



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 October 2019
EMA/552278/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: trandolapril

Procedure no.: PSUSA/00003004/201902

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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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
Gopten 0,5 mg	not available	58/0122/95-S	MYLAN IRE HEALTHCARE LIMITED	SK
Gopten 0,5 mg cápsulas	not available	2181188	BGP PRODUCTS UNIPessoal, LDA.	PT
Gopten 0,5 mg cápsulas	not available	4543088	BGP PRODUCTS UNIPessoal, LDA.	PT
Gopten 0,5 mg cápsulas	not available	2181287	BGP PRODUCTS UNIPessoal, LDA.	PT
GOPTEN 0,5 mg cápsulas duras	not available	59984	MYLAN IRE HEALTHCARE LIMITED	ES
Gopten 0,5 mg capsule	not available	11131/2018/04	MYLAN HEALTHCARE GMBH	RO
Gopten 0,5 mg capsule	not available	11131/2018/01	MYLAN HEALTHCARE GMBH	RO
Gopten 0,5 mg capsule	not available	11131/2018/02	MYLAN HEALTHCARE GMBH	RO
Gopten 0,5 mg capsule	not available	11131/2018/03	MYLAN HEALTHCARE GMBH	RO

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
GOPTEN 0,5 mg capsule rigide	not available	028267021	MYLAN ITALIA S.R.L.	IT
GOPTEN 0,5 mg capsule rigide	not available	028267045	MYLAN ITALIA S.R.L.	IT
Gopten 0,5 mg kapsule	not available	HR-H-387014960	MYLAN HRVATSKA D.O.O.	HR
Gopten 0,5 mg trde kapsule	not available	H/95/00713/001	MYLAN IRE HEALTHCARE LIMITED	SI
Gopten 0,5 mg Tvrde tobolky	not available	58/067/95-A/C	MYLAN IRE HEALTHCARE LIMITED	CZ
Gopten 0,5, 0,5 mg, kapsułki twarde	not available	R/3585	MYLAN HEALTHCARE SP. Z.O.O.	PL
Gopten 2 mg	not available	58/0301/18-S	MYLAN IRE HEALTHCARE LIMITED	SK
Gopten 2 mg cápsulas	not available	4543187	BGP PRODUCTS UNIPESOAL, LDA.	PT
Gopten 2 mg cápsulas	not available	5800487	BGP PRODUCTS UNIPESOAL, LDA.	PT

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
Gopten 2 mg cápsulas	not available	2181485	BGP PRODUCTS UNIPESOAL, LDA.	PT
GOPTEN 2 mg cápsulas duras	not available	59985	MYLAN IRE HEALTHCARE LIMITED	ES
Gopten 2 mg capsule	not available	11132/2018/01	MYLAN HEALTHCARE GMBH	RO
Gopten 2 mg capsule	not available	11132/2018/02	MYLAN HEALTHCARE GMBH	RO
GOPTEN 2 mg capsule rigide	not available	028267019	MYLAN ITALIA S.R.L.	IT
GOPTEN 2 mg capsule rigide	not available	028267033	MYLAN ITALIA S.R.L.	IT
Gopten 2 mg cietās kapsulas	not available	97-0390	BGP PRODUCTS SIA	LV
Gopten 2 mg kapsule	not available	HR-H-960018093	MYLAN HRVATSKA D.O.O.	HR
Gopten 2 mg kemény kapszula	not available	OGYI-T-9301/02	MYLAN EPD KFT.	HU

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
Gopten 2 mg kietosios kapsulės	not available	LT/1/94/0356/002	BGP PRODUCTS SIA	LT
Gopten 2 mg kietosios kapsulės	not available	LT/1/94/0356/003	BGP PRODUCTS SIA	LT
Gopten 2 mg trde kapsule	not available	H/95/00713/002	MYLAN IRE HEALTHCARE LIMITED	SI
Gopten 2 mg Tvrde tobolky	not available	58/067/95-B/C	MYLAN IRE HEALTHCARE LIMITED	CZ
Gopten 2,0, 2 mg, kapsułki twarde	not available	R/3584	MYLAN HEALTHCARE SP. Z.O.O.	PL
Gopten 4 mg	not available	58/0244/04-S	MYLAN IRE HEALTHCARE LIMITED	SK
Gopten 4 mg capsule	not available	11133/2018/01	MYLAN HEALTHCARE GMBH	RO
Gopten 4 mg capsule	not available	11133/2018/02	MYLAN HEALTHCARE GMBH	RO
Gopten 4 mg cietās kapsulas	not available	08-0198	BGP PRODUCTS SIA	LV

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
Gopten 4 mg kapsule	not available	HR-H-201573480	MYLAN HRVATSKA D.O.O.	HR
Gopten 4 mg kemény kapszula	not available	OGYI-T-9301/03	MYLAN EPD KFT.	HU
Gopten 4 mg kietosios kapsulės	not available	LT/1/94/0356/005	BGP PRODUCTS SIA	LT
Gopten 4 mg kietosios kapsulės	not available	LT/1/94/0356/006	BGP PRODUCTS SIA	LT
Gopten 4 mg kietosios kapsulės	not available	LT/1/94/0356/004	BGP PRODUCTS SIA	LT
Gopten 4 mg trde kapsule	not available	H/95/00713/003	MYLAN IRE HEALTHCARE LIMITED	SI
Gopten 4 mg trde kapsule	not available	H/95/00713/004	MYLAN IRE HEALTHCARE LIMITED	SI
Gopten 4 mg Tvrde tobolky	not available	58/001/05-C	MYLAN IRE HEALTHCARE LIMITED	CZ
Gopten 4,0, 4 mg, kapsulki twarde	not available	17127	MYLAN HEALTHCARE SP. Z.O.O.	PL

