



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 April 2024
EMA/160525/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): modafinil

Procedure No. PSUSA/00010242/202308



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/2465/002	55011	ORION CORPORATION	DK
Modafinil 100 mg Tablets	not available	PL 30684/0220	DAWA LIMITED	XI
Modafinil 100 mg Tablets	not available	PL 20416/0377	CRESCENT PHARMA LIMITED	XI
Modafinil 100mg tablets	not available	PL 20117/0206	MORNINGSIDE HEALTHCARE LTD	XI
Modafinil 200 mg Tablets	not available	PL 30684/0221	DAWA LIMITED	XI
Modafinil 200mg Tablets	not available	PL 20416/0378	CRESCENT PHARMA LIMITED	XI
Modafinil Orion 200 mg tabletter	DK/H/2465/002	32819	ORION CORPORATION	FI
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
Modasomil 100 mg Tabletten	DE/H/3259/001	1-22670	TEVA B.V	AT
MODIODAL 100 mg comprimidos	DE/H/3259/001	61540	TEVA PHARMA B.V.	ES
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 B.V	NL
MODIODAL 100 mg tabletter	DE/H/3259/001	98-4558	TEVA PHARMA B.V.	NO
Modiodal 100 mg töflur	DE/H/3259/001	980360	TEVA PHARMA B.V.	IS
MODIODAL 100 mg δισκία	DE/H/3259/001	18944	TEVA B.V	CY
MODIODAL 100 mg, comprimé	DE/H/3259/001	NL15713	TEVA PHARMA B.V.	FR

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 δισκία 100 mg	DE/H/3259/001	62346/16/10-12-2018	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	TEVA ITALIA S.R.L.	IT
Provigil 100 mg comprimés	DE/H/3259/001	BE184746	TEVA PHARMA B.V.	BE
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.	XI
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
Vigil 100 mg Tabletten	DE/H/3259/001	34134.00.00	TEVA GMBH	DE
Vigil 100 mg tablety	DE/H/3259/001	06/208/99-C	TEVA B.V	CZ
Vigil 200 mg Tabletten	DE/H/3259/002	77082.00.00	TEVA GMBH	DE