



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 May 2016
EMA/346564/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: levofloxacin

Procedure no.: PSUSA/00001854/201510



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
Levoxacin		033940014 \$ 033940026 \$ 033940038 \$ 033940040 \$ 033940053	Glaxosmithkline S.P.A.	Italy
Levoxacin		033940065	Glaxosmithkline S.P.A.	Italy
Oftaquix		10825	Santen Oy	Poland
Oftaquix	MRP UK/H/0464/002	IS/1/07/020/01	Santen Oy	Iceland
Oftaquix	MRP UK/H/464/001	53538.00.00	Santen Oy	Germany
Oftaquix	MRP UK/H/464/001	IS/1/02/003/01	Santen Oy	Iceland
Oftaquix	UK/H/0464/001	035728017	Santen Oy	Italy
Oftaquix	UK/H/0464/001	05-0196	Santen Oy	Latvia
Oftaquix	UK/H/0464/001	1-24655	Santen Oy	Austria
Oftaquix	UK/H/0464/001	1345/02/05/0011	Santen Oy	Luxembourg

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Oftaquix	UK/H/0464/001	16992	Santen Oy	Finland
Oftaquix	UK/H/0464/001	17994	Santen Oy	Sweden
Oftaquix	UK/H/0464/001	33160	Santen Oy	Denmark
Oftaquix	UK/H/0464/001	4041786	Santen Oy	Portugal
Oftaquix	UK/H/0464/001	4609/2012/01	Santen Oy	Romania
Oftaquix	UK/H/0464/001	472305	Santen Oy	Estonia
Oftaquix	UK/H/0464/001	64/0 180/05/-S	Santen Oy	Slovakia
Oftaquix	UK/H/0464/001	64/175/05-C	Santen Oy	Czech Republic
Oftaquix	UK/H/0464/001	OGYI-T-10257/01	Santen Oy	Hungary

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Oftaquix	UK/H/0464/001	PL 16058/0006	Santen Oy	United Kingdom
Oftaquix	UK/H/0464/002	035728029 \$ 035728031 \$ 035728043 \$ 035728056	Santen Oy	Italy
Oftaquix	UK/H/0464/002	23157	Santen Oy	Finland
Oftaquix	UK/H/0464/002	25042	Santen Oy	Sweden
Oftaquix	UK/H/0464/002	40612	Santen Oy	Denmark
Oftaquix	UK/H/464/001	LT/1/05/0325/001	Santen Oy	Lithuania
Oftaquix Sine		17128	Santen Oy	Poland
Oftaquix Sine	UK/H/0464/002	67435.00.00	Santen Oy	Germany
Oftaquix Unit Dose	UK/H/0464/002	PL 16058/0007	Santen Oy	United Kingdom

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
Prixar		033633013 \$ 033633025	Sanofi-Aventis Spa	Italy
Prixar		033633037 \$ 033633049 \$ 033633052	Sanofi-Aventis Spa	Italy
Prixar		033633064	Sanofi-Aventis Spa	Italy
Tavanic	UK/H/0203/002	19283	Sanofi-Aventis Cyprus Ltd	Cyprus
Tavanic		942/2008/01 \$ 942/2008/02 \$ 942/2008/03 \$ 942/2008/04 \$ 943/2008/01 \$ 943/2008/02 \$ 943/2008/03	Terapia S.A.	Romania
Tavanic	UK/H/0203/001	2008/06/9838	Sanofi Belgium	Luxembourg
Tavanic	UK/H/0203/001	033634015 \$ 033634027	Sanofi Spa	Italy
Tavanic	UK/H/0203/001	12946	Sanofi Oy	Finland
Tavanic	UK/H/0203/001	14135	Sanofi Ab	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
Tavanic	UK/H/0203/001	2627982 \$ 2628089 \$ 2628188 \$ 2628386 \$ 3088085 \$ 3088184 \$ 3484680	Sanofi - Produtos Farmaceuticos Lda	Portugal
Tavanic	UK/H/0203/001	41382.00.00	Sanofi-Aventis Deutschland Gmbh	Germany
Tavanic	UK/H/0203/001	424203	Sanofi-Aventis Estonia Oü	Estonia
Tavanic	UK/H/0203/001	BE192866	Sanofi Belgium	Belgium
Tavanic	UK/H/0203/001	LT R 02/7796/6	Uab Sanofi-Aventis Lietuva	Lithuania
Tavanic	UK/H/0203/001	PL 04425/0673	Aventis Pharma Ltd	United Kingdom
Tavanic	UK/H/0203/001	RVG 21811	Sanofi-Aventis Netherlands B.V.	Netherlands
Tavanic	UK/H/0203/001 \$ UK/H/0203/002	1-22319 \$ 1-22320	Sanofi-Aventis Gmbh Österreich	Austria
Tavanic	UK/H/0203/001	19284	Sanofi-Aventis Cyprus Ltd	Cyprus

