



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

9 June 2016  
EMA/423705/2016  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance: clindamycin

Procedure no.: PSUSA/00000795/201510



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
Dalacin		1-20589	Pfizer Corporation Austria Gesellschaft M.B.H.	Austria
Dalacin C		1-16138	Pfizer Corporation Austria Gesellschaft M.B.H.	Austria
Dalacin C		1-16190	Pfizer Corporation Austria Gesellschaft M.B.H.	Austria
Clindamycin Kabi	DE/H/0963/001	14645	Fresenius Kabi Polska Sp. Z O.O.	Poland
Clindamycin Kabi	DE/H/0963/001	64477/8-10-2008	Fresenius Kabi Hellas A.E.	Greece
Clindamycin Mip	DE/H/0346/003	42725.02.01	Mip Pharma Gmbh	Germany
Clindamycin Mip	DE/H/0346/003 \$ DE/H/346/003	17683	Mip Pharma Gmbh	Finland
Clindamycin Ratiopharm		42727.00.01	Ratiopharm Gmbh	Germany
Clindamycin Ratiopharm		45321.01.00	Ratiopharm Gmbh	Germany

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Clindamycine Fresenius Kabi	DE/H/0963/001	BE345125 \$ BE345134 \$ BE345143	Fresenius Kabi Nv/Sa	Belgium
Clindamycine Fresenius Kabi	DE/H/0963/001	RVG 101396	Fresenius Kabi Nederland B.V.	Netherlands
Clindamycine Teva		RVG 108315	Teva Nederland B.V.	Netherlands
Clindasol		48537.00.00	Cnp Pharma Gmbh	Germany
Clinwas		60361 \$ 60362	Chiesi España, S.A.	Spain
Dalacin C		1-18937	Pfizer Corporation Austria Gesellschaft M.B.H.	Austria
Dalacin C Phosphat		1-16059 \$ 1-16060 \$ 1-16061	Pfizer Corporation Austria Gesellschaft M.B.H.	Austria
Dalacin C		BE061765 \$ BE091122	Pfizer S.A. (Belgium)	Belgium
Dalacin C		BE061862	Pfizer S.A. (Belgium)	Belgium

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Dalacin C		BE092206 \$ BE092215 \$ BE092224	Pfizer S.A. (Belgium)	Belgium
Dalacin Topical		BE124257	Pfizer S.A. (Belgium)	Belgium
Dalacin Topical		BE173144	Pfizer S.A. (Belgium)	Belgium
Dalacin Vaginal		BE165584	Pfizer S.A. (Belgium)	Belgium
далацин		20040015	Pfizer Enterprises Sarl	Bulgaria
далацин C		20030573	Pfizer Enterprises Sarl	Bulgaria
далацин C		20030574	Pfizer Enterprises Sarl	Bulgaria
далацин C		20030575	Pfizer Enterprises Sarl	Bulgaria
далацин C		9600032	Pfizer Enterprises Sarl	Bulgaria

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далацин Т		20040152	Pfizer Enterprises Sarl	Bulgaria
Dalacin C		UP/I-530-09/12-02/514	Pfizer Croatia D.O.O.	Croatia
Dalacin C		UP/I-530-09/12-02/516	Pfizer Croatia D.O.O.	Croatia
Dalacin Vaginální krém		54/360/93-C	Pfizer, Spol. S R.O.	Czech Republic
Dalacin C		15/111/74-C	Pfizer, Spol. S R.O.	Czech Republic
Dalacin C		15/166/72-A/C \$ 15/166/72-B/C	Pfizer, Spol. S R.O.	Czech Republic
Dalacin T Kožní roztok		15/131/91-C	Pfizer, Spol. S R.O.	Czech Republic
Dalacin		05900 \$ 14545	Pfizer Aps	Denmark
Dalacin		06418	Pfizer Aps	Denmark

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Dalacin		11032	Pfizer Aps	Denmark
Dalacin		13322	Pfizer Aps	Denmark
Dalacin		15541	Pfizer Aps	Denmark
Dalacin		239198	Pfizer Enterprises Sarl	Estonia
Dalacin		352101	Pfizer Enterprises Sarl	Estonia
Dalacin C		047094 \$ 047194	Pfizer Enterprises Sarl	Estonia
Dalacin C		047294	Pfizer Enterprises Sarl	Estonia
Dalacin T		239298	Pfizer Enterprises Sarl	Estonia
Dalacin		10224	Pfizer Oy	Finland

