

Domosedan injekció AUV  
 Gysz:1695334 Lej:17/12/31  
 Kisz:5ml Me.:darab  
 TOLNAGRO KFT. részére

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



CERTIFICATE OF ANALYSIS

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**DOMOSÉDAN 100MG/ML VET INJ 5ML HUEN**

Product Number: 133976  
 Batch Number: 1808394  
 Order Number: 80686866

Date of Manufacture: 30.12.2014  
 Date of Expiration: 12.2017  
 Storage: Room temp: +15...25°C  
 Specification: Hungary/108880/22.10.2008

TESTS	METHOD	REQUIREMENTS	RESULTS	QUALITY CTRL STATE
Volume in cool	100477-2	5,00 ml - 5,75 ml	5,30 ml	Esposo
Clarity of solution	100489-2	clear	clear	Esposo
Colour of solution	100494-2	colourless	colourless	Esposo
Particulates, pres. of foreign matter.	100473-2	practically no particles	practically no particles	Esposo
pH	100432-2	4,0 - 6,5	4,3	Esposo
Ident., deionidone HCl, HPLC	100542-1	positive	positive	Esposo
Assay, deionidone HCl	100542-4	9,5 mg/ml - 10,5 mg/ml	10,3 mg/ml	Esposo
Ident., methyl paralydroxybenzoate, HPLC	100542-4	positive	positive	Esposo
Assay methyl paralydroxybenzoate	100542-4	0,3 mg/ml - 1,1 mg/ml	1,0 mg/ml	Esposo
Releated substances	100542-4	nm 1 %	nm 1 %	Esposo
Test for sterility	113205-1	sterile	sterile	Esposo
Bacterial endotoxins	100570-2	nm 25 EU/ml	nm 25 EU/ml	Esposo

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 27.01.2016 15:45:55 by a Qualified Person Kálmán Salonen

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Manufacturing license number: 0027106 05 0004/2015

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PHOENIX Pharma Zrt.  
 Föti Telephely  
 2151 Föt, Keleti Márton út 19.  
 20-03



BATCH CERTIFICATE

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**DONOSEBAN 10MG/ML VET INJ BML HUEN**

Product Number: 133875  
Batch Number: 1695334  
Order Number: 80989998

Date of Manufacture: 30.12.2014  
Date of Expiration: 12.2017

Quantity: 600 PCE

Marketing authorization number:

UPA-322-09/13-01/556  
140013, NFM/2008/001, 1464  
2079/008, LT/202/1418/01  
VMR/P02/1451  
0022-1819-04-01-2013, 323-01-00026-14-004

Manufacturing site:

Orion Corporation, Espoo plant  
Oskariitie 3 FI-02200 ESPOO

GMP Compliance of Manufact. site:

122/12.01.01/2014

Quality control site:

Orion Corporation, Espoo plant  
PO Box 65 FI-02301 ESPOO

GMP Compliance of Quality Ctrl site:

122/12.01.01/2014

Packaging site:

Orion Corporation, Espoo plant  
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GMP Compliance of Packaging site:

122/12.01.01/2014

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Manufacturing license number: 00201/06-03-004/2013

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Csak a piros színű hitelesít  
20-03



BATCH CERTIFICATE

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DOMOSSEDAN 10MG/ML VET INJ SML HUEN  
Product Number 133375  
Batch Number 1093334  
Order Number 80688898

This 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 27.01.2016 15:45:55 by a Qualified Person Kent Salonen

Order Description

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