



BATCH CERTIFICATE

Page: 2/4

ANTISEDAN SMGM, VET INJ 10ML HUEN

Product Number: 133981
Batch Number: 1088922
Order Number: 00884748

Date of Manufacture: 02.09.2015
Date of Expiration: 09.2018

Quantity: 450 PCE

Marketing authorization numbers:

NPV/0019001
LPI/1322-05/13-01/836
VNR/R/02/462, 3298/113, 1452
L/7202/14/7/091, 349014
0022-192-04, 01.2013, 323-01-00026-14-001

Manufacturing site:

Orion Corporation, Espoo plant
Oskenitie 3, FI-02200 ESPOO
12212.01.01/2014

Quality control site:

Orion Corporation, Espoo plant
P.O. Box 65 FI-02101 ESPOO
12212.01.01/2014

Packaging site:

Orion Corporation, Espoo plant
Oskenitie 3, FI-02200 ESPOO
12212.01.01/2014

GMP Compliance of Packaging site:

Orion Corporation Manufacturing license number: 002119619 (09.04.2011)

ORION TILAAJAA
Suomen 1, 02200 ESPOO
P.O. Box 65, 02101 ESPOO
Tel. +358 10 428 111
Fax +358 10 428 113

Responsible person: Jarmo Tuomi
P.O. Box 65, 02101 ESPOO
Tel. +358 10 428 111
Fax +358 10 428 113

Valtuutus: Jarmo Tuomi
P.O. Box 65, 02101 ESPOO
Tel. +358 10 428 111
Fax +358 10 428 113

Ilmoitusluvu: 7, 2100 54/0
Tel. +358 10 428 111

Orion Corporation Registered office and domicile: Oskenitie 1, FI-02200 Espoo, Finland

Handwritten signature and stamp at the bottom right of the page.



BATCH CERTIFICATE

Page: 4(4)

ANTISEDAN 8MIGMIL VET INJ 10ML HUEN

Product Number: 133391
Batch Number: 1698827
Order Number: 80984748

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 17.12.2018 09:25:58 by a Qualified Person Kati Salonen

<p>Orion Corporation Oulun Erityiskoti Lemminkäinenkatu 1 P.O. Box 57, 00101 Espoo Tel. +358 10 4281 Fax +358 10 42828413</p>	<p>Manufacturer (License number 002871/06/08 OR-D/2003) Teollisuuslaitos, Oulu Lemminkäinenkatu 7 P.O. Box 423, 90101 Oulu Tel. +358 10 4281 Fax +358 10 4287777</p>	<p>Valmistaja (Lisensinumeri) P.O. Box 423, 90101 Oulu Tel. +358 10 4281 Fax +358 10 4287777</p>	<p>Orion Corporation Registration Office and Domestic Operations - Finland Lemminkäinenkatu 7, 00101 Espoo, Finland Tel. +358 10 4281</p>
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Min. biz. sz. 16/05/04
 Min. biz. sz. 16/05/04
 Min. biz. sz. 16/05/04
 Min. biz. sz. 16/05/04

Antisedan 5mg/ml oldatos injekció
 Gysz:1688827 Lej:18/09/30
 Kisz:10ml Me.:darab
 DR. SZÉKELY KFT. részére

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



CERTIFICATE OF ANALYSIS

Page: 1/4

ANTISEDAN 5MG/ML VET INJ 10ML HUEN
 Product Number: 133981
 Batch Number: 1688827
 Order Number: 80884749

Date of Manufacture: 02.09.2015
 Date of Expiration: 09.2016
 Storage: Room temp. +15...25°C
 Specifications: Hungary(1688827) 04.04.2013

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
Colour of solution	100494-2	colourless	colourless	Expoo
Average volume in container	100229-2	ml 10.0 ml	10.5 ml	Expoo
Volume in cont.	100229-2	10.0 ml - 11.0 ml	10.5 ml	Expoo
Particulate, presence of visible partic	100473-2	practically no particles	practically no particles	Expoo
Clarity of solution	100493-2	clear	clear	Expoo
pH	100432-2	4.0 - 6.0	4.4	Expoo
Ident., alphanazole HCl, HPLC	100643-3	positive	positive	Expoo
Ident., methylparathionhydrobenzoate, HPLC	100643-3	positive	positive	Expoo
Assay, alphanazole HCl	100643-3	4.75 mg/ml - 5.25 mg/ml	5.05 mg/ml	Expoo
Assay, methyl parathionhydrobenzoate	100643-3	0.80 mg/ml - 1.10 mg/ml	1.01 mg/ml	Expoo
Related substances	100643-3	ml 1.0 %	< 0.1 %	Expoo
Test for sterility	133205-1	sterile	sterile	Expoo
Bacterial endotoxins	100950-2	ml 10 EU/ml	ml 10 EU/ml	Expoo

Orion Corporation
 Oroszország, Budapest
 P.O. Box 65, 02101 ESZAK
 Tel: +36 1 46 82 811
 Fax: +36 1 46 82 813

Magyarországi kizárólagos forgalmazó
 Dr. Székely Kft.
 P.O. Box 53, 2101 FÓT
 Tel: +36 27 537 100
 Fax: +36 27 537 100

Orion Corporation, Registered office and domicile: Oroszország, Moszkva
 P.O. Box 7700, 125070 Moscow, Russia

DR. SZÉKELY KFT.
 Fót központ
 2151 Fót, Keleti Márton út 19.
 és másoktól is rendelhető
 Orion a plusz ajánlatokkal
 2015



CERTIFICATE OF ANALYSIS

Page: 2/4

ANTISEDAN SINGIL VET INJ 10ML HUEN

Product Number: 133961
Batch Number: 1589827
Order Number: 80884748

TESTS	METHOD	REQUIREMENTS	RESULTS	Q.L.T.Y CTRL SITE
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The batch has been manufactured, holding 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 17.12.2015 09:25:58 by: R Qualified Person (Kari Salonen)

Drug Composition: [View composition/ingredient number 00281106/01 04 2015/3](#)

ORION OY AB
Suomenkatu 1, 02200 ESPOO
P.O. Box 61, 01501 ESPOO
Tel: +358 10 4241
Fax: +358 10 38 3813

Touhokatu 1, 00100 TURKU
P.O. Box 421, 20011 TURKU
Tel: +358 10 4292
Fax: +358 10 414 3111

Orion Corporation Registered Office: Siltavuori Opisto 1, 04210 Espoo, Finland

Vehiäkeä 4, 01600 KUUSINKO
P.O. Box 170, 02001 KUUSINKO
Tel: +358 10 421 011
Fax: +358 10 421 5422

Kommentit 7, 21100 VALKO
Tel: +358 10 4204

PHOENIX Pharma Zrt.
Főút Telcsőhely
2751 Főút, Keresztmón ut 18.
..... sz. művelési példány
Csekeg, piros színű művelési
20-05