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
Gopten Mite kemény kapszula	not available	OGYI-T-9301/01	MYLAN EPD KFT.	HU
Gopten, 2 mg kövakapszlid	not available	121195	BGP PRODUCTS SIA	EE
Gopten, 4 mg kövakapszlid	not available	655509	BGP PRODUCTS SIA	EE
Odrik 0,5 mg cápsula	not available	4600680	LABORATÓRIOS VITÓRIA, SA	PT
Odrik 0,5 mg cápsula	not available	2176089	LABORATÓRIOS VITÓRIA, SA	PT
Odrik 0,5 mg cápsula	not available	2175982	LABORATÓRIOS VITÓRIA, SA	PT
ODRIK 0,5 mg, gélule	not available	34009 334 731 3 6	MYLAN MEDICAL SAS	FR
ODRIK 0,5 mg, gélule	not available	34009 337 611 9 6	MYLAN MEDICAL SAS	FR
ODRIK 0,5 mg, gélule	not available	34009 371 462 2 7	MYLAN MEDICAL SAS	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
ODRIK 0,5 mg, gélule	not available	34009 371 463 9 5	MYLAN MEDICAL SAS	FR
Odrik 0.5 mg Hard Capsules	not available	PA 2010/5/1	MYLAN IRE HEALTHCARE LIMITED	IE
Odrik 1 mg Hard Capsules	not available	PA 2010/5/2	MYLAN IRE HEALTHCARE LIMITED	IE
Odrik 2 mg cápsula	not available	4600789	LABORATÓRIOS VITÓRIA, SA	PT
Odrik 2 mg cápsula	not available	2176287	LABORATÓRIOS VITÓRIA, SA	PT
Odrik 2 mg cápsula	not available	2176188	LABORATÓRIOS VITÓRIA, SA	PT
Odrik 2 mg Hard Capsules	not available	PA 2010/5/3	MYLAN IRE HEALTHCARE LIMITED	IE
ODRIK 2 mg, gélule	not available	34009 334 733 6 5	MYLAN MEDICAL SAS	FR
ODRIK 2 mg, gélule	not available	34009 337 610 2 8	MYLAN MEDICAL SAS	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
ODRIK 2 mg, gélule	not available	34009 371 525 4 9	MYLAN MEDICAL SAS	FR
ODRIK 2 mg, gélule	not available	34009 371 526 0 0	MYLAN MEDICAL SAS	FR
ODRIK 4 mg, gélule	not available	34009 364 412 3 1	MYLAN MEDICAL SAS	FR
ODRIK 4 mg, gélule	not available	34009 371 372 3 2	MYLAN MEDICAL SAS	FR
ODRIK 4 mg, gélule	not available	34009 371 374 6 1	MYLAN MEDICAL SAS	FR
ODRIK 4 mg, gélule	not available	34009 371 375 2 2	MYLAN MEDICAL SAS	FR
Odrik, hårde kapsler	not available	14939	BGP PRODUCTS AB	DK
Odrik, hårde kapsler	not available	14938	BGP PRODUCTS AB	DK
Tomalon 4 mg trde kapsule	DK/H/1501/004	H/09/01538/009	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	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
Tomalon 4 mg trde kapsule	DK/H/1501/004	H/09/01538/010	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	SI
Tomalon 4 mg trde kapsule	DK/H/1501/004	H/09/01538/011	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	SI
Tomalon 4 mg trde kapsule	DK/H/1501/004	H/09/01538/012	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	SI
Trandolapril "Mylan", hårde kapsler	DK/H/1113/004	40562	MYLAN AB	DK
Trandolapril "Mylan", hårde kapsler	DK/H/1113/002	40560	MYLAN AB	DK
Trandolapril "Teva", hårde kapsler	DK/H/1114/002	40464	TEVA B.V	DK
Trandolapril "Teva", hårde kapsler	DK/H/1114/004	40466	ACTAVIS GROUP PTC EHF.	DK
Trandolapril 1 mg capsules, hard	DK/H/1113/002	PL 04569/0818	GENERICS [UK] LIMITED	UK
Trandolapril 4 mg capsules, hard	DK/H/1113/004	PL 04569/0820	GENERICS [UK] LIMITED	UK

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
Trandolapril Mylan 4 mg tvrdé kapsuly	DK/H/1113/004	58/0003/08-S	MYLAN IRELAND LIMITED	SK
TRANDOLAPRIL MYLAN 4 mg, gélule	DK/H/1113/004	NL 33748	MYLAN S.A.S	FR
Udrik 0,5 mg Hartkapseln	not available	38442.00.00	MYLAN HEALTHCARE GMBH	DE
Udrik 1 mg Hartkapseln	not available	38442.02.00	MYLAN HEALTHCARE GMBH	DE
Udrik 2 mg Hartkapseln	not available	38442.01.00	MYLAN HEALTHCARE GMBH	DE
Udrik 2 mg, Hartkapseln	not available	2010040732	MYLAN HEALTHCARE GMBH	LU
Гоптен 0,5 mg твърди капсули	not available	9600166	MYLAN HEALTHCARE GMBH	BG
Гоптен 2 mg твърди капсули	not available	9600167	MYLAN HEALTHCARE GMBH	BG
Гоптен 4 mg твърди капсули	not available	20060731	MYLAN EOOD	BG