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Dalacin		11433	Pfizer Oy	Finland
Dalacin		11508	Pfizer Oy	Finland
Dalacin		11591 \$ 9647	Pfizer Oy	Finland
Dalacin		6822	Pfizer Oy	Finland
Dalacin		6963	Pfizer Oy	Finland
Dalacin	IE/H/0119/001	31699	Pfizer Oy	Finland
Sobelin	IE/H/0119/001	90615.00.00	Pfizer Pharma Gmbh	Germany
Dalacin C		21159/2.05.03	Pfizer Hellas, A.E.	Greece
Dalacin C		21160/2.5.03	Pfizer Hellas, A.E.	Greece

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Dalacin C		21161/2.5.03	Pfizer Hellas, A.E.	Greece
Dalacin C		22890/9.05.03	Pfizer Hellas, A.E.	Greece
Dalacin C		22894/9.5.03	Pfizer Hellas, A.E.	Greece
Dalacin-C		21162/2.5.2003	Pfizer Hellas, A.E.	Greece
Dalacin		OGYI-T- 958/04 \$ OGYI-T- 958/05	Pfizer Kft.	Hungary
Dalacin		OGYI-T-958/01 \$ OGYI-T-958/02	Pfizer Kft.	Hungary
Dalacin		OGYI-T-958/03	Pfizer Kft.	Hungary
Dalacin		OGYI-T-958/07 \$ OGYI-T-958/08	Pfizer Kft.	Hungary
Dalacin		OGYI-T-958/09	Pfizer Kft.	Hungary



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
Dalacin		OGYI-T-958/10	Pfizer Kft.	Hungary
Dalacin		691234 (IS) \$ 940126 (IS)	Pfizer Aps	Iceland
Dalacin		741748 (IS)	Pfizer Aps	Iceland
Dalacin		822986 (IS)	Pfizer Aps	Iceland
Dalacin		930251 (IS)	Pfizer Aps	Iceland
Dalacin		940045 (IS)	Pfizer Aps	Iceland
Dalacin		PA 822/119/2	Pfizer Healthcare Ireland	Ireland
Dalacin	IE/H/0119/001	PA 0822/119/1	Pfizer Healthcare Ireland	Ireland
Dalacin C		PA 0822/120/1	Pfizer Healthcare Ireland	Ireland

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Dalacin C Phosphate		PA 822/120/3	Pfizer Healthcare Ireland	Ireland
Dalacin C Phosphate 2 MI		PA 822/120/2	Pfizer Healthcare Ireland	Ireland
Dalacin T Topical		PA 822/121/1	Pfizer Healthcare Ireland	Ireland
Dalacin T Topical		PA 0822/121/2	Pfizer Healthcare Ireland	Ireland
Cleocin		028535019 - 028535021	Pfizer Italia S.R.L.	Italy
Cleocin	IE/H/0119/001	028535033	Pfizer Italia S.R.L.	Italy
Dalacin C		022633059	Pfizer Italia S.R.L.	Italy
Dalacin C Fosfato		023868019	Pfizer Italia S.R.L.	Italy
Dalacin C Fosfato		023868021	Pfizer Italia 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
Dalacin T		025314016	Pfizer Italia S.R.L.	Italy
Dalacin T		025314030	Pfizer Italia S.R.L.	Italy
Dalacin T		025314042	Pfizer Italia S.R.L.	Italy
Dalacin		03-0034	Pfizer Europe Ma Eeig	Latvia
Dalacin		98-0608	Pfizer Europe Ma Eeig	Latvia
Dalacin C		98-0397 \$ 98-0398	Pfizer Europe Ma Eeig	Latvia
Dalacin C		98-0609 \$ 98-0610	Pfizer Europe Ma Eeig	Latvia
Dalacin T		03-0466	Pfizer Europe Ma Eeig	Latvia
Dalacin C		LT/1/94/2047/001 \$ LT/1/94/2047/002	Pfizer Europe Ma Eeig	Lithuania

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Dalacin C		2009030220	Pfizer S.A. (Belgium)	Luxembourg
Dalacin C		2009030221	Pfizer S.A. (Belgium)	Luxembourg
Dalacin C		2009030222	Pfizer S.A. (Belgium)	Luxembourg
Dalacin C		2009030223 \$ 2009030224 \$ 2009030225	Pfizer S.A. (Belgium)	Luxembourg
Dalacin Topical		2007069332	Pfizer S.A. (Belgium)	Luxembourg
Dalacin Topical		2007069333	Pfizer S.A. (Belgium)	Luxembourg
Dalacin Vaginal		2009030226	Pfizer S.A. (Belgium)	Luxembourg
Dalacin C		MA505/01903	Pfizer Hellas, A.E.	Malta
Dalacin C Phosphate		MA505/01902	Pfizer Hellas, A.E.	Malta

