

DEXDOMITOR 0,5MG/ML INJEKCIÓS OLD. 10ML
 Gysz:1792307 Lej:20/04/30
 Kisz:10ML Me.:Doboz
 SZÉKELY KFT részére

Medimpex Gy. Zrt.
 1158 Budapest
 Rákospalotaihatárút2
 Tel:+36-1-414-6477
 Fax:+36-1-414-6479

Dexdomitor 0,5mg/ml injekciós oldat
 Gysz:1792307 Lej:20/04/30
 Kisz:10ml Me.:darab
 MEDIMPEX GYÓGYSZER ZRT. részére

2151 Főth
 Keleti Márton u. 19.
 Tel:27/537-100
 Fax:27/537-100



CERTIFICATE OF ANALYSIS

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DEXDOMITOR 0,5MG/ML VET INJ1X10ML BQHURO

Product Number: 134010
 Batch Number: 1792307
 Order Number: 80823177
 Date of Manufacture: 11.05.2017
 Date of Expiration: 04.2020
 Storage: Room Temp: +15...25°C
 Specification: Hungary (100859) 03.05.2017

TESTS	METHOD	REQUIREMENTS	RESULTS	QALTY CTRL SITE
Clarity of solution	100182-2	clear	clear	Esppo
Colour of solution	100182-2	colourless	colourless	Esppo
Partic. matter, presence of visible partic.	100178-2	Practically no particles	Practically no particles	Esppo
Volume in container	100179-2	10,0 ml - 11,0 ml	10,6 ml	Esppo
pH	100177-2	4,0 - 6,0	5,0	Esppo
Ident., dexametomidine, HPLC	100173-2	positive	positive	Esppo
Ident., dexametomidine, UV	100175-3	positive	positive	Esppo
Assay, dexametomidine HCl, %	100175-3	95,0 % - 105,0 %	100,7 %	Esppo
Ident., methyl parahydroxybenzoate, HPLC	100175-3	positive	positive	Esppo
Ident., methyl parahydroxybenzoate, UV	100175-3	positive	positive	Esppo
Assay, methyl parahydroxybenzoate %	100175-3	95 % - 105 %	100 %	Esppo
Ident., propyl parahydroxybenzoate, HPLC	100175-3	positive	positive	Esppo
Ident., propyl parahydroxybenzoate, UV	100175-3	positive	positive	Esppo
Assay, propyl parahydroxybenzoate %	100173-2	95 % - 105 %	<0,5 %	Esppo
Optical purity, levonemetomidine	100173-2	nmt 1,0 %	13	Esppo
Partic. matter, 10 µm or larger in cont.	113289-2	nmt 6000	3	Esppo
Partic. matter, 25 µm or larger in cont.	113289-2	nmt 600	3	Esppo
Test for sterility	113205-1	sterile	sterile	Esppo
Bacterial endotoxins	100590-2	nmt 10 EU/ml	nmt 10 EU/ml	Esppo

Orion Corporation
 Orion Farma
 Oskalanen 1, 02300 ESPOO
 P.O.Box 65, 02101 ESPOO
 Tel: +358 10 426 1
 Fax: +358 10 426 9415
 Manufacturing license number: 00207106,00200002013

Tengelyvár utca 8, 20300 TÜRKKÜ
 P.O.Box 433 3010 TÜRKKÜ
 Tel: +358 10 323 991
 Fax: +358 10 323 9777

Vahczai 8, 70700 KUDORÓ
 P.O.Box 1280 70701 KUDORÓ
 Tel: +358 10 423 811
 Fax: +358 10 423 8444

Juvonmieskanen 7, 31100 SAUVO
 Tel: +358 10 424 141

Medimpex Gy. Zrt.
 1158 Budapest
 Rákospalotaihatárút2
 Tel: +36-1-414-6477
 Fax: +36-1-414-6479

MEDIMPEX GYÓGYSZER ZRT.
 1158 Bp., Rákospalotai határút 2.
 Nagyné Kán Éva
 Minőségbiztosító szakasszisztens
 Csak a piros szín hiteles

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CERTIFICATE OF ANALYSIS

Page: 2(3)

DEXDOMITOR 0,5MG/ML VET INJ1X10ML BQHUR0

Product Number: 134010
 Batch Number: 1792307
 Order Number: 80823177

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
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The batch has been manufactured, including packaging and quality control, in accordance with the requirements of the Marketing Authorisation and in compliance with current Good Manufacturing Practices. The batch complies with the agreed specification and has been released for dispatch, sale and marketing by a Qualified Person.

