

DOMOSSEDAN GEL 7,6MG/ML 1X3ML

Gysz: 1991273

Kisz: 1X3ML

SZÉKELY KFT részére

Lej: 2022-12-31

Me: Doboz

Szállító:

Medimpex Gy. Zrt.

1158 Budapest

Rákospalotaihatárút2

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CERTIFICATE OF ANALYSIS

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DOMOSSEDAN GEL 7.6 MG/ML VET 1X3ML PL HU

Product Number: 129659
Batch Number: 1991273
Order Number: 61035576

Date of Manufacture: 28.01.2020
Date of Expiration: 12.2022
Storage: +15..25 °C
Specification: Hungary (125875) 20.06.2016

TESTS	METHOD	REQUIREMENTS	RESULTS	QALTY CTRL SITE
State	114487-2	even, translucent gel	even, translucent gel	Turku
Colour	114487-2	blue	blue	Turku
Air bubbles	114487-2	essentially free	essentially free	Turku
Uniformity of dosage units	114439-3	conforms to Ph.Eur.	conforms to Ph.Eur.	Turku
Uniform. of dos. units, accept. val.	114439-3	nmt 15,0	0,5	Turku
pH	114489-1	5,0 - 6,2	6,1	Turku
Viscosity	114488-2	6000 cP - 17000 cP	14100 cP	Turku
Identification, delonidine, HPLC	114439-3	positive	positive	Turku
Ident., delonidine, UV	114439-3	positive	positive	Turku
Ident., blue colour	114447-2	positive	positive	Turku
Ident., blue colour	114439-3	nmt 0,5 %	0,1 %	Turku
Related substances, individual	114439-3	nmt 1,0 %	0,1 %	Turku
Related substances, total	114439-3	nmt 1,0 %	0,1 %	Turku
Assay, delonidine HCl	114439-3	95,0 % - 105,0 %	101,6 %	Turku

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and with the requirements of the Marketing Authorisation(s) of the destination country/countries.

Electronically approved 23.03.2020 15:51:46 by a Qualified Person Essi Mainberg

Orion Corporation
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Fax +358 10 426 3815
Manufacturing license number: FINELA2019/069732
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Orion Corporation Registered office and domicile: Oriontie 1, FI-02200 Espoo, Finland

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DOMOSEDAN GEL 7.6 MG/ML VET 1X3ML PL HU

BATCH CERTIFICATE

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Product Number: 128658
Batch Number: 1991273
Order Number: 81035576

Date of Manufacture: 28.01.2020
Date of Expiration: 12.2022

Quantity: 140 PCE
Strength/Potency: 7.6 mg/ml
Dosage form: Oromucosal gel
Package size: 3 ml
Package type: Pre-filled syringe

Marketing authorization number: 25184/109/MGSZH #TI
1907/09

Manufacturing site: Orion Corporation, Turku plant

Quality control site: Tengsätörinkatu 8 20360 TURKU

GMP Compliance of Manufact. site: 004580/06.08.02.00/2017

Quality control site: Orion Corporation, Turku plant

GMP Compliance of Quality Ctrl site: 004580/06.08.02.00/2017

Packaging site: Orion Corporation, Turku plant

GMP Compliance of Packaging site: 004580/06.08.02.00/2017

Orion Corporation	Manufacturing license number: FIN/EA/2019/000732	
ORION PHARMA Oriontie 1, 02300 ESPOO P.O.Box 65, 02101 ESPOO Tel: +358 10 426 111 Fax: +358 10 426 3833	Tengsätörinkatu 8, 20360 TURKU P.O.Box 425, 20101 TURKU Tel: +358 10 426 92 Fax: +358 10 426 7777	Vahinkatu 8, 70700 KUOPIO P.O.Box 1780, 70701 KUOPIO Tel: +358 10 426 611 Fax: +358 10 426 6444
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Gysz: 1991273

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SZÉKELY KFT részére

Lej: 2022-12-31

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BATCH CERTIFICATE

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DOMOSSEDAN GEL 7.6 MG/ML VET 1X3ML PL HU

Product Number: 128659
Batch Number: 1991273
Order Number: 81035576

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Electronically approved 23.03.2020 15:51:46 by a Qualified Person Essi Malmberg

Orion Corporation
Manufacturing license number FIN/EA/2019/000732

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