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Dalacin T Topical		MA505/01901	Pfizer Hellas, A.E.	Malta
Dalacin C		RVG 05871	Pfizer B.V.	Netherlands
Dalacin C		RVG 06354	Pfizer B.V.	Netherlands
Dalacin C		RVG 06903	Pfizer B.V.	Netherlands
Dalacin C		RVG 14457	Pfizer B.V.	Netherlands
Dalacin-T		RVG 09728	Pfizer B.V.	Netherlands
Dalacin		5695 \$ 5696 \$ 7362	Pfizer As	Norway
Dalacin		5970	Pfizer As	Norway
Dalacin		6111	Pfizer As	Norway

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Dalacin		7213	Pfizer As	Norway
Dalacin		7953	Pfizer As	Norway
Dalacin		8078	Pfizer As	Norway
Dalacin		99-3557	Pfizer As	Norway
Dalacin		R/7131	Pfizer Europe Ma Eeig	Poland
Dalacin C		R/0711	Pfizer Europe Ma Eeig	Poland
Dalacin C		R/0712	Pfizer Europe Ma Eeig	Poland
Dalacin C		R/0713	Pfizer Europe Ma Eeig	Poland
Dalacin C		R/3064	Pfizer Europe Ma Eeig	Poland

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Dalacin C		R/3450	Pfizer Europe Ma Eeig	Poland
Dalacin T		7491	Pfizer Europe Ma Eeig	Poland
Dalacin T		R/1464	Pfizer Europe Ma Eeig	Poland
Dalacin T		R/2910	Pfizer Europe Ma Eeig	Poland
Dalacin C		8234/2006/01	Pfizer Europe Ma Eeig	Romania
Dalacin C		8235/2006/01	Pfizer Europe Ma Eeig	Romania
Dalacin C		15/0166/72-C/S	Pfizer Europe Ma Eeig	Slovakia
Dalacin C		15/0716/92-C/S	Pfizer Europe Ma Eeig	Slovakia
Dalacin T		15/0131/91-C/S	Pfizer Europe Ma Eeig	Slovakia

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
Dalacin T		15/0411/92-C/S	Pfizer Europe Ma Eeig	Slovakia
Dalacin V		15/0653/94-S	Pfizer Europe Ma Eeig	Slovakia
Dalacin		5363-I-716/11	Pfizer Luxembourg Sarl	Slovenia
Dalacin		H/13/00439/001 \$ H/13/00439/002	Pfizer Luxembourg Sarl	Slovenia
Dalacin		49.152	Pfizer, S.L.	Spain
Dalacin		58.782	Pfizer, S.L.	Spain
Dalacin		58.783	Pfizer, S.L.	Spain
Dalacin		60.034	Pfizer, S.L.	Spain
Dalacin	IE/H/0119/001	62.911	Pfizer, S.L.	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
Dalacín Tópico		56.769	Pfizer, S.L.	Spain
Dalacin		10525 \$ 8968 \$ 8969	Pfizer Ab	Sweden
Dalacin		10676	Pfizer Ab	Sweden
Dalacin		11472	Pfizer Ab	Sweden
Dalacin		11773	Pfizer Ab	Sweden
Dalacin		9178	Pfizer Ab	Sweden
Dalacin		9235	Pfizer Ab	Sweden
Dalacin	IE/H/0119/001	15429	Pfizer Ab	Sweden
Sobelin Vaginalcreme		28680.00.00	Pharmacia 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
Sobelin		6888.00.00 \$ 6888.01.00 \$ 6888.02.00	Pharmacia Gmbh	Germany
Sobelin Granulat		6888.00.01	Pharmacia Gmbh	Germany
Sobelin Solubile		6892.00.00 \$ 6892.01.00	Pharmacia Gmbh	Germany
Zindaclin		PL 20074/0002	Crawford Healthcare Ltd	United Kingdom
Zindaclin	UK/H/0503/001	11239	Crawford Healthcare Ltd	Poland
Zindaclin	UK/H/0503/001	54182.00.00	Infectopharm Arzneimittel und Consilium GmbH	Germany
Zindaclin	UK/H/503/01	1353/03/04/0018	Crawford Healthcare Ltd	Luxembourg
Zindaclin	UK/H/503/01	362 549-1; 361 569-9; 362 551-6	Crawford Healthcare Ltd	France
Zindaclin	UK/H/503/01	5363-1-1642/13 \$ 5363-1-1643/13 \$ 5363-1-1644/13	Crawford Healthcare Ltd	Slovenia