Electronically approved 30.08.2017 14:28:38 by a Qualified Person Johanna Helman

Orion Corporation
 Orion Pharma
 Orionintie 1, 02100 Espoo
 P.O. Box 65, 02101 Espoo
 Tel: +358 10 4281
 Fax: +358 10 428 5015

Tampere
 Tuusulankatu 1, 33100 Tuusula
 P.O. Box 52, 33200 Tuusula
 Tel: +358 10 428 7717
 Fax: +358 10 428 6444

Finland
 Orionintie 1, 02100 Espoo, Finland

Moscow
 Moskovskiy Prospekt, number 02037100, 125080, Moscow
 Tel: +7 495 780 2070
 Fax: +7 495 780 2070

Madrid
 Avenida de la Industria 1, 28050 Alcorcón
 P.O. Box 1780, 28070 Alcorcón
 Tel: +358 10 428 6411
 Fax: +358 10 428 6444

Barcelona
 Avda. de la Indústria 1, 28050 Alcorcón
 P.O. Box 1780, 28070 Alcorcón
 Tel: +358 10 428 6411
 Fax: +358 10 428 6444

Medimpex Gy. Zrt.
 1158 Budapest
 Rákospalotai határút 2.
 Nagyné Kári Éva
 Minőségbiztosító szakasszisztens

MEDIMPEX GYÓGYSZER ZRT.
 1158 Bp., Rákospalotai határút 2.
 Nagyné Kári Éva
 Minőségbiztosító szakasszisztens
 Csak a piros szín hiteles

DEXDOMITOR 0,5MG/ML INJEKCIÓS OLD. 10ML
Gysz:1792307 Lej:20/04/30
Kisz:10ML Me.:Doboz
SZÉKELY KFT részére

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1158 Budapest
Rákospalotaihatárút2
Tel:+36-1-414-6477
Fax:+36-1-414-6479



BATCH CERTIFICATE

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DEXDOMITOR 0,5MG/ML VET INJ1X10ML BQHURO

Product Number: 134010
Batch Number: 1792307
Order Number: 80823177
Date of Manufacture: 11.05.2017
Date of Expiration: 04.2020
Quantity: 1890 PCE
Marketing authorization number: EU/2/02/033/001
Manufacturing site: Orion Corporation, Espoo plant
Orionite 1 FI-02200 ESPCO
GMP Compliance of Manufact. site: 005703/08.08.02.00/2015
Quality control site: Orion Corporation, Espoo plant
Orionite 1 FI-02200 ESPCO
GMP Compliance of Quality Ctrl site: 005703/08.08.02.00/2015
Packaging site: Orion Corporation, Espoo plant
Orionite 1 FI-02200 ESPCO
GMP Compliance of Packaging site: 005703/08.08.02.00/2015

The batch has been manufactured, including packaging and quality control, in accordance with the requirements of the Marketing Authorisation and in compliance with current Good Manufacturing Practices. The batch complies with the agreed specification and has been released for dispatch, sale and marketing by a Qualified Person.

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Orion Corporation	Manufacturing license number: 0057106/08.02.00/2015
ORION PHARMA Orionite 1, 02200 ESPCO P.O.Box 65, 02101 ESPOO Tel: +358 10 4261 Fax: +358 10 426 3815	Tekijälleluoto 1, 20100 TURKU P.O.Box 423, 20101 TURKU Tel: +358 10 4262 Fax: +358 10 426 777
Orion Corporation, Reproductive and Genetic Orionite 1, FI-02200 Espoo Finland	Vähämaa 1, 07000 KUOPIO P.O.Box 1798, 07001 KUOPIO Tel: +358 10 428 911 Fax: +358 10 428 0444
	Järvenpää 7, 24100 SAVO Tel: +358 10 4261

Meoszám:171100579/07/T 1.pld. Kiadva: 19/03/29

Meoszám:190400066MBT 2.pld. Kiadva: 20/01/20

Min. biz. ...
2017.01.20. ...
Min. biz. ...
Gyógyszerészeti ...

MEDIMPEX GYÓGYSZER ZRT.
1158 Bp., Rákospalotai határút 2.
Nagyé Kálmán Min. biz.:
Minőségbiztosító szakasszisztens
Csak a piros szín hiteles