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Tavanic	UK/H/0203/001 \$ UK/H/0203/002	34009 348 995 8 4 \$ 34009 349 652 7 2 \$ 34009 349 653 3 3 \$ 34009 349 655 6 2 \$ 34009 561 902 3 2	Sanofi-Aventis France	France
Tavanic	UK/H/0203/001 \$ UK/H/0203/002	424103 \$ 424203	Sanofi-Aventis Estonia Oü	Estonia
Tavanic	UK/H/0203/001 \$ UK/H/0203/002	5363-I-1973/11 \$ 5363-I-1974/11 \$ 5363-I-1975/11	Sanofi-Aventis D.O.O.	Slovenia
Tavanic	UK/H/0203/001 \$ UK/H/0203/002	6159/17-02-99 \$ 6160/17-02-99	Sanofi-Aventis Aebe	Greece
Tavanic	UK/H/0203/001 \$ UK/H/0203/002	OGYI-T-6837/03 \$ OGYI-T-6837/04 \$ OGYI-T-6837/05 \$ OGYI-T-6837/06 \$ OGYI-T-6837/07 \$ OGYI-T-6837/14	Sanofi-Aventis Zrt	Hungary
Tavanic	UK/H/0203/001 \$ UK/H/0203/002	PA 540/77/2 \$ PA 540/77/3	Sanofi-Aventis Ireland Ltd	Ireland
Tavanic	UK/H/0203/002	2008/06/9839	Sanofi Belgium	Luxembourg
Tavanic	UK/H/0203/002	033634039 \$ 033634041 \$ 033634054	Sanofi Spa	Italy
Tavanic	UK/H/0203/002	12947	Sanofi Oy	Finland

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Tavanic	UK/H/0203/002	14136	Sanofi Ab	Sweden
Tavanic	UK/H/0203/002	2628485 \$ 2628584 \$ 2628683 \$ 2628881 \$ 3088283 \$ 3088382 \$ 3088481	Sanofi - Produtos Farmaceuticos Lda	Portugal
Tavanic	UK/H/0203/002	34009 348 996 4 5 \$ 34009 349 656 2 3 \$ 34009 561 904 6 1 \$ 34009 574 907 9 9	Sanofi-Aventis France	France
Tavanic	UK/H/0203/002	41382.01.00	Sanofi-Aventis Deutschland Gmbh	Germany
Tavanic	UK/H/0203/002	42/0161/99-S	Sanofi-Aventis Slovakia Sro	Slovakia
Tavanic	UK/H/0203/002	62.065	Sanofi-Aventis, S.A.	Spain
Tavanic	UK/H/0203/002	BE192884	Sanofi Belgium	Belgium
Tavanic	UK/H/0203/002	LT R 02/7797/6	Uab Sanofi-Aventis Lietuva	Lithuania
Tavanic	UK/H/0203/002	MA082/03502	Sanofi Malta Ltd	Malta

