



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 September 2020
EMA/476734/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: tizanidine

Procedure no.: PSUSA/00002977/201912



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
Sirdalud 2 mg - Tabletten	not available	1-18197	NOVARTIS PHARMA GMBH	AT
SIRDALUD 2 mg compresse	not available	025852068	NOVARTIS FARMA S.P.A.	IT
Sirdalud 2 mg comprimido	not available	58.313	LAUS FARMA S.L.	ES
Sirdalud 2 mg comprimidos	not available	2055184	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Sirdalud 2 mg comprimidos	not available	2055283	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Sirdalud 2 mg tablet	not available	9259	NOVARTIS FINLAND OY	FI
Sirdalud 2 mg tablete	not available	H/92/01428/001	NOVARTIS PHARMA GMBH	SI
Sirdalud 2 mg tabletes	not available	93-0438	SIA "NOVARTIS BALTICS"	LV
Sirdalud 2 mg tabletės	not available	LT/1/94/0947/001	SIA "NOVARTIS BALTICS"	LT

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
Sirdalud 2 mg tabletti	not available	9259	NOVARTIS FINLAND OY	FI
SIRDALUD 2 mg tablety	not available	63/209/88-A/C	NOVARTIS S.R.O.,	CZ
Sirdalud 2 mg tablety	not available	63/0209/88-CS	NOVARTIS SLOVAKIA S.R.O.	SK
Sirdalud 4 mg - Tabletten	not available	1-18196	NOVARTIS PHARMA GMBH	AT
SIRDALUD 4 mg compresse	not available	025852029	NOVARTIS FARMA S.P.A.	IT
Sirdalud 4 mg comprimés	not available	BE400793	NOVARTIS PHARMA N.V.	BE
Sirdalud 4 mg comprimés	not available	1986110393	NOVARTIS PHARMA N.V.	LU
Sirdalud 4 mg comprimido	not available	58.314	LAUS FARMA S.L.	ES
Sirdalud 4 mg tablete	not available	H/92/01428/002	NOVARTIS PHARMA GMBH	SI

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
Sirdalud 4 mg tabletēs	not available	00-0449	SIA "NOVARTIS BALTICS"	LV
Sirdalud 4 mg tabletēs	not available	LT/1/94/0947/002	SIA "NOVARTIS BALTICS"	LT
Sirdalud 4 mg tableta	not available	OGYI-T-5903/04	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Sirdalud 4 mg Tabletten	not available	BE400793	NOVARTIS PHARMA N.V.	BE
Sirdalud 4 mg tabletten	not available	BE400793	NOVARTIS PHARMA N.V.	BE
Sirdalud 4 mg Tabletten	not available	1986110393	NOVARTIS PHARMA N.V.	LU
Sirdalud 4 mg tabletti	not available	9260	NOVARTIS FINLAND OY	FI
Sirdalud 4 mg tabletti	not available	9260	NOVARTIS FINLAND OY	FI
SIRDALUD 4 mg tablety	not available	63/209/88-B/C	NOVARTIS S.R.O.,	CZ

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
Sirdalud 4 mg tablety	not available	63/0209/88-CS	NOVARTIS SLOVAKIA S.R.O.	SK
SIRDALUD 6 mg compresse	not available	025852031	NOVARTIS FARMA S.P.A.	IT
Sirdalud MR 6 mg - Kapseln	not available	1-19584	NOVARTIS PHARMA GMBH	AT
Sirdalud MR 6 mg cápsulas de libertação modificada	not available	2055580	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Sirdalud MR 6 mg retard kapszula	not available	OGYI-T-5903/05	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Sirdalud MR 6 mg retard kapszula	not available	OGYI-T-5903/06	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Sirdalud MR 6 mg retard kapszula	not available	OGYI-T-5903/01	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Sirdalud MR 6 mg retard kapszula	not available	OGYI-T-5903/02	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Sirdalud MR 6 mg, capsules met gereguleerde afgifte	not available	RVG 12983	NOVARTIS PHARMA B.V.	NL

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
Sirdalud MR, 6 mg, kapsułki o zmodyfikowanym uwalnianiu, twarde	not available	R/6714	NOVARTIS POLAND SP. Z O. O.	PL
Sirdalud Retard 6 mg depotkapsel, hård	not available	10604	NOVARTIS FINLAND OY	FI
Sirdalud Retard 6 mg depotkapseli	not available	10604	NOVARTIS FINLAND OY	FI
Sirdalud Retard, depotkapsler, hårde	not available	13234	NOVARTIS HEALTHCARE A/S	DK
Sirdalud, 2 mg tabletid	not available	217698	SIA "NOVARTIS BALTICS"	EE
Sirdalud, 4 mg tabletid	not available	217798	SIA "NOVARTIS BALTICS"	EE
Sirdalud, 4 mg, tabletki	not available	R/6713	NOVARTIS POLAND SP. Z O. O.	PL
Sirdalud®	not available	193130101	NOVARTIS (HELLAS) S.A.C.I.	GR
Sirdalud®	not available	193130201	NOVARTIS (HELLAS) S.A.C.I.	GR

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
Sirdalud® 2 mg Tabletten	not available	4844.00.00	NOVARTIS PHARMA GMBH	DE
SIRDALUD® 2 MG, TABLETTEN	not available	RVG 10036	NOVARTIS PHARMA B.V.	NL
Sirdalud® 4 mg Tabletten	not available	4844.01.00	NOVARTIS PHARMA GMBH	DE
SIRDALUD® 4 MG, TABLETTEN	not available	RVG 10037	NOVARTIS PHARMA B.V.	NL
Sirdalud® 6 mg Tabletten	not available	4844.02.00	NOVARTIS PHARMA GMBH	DE