



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 May 2018
EMA/326462/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: modafinil

Procedure no.: PSUSA/00010242/201708



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
Modafinil "Orion", tabletter	DK/H/2465/001	55010	ORION CORPORATION	DK
Modafinil "Orion", tabletter	DK/H/2465/002	55011	ORION CORPORATION	DK
Modafinil 100 mg Tablets	not available	PL 30684/0220	DAWA LIMITED	UK
Modafinil 200 mg Tablets	not available	PL 04569/1367	GENERICS [UK] LIMITED	UK
Modafinil 200 mg Tablets	not available	PL 30684/0221	DAWA LIMITED	UK
Modafinil Orion 200 mg tabletter	DK/H/2465/002	52047	ORION CORPORATION	SE
Modafinil Orion 200 mg tabletti	DK/H/2465/002	32819	ORION CORPORATION	FI
Modafinil Orion 200 mg tabletti	DK/H/2465/002	32819	ORION CORPORATION	FI
Modasomil 100 mgTabletten	DE/H/3259/001	1-22670	TEVA PHARMA B.V.	AT
MODIODAL 100 mg comprimidos	DE/H/3259/001	61.540	TEVA PHARMA B.V.	ES

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
Modiodal 100 mg comprimidos	DE/H/3259/001	2547081	TEVA PHARMA B.V.	PT
Modiodal 100 mg comprimidos	DE/H/3259/001	2547289	TEVA PHARMA B.V.	PT
Modiodal 100 mg comprimidos	DE/H/3259/001	2727980	TEVA PHARMA B.V.	PT
Modiodal 100 mg comprimidos	DE/H/3259/001	2547180	TEVA PHARMA B.V.	PT
Modiodal 100 mg tabletten	DE/H/3259/001	RVG 18535	TEVA PHARMA B.V.	NL
MODIODAL 100 mg tabletter	DE/H/3259/001	98-4558	TEVA PHARMA B.V.	NO
Modiodal 100 mg tabletter	DE/H/3259/001	14191	TEVA PHARMA B.V.	SE
Modiodal 100 mg töflur	DE/H/3259/001	980360 (IS)	TEVA PHARMA B.V.	IS
MODIODAL 100 mg, comprimé	DE/H/3259/001	NL15713	TEVA PHARMA B.V.	FR

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Modiodal δισκία 100 mg	DE/H/3259/001	18944	TEVA B.V	CY
Modiodal δισκία 100 mg	DE/H/3259/001	85087/16.12.2014	TEVA B.V	GR
Modiodal, tabletter	DE/H/3259/001	17007	TEVA PHARMA B.V.	DK
Provigil 100 mg compresse	DE/H/3259/001	034369013/M	TEVA ITALIA S.R.L.	IT
Provigil 100 mg comprimés	DE/H/3259/001	BE184746	TEVA PHARMA B.V.	BE
Provigil 100 mg comprimés	not available	0264723	TEVA PHARMA B.V.	LU
Provigil 100 mg comprimés	not available	0264737	TEVA PHARMA B.V.	LU
Provigil 100 mg comprimés	not available	0264741	TEVA PHARMA B.V.	LU
Provigil 100 mg comprimés	not available	0264723	TEVA PHARMA B.V.	LU

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Provigil 100 mg comprimés	DE/H/3259/001	1997070463	TEVA PHARMA B.V.	LU
Provigil 100 mg tablets	DE/H/3259/001	PA 749/198/1	TEVA PHARMA B.V.	IE
PROVIGIL 100 mg tablets	DE/H/3259/001	PL 14776/0098	TEVA PHARMA B.V.	UK
Provigil 100 mg tabletten	DE/H/3259/001	BE184746	TEVA PHARMA B.V.	BE
Provigil 100 mg Tabletten	DE/H/3259/001	BE184746	TEVA PHARMA B.V.	BE
Provigil 200 mg tablets	DE/H/3259/002	PA 749/198/2	TEVA PHARMA B.V.	IE
PROVIGIL 200 mg tablets	DE/H/3259/002	PL 14776/0099	TEVA PHARMA B.V.	UK
Vigil 100 mg tablet	DE/H/3259/001	06/208/99-C	TEVA PHARMACEUTICALS CR, S.R.O.	CZ
Vigil 100 mg Tabletten	DE/H/3259/001	34134.00.00	TEVA GMBH	DE

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Vigil 200 mg Tabletten	DE/H/3259/002	77082.00.00	TEVA GMBH	DE