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Tavanic	UK/H/0203/002	PL 04425/0674	Aventis Pharma Ltd	United Kingdom
Tavanic	UK/H/0203/002	RVG 21812	Sanofi-Aventis Netherlands B.V.	Netherlands
Tavanic	UK/H/0203/003	2008/06/9840	Sanofi Belgium	Luxembourg
Tavanic	UK/H/0203/003	033634066 \$ 033634080	Sanofi-Aventis Spa	Italy
Tavanic	UK/H/0203/003	033634078	Sanofi-Aventis Spa	Italy
Tavanic	UK/H/0203/003	1-22321	Sanofi-Aventis Gmbh Österreich	Austria
Tavanic	UK/H/0203/003	12948	Sanofi Oy	Finland
Tavanic	UK/H/0203/003	14134	Sanofi Ab	Sweden
Tavanic	UK/H/0203/003	19282	Sanofi-Aventis Cyprus Ltd	Cyprus

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Tavanic	UK/H/0203/003	20020444	Sanofi-Aventis Bulgaria Eood	Bulgaria
Tavanic	UK/H/0203/003	2628980 \$ 2978682 \$ 3088580 \$ 3088689 \$ 3088788	Sanofi - Produtos Farmaceuticos Lda	Portugal
Tavanic	UK/H/0203/003	34009 561 898 6 1 \$ 34009 561 900 0 3 \$ 34009561 901 7 1	Sanofi-Aventis France	France
Tavanic	UK/H/0203/003	34009 561 899 2 2	Sanofi-Aventis France	France
Tavanic	UK/H/0203/003	41384.00.00	Sanofi-Aventis Deutschland Gmbh	Germany
Tavanic	UK/H/0203/003	42/176/01-C	Sanofi-Aventis Sro	Czech Republic
Tavanic	UK/H/0203/003	424003	Sanofi-Aventis Estonia Oü	Estonia
Tavanic	UK/H/0203/003	5363-I-1976/11	Sanofi-Aventis D.O.O.	Slovenia
Tavanic	UK/H/0203/003	6161/17-02-99	Sanofi-Aventis Aebe	Greece

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Tavanic	UK/H/0203/003	62.066	Sanofi-Aventis, S.A.	Spain
Tavanic	UK/H/0203/003	8766	Sanofi-Aventis Deutschland Gmbh	Poland
Tavanic	UK/H/0203/003	BE192875 \$ BE230237	Sanofi Belgium	Belgium
Tavanic	UK/H/0203/003	LT R 02/7798/5 \$ LT R 02/7799/5	Uab Sanofi-Aventis Lietuva	Lithuania
Tavanic	UK/H/0203/003	MA082/03503	Sanofi Malta Ltd	Malta
Tavanic	UK/H/0203/003	OGYI-T-6837/01	Sanofi-Aventis Zrt	Hungary
Tavanic	UK/H/0203/003	PA 540/077/001	Sanofi-Aventis Ireland Ltd	Ireland
Tavanic	UK/H/0203/003	PL 04425/0675	Aventis Pharma Ltd	United Kingdom
Tavanic I.V.		1016/2008/01 \$ 1017/2008/01	Terapia S.A.	Romania

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Tavanic I.V.	UK/H/0203/003	42/0162/99-S	Sanofi-Aventis Slovakia Sro	Slovakia
Tavanic Iv	UK/H/0203/003	RVG 21810	Sanofi-Aventis Netherlands B.V.	Netherlands
офтакуикс		20040266	Santen Oy	Bulgaria
таваник	UK/H/0203/002	20020443	Sanofi-Aventis Bulgaria Eood	Bulgaria
Levofloxacin Mylan 250 mg	UK/H/5634/001	02207-01 021706	Mylan S.A.S.	Cyprus
Levofloxacin Mylan 250 mg/50 ml, solution for infusion	UK/H/5634/001	MA767/00201	Mylan S.A.S.	Malta
Levofloxacin 250 mg/50 ml, solution for infusion	UK/H/5634/001	PL 04569/1010	Generics [UK] Limited t/a Mylan	United Kingdom