

ANTISEDAN 5MG/ML OLDATOS INJEKCIÓ 10ML  
Gysz: 2036256 Lej: 2023-12-07  
Kisz: 10 ML Me: Darab  
ALPHA-VET KFT SZÉKESFEHÉR részére

Szállító:  
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CERTIFICATE OF ANALYSIS

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ANTISEDAN 5 mg/ml Solution for injection 10 ml

Product Number: 133981  
Orion Batch Number: 2036256  
Date of Manufacture: 07.12.2020  
Date of Expiration: 12.2023  
Strength/Potency: 5 mg/ml  
Dosage form: Solution for injection  
Package size: 10 ml  
Package type: Vial  
Storage: +15..25 °C  
Country of destination: Bulgaria,Croatia,Hungary,Serbia,Slovenia

TESTS	METHOD	REQUIREMENTS	RESULTS
Colