireland) Limited	Ireland
Zovirax		PA 1077/084/7	Glaxosmithkline (Ireland) Limited	Ireland

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Zovirax		PA 1077/084/9	Glaxosmithkline (Ireland) Limited	Ireland
Zovirax		PA 1077/084/1	Glaxosmithkline (Ireland) Limited	Ireland
Zovirax		PA 1077/084/2	Glaxosmithkline (Ireland) Limited	Ireland
Zovirax		PL 00003/0345	The Wellcome Foundation Ltd	United Kingdom
Zovirax		PL 00003/0150	The Wellcome Foundation Ltd	United Kingdom
Zovirax		PL 00003/0202	The Wellcome Foundation Ltd	United Kingdom
Zovirax		R/2838	Glaxosmithkline Export Ltd	Poland
Zovirax		R/3006	Glaxosmithkline Export Ltd	Poland
Zovirax		R/3669	Glaxosmithkline Export Ltd	Poland

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Zovirax		RVG 09248	Glaxosmithkline B.V.	Netherlands
Zovirax		RVG 12162	Glaxosmithkline B.V.	Netherlands
Zovirax		S00474	The Wellcome Foundation Ltd	Cyprus
Zovirax		UP/I-530-09/11-02/140	Glaxosmithkline D.O.O.	Croatia
Zovirax		2725.00.03	Glaxosmithkline Gmbh & Co. Kg	Germany
Zovirax		0260/07/11/9546	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Zovirax		0260/07/11/9546	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Zovirax		2009 01 0280	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Zovirax		0260/03/06/7406	Glaxosmithkline Pharmaceuticals Sa	Luxembourg

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Zovirax		BE119463	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zovirax		BE119463	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zovirax		BE127285	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zovirax		BE127285	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zovirax		BE124442	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zovirax I.V.		0260/03/08/7541	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Zovirax I.V.		BE123751	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zovirax I.V.		BE123751	Glaxosmithkline Pharmaceuticals Sa	Belgium
Zovirax I.V.		BE123751	Glaxosmithkline Pharmaceuticals Sa	Belgium

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Zovirax 125 mg		RVG 09696	Glaxosmithkline B.V.	Netherlands
Zovirax 250 mg		RVG 09696	Glaxosmithkline B.V.	Netherlands
Zovirax 500 mg		RVG 09696	Glaxosmithkline B.V.	Netherlands
Zovirax Ajakherpesz		OGYI-T-7693/01	Glaxosmithkline Consumer Healthcare, Glaxosmithkline Export Ltd	Hungary
Zovirax Cold Sore		PA 678/90/2	Glaxosmithkline Consumer Healthcare (Ireland) Ltd	Ireland
Zovirax Cold Sore		PL 00079/0634	Beecham Group Plc	United Kingdom
Zovirax Double Strength		00003/0264	The Wellcome Foundation Ltd	United Kingdom
Zovirax Forte		59226	Stiefel Farma, S.A.	Spain
Zovirax I.V.		0260/03/08/7541	Glaxosmithkline Pharmaceuticals Sa	Luxembourg

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Zovirax I.V.		0260/03/08/7541	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Zovirax I.V.		091894	Glaxo Wellcome Ltd	Estonia
Zovirax I.V.		97-0346	Glaxosmithkline Latvia Sia	Latvia
Zovirax I.V. 250mg		PL 00003/0159	The Wellcome Foundation Ltd	United Kingdom
Zovirax I.V. 500 mg		PL 00003/0159	The Wellcome Foundation Ltd	United Kingdom
Zovirax Intensive		R/2141	Glaxosmithkline Consumer Healthcare Sp. Z O.O.	Poland
Zovirax Intravenoso		56.634	Stiefel Farma, S.A.	Spain
Zovirax Koortslip		RVG 19078	Glaxosmithkline Consumer Healthcare B.V	Netherlands
Zovirax Labialis		BE179243	Glaxosmithkline Consumer Healthcare S.A/N.V.	Belgium

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Zovirax Labialis		1994100844	Glaxosmithkline Consumer Healthcare S.A/N.V.	Luxembourg
Zovirax Labialis		1994100844	Glaxosmithkline Consumer Healthcare S.A/N.V.	Luxembourg
Zovirax Labialis		BE166196 \$ BE179243	Glaxosmithkline Consumer Healthcare S.A/N.V.	Belgium
Zovirax Labialis		BE166196 \$ BE179243	Glaxosmithkline Consumer Healthcare S.A/N.V.	Belgium
Zovirax Labialis		BE166196 \$ BE179243	Glaxosmithkline Consumer Healthcare S.A/N.V.	Belgium
Zovirax Lippenherpes		28084.00.00	Glaxosmithkline Consumer Healthcare Gmbh & Co. Kg	Germany
зовиракс		20020050	Glaxosmithkline Consumer Healthcare, Glaxosmithkline Export Ltd	Bulgaria
зовиракс		20020069	Glaxosmithkline Eood	Bulgaria
зовиракс		20020083	Glaxosmithkline Eood	Bulgaria