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
Zindaclin	UK/H/503/01	OGYI-T-9981/01	Crawford Healthcare Ltd	Hungary
Dalacin		PL 00057/0960	Pfizer Limited	United Kingdom
Dalacin C		PL 00057/0957 \$ PL 00057/0958	Pfizer Limited	United Kingdom
Dalacin C Phosphate		PL 00057/0959	Pfizer Limited	United Kingdom
Dalacin T		PL 00057/0961	Pfizer Limited	United Kingdom
Dalacin T		PL 00057/0962	Pfizer Limited	United Kingdom
клиндамицин абр антибиотик-разград		20140095	Antibiotic-Razgrad Ad	Bulgaria
клиндамицин каби	DE/H/0963/001	20080098	Fresenius Kabi Bulgaria Eood	Bulgaria
Dalacin C		2/39/70	Laboratórios Pfizer, Lda.	Portugal

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
Dalacine		VNL 8276	Pfizer Holding France (S.C.A.)	France
Dalacin		OGYI-T-958/06	Pfizer Kft.	Hungary
Dalacin C		S00085	Pfizer Hellas, A.E.	Cyprus
Dalacin C		S00058	Pfizer Hellas, A.E.	Cyprus
Dalacin C		S00044	Pfizer Hellas, A.E.	Cyprus
Dalacin C		S00045	Pfizer Hellas, A.E.	Cyprus
Dalacine		NL 20649	Pfizer Holding France (S.C.A.)	France
Dalacine		VNL 8277	Pfizer Holding France (S.C.A.)	France
Dalacine T Topic		NL 12810	Pfizer Holding France (S.C.A.)	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
Dalacine		VNL 11 248	Pfizer Holding France (S.C.A.)	France
Dalacine		VNL 11 247	Pfizer Holding France (S.C.A.)	France
Sobelin Solubile		6892.00.01	Pfizer Pharma Gmbh	Germany
Dalacin C		S00046	Pfizer Hellas, A.E.	Cyprus
Dalacin T		6/08/83	Laboratórios Pfizer, Lda.	Portugal
Dalacin V		6/53/92	Laboratórios Pfizer, Lda.	Portugal
Dalacine		VNL 11 249	Pfizer Holding France (S.C.A.)	France
Zindaclin	UK/H/503/01	OGYI-T-9981/01-02	Crawford Healthcare Ltd	Hungary
Zindaclin	UK/H/503/01	OGYI-T-9981/01-03	Crawford Healthcare Ltd	Hungary

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Zindaclin	UK/H/0503/001	5573 IE 1 F7	Crawford Healthcare Ltd	Belgium
Zindaclin	UK/H/0503/001	PA 731/3/1	Crawford Healthcare Ltd	Ireland
Zindaclin	UK/H/0503/001	66610	Industrial Farmaceutica Cantabria, S.A.	Spain
Zindaclin	UK/H/0503/001	650808-4	Industrial Farmaceutica Cantabria, S.A.	Spain
Zindaclin	UK/H/0503/001	650809-1	Industrial Farmaceutica Cantabria, S.A.	Spain
Zindaclin	UK/H/0503/001	650810-7	Industrial Farmaceutica Cantabria, S.A.	Spain
Zindaclin	UK/H/0503/001	036862011/M	Difa Cooper SPA	Italy
Zindaclin	UK/H/0503/001	036862023/M	Difa Cooper SPA	Italy
Zindaclin	UK/H/0503/001	036862035/M	Difa Cooper SPA	Italy

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Zindaclin	UK/H/0503/001	4345989	Crawford Healthcare Ltd	Portugal
Zindaclin	UK/H/0503/001	4164687	Crawford Healthcare Ltd	Portugal
Zindaclin	UK/H/0503/001	19487	Crawford Healthcare Ltd	Cyprus
Clindamycin Aristo	AT/H/0267/001-002	90469.00.00	Aristo Pharma GmbH	Germany
Clindamycin Aristo	AT/H/0267/001-002	90470.00.00	Aristo Pharma GmbH	Germany
Clindamycin Kabi	DE/H/0963/001	15/301/08-C	Fresenius Kabi s.r.o.	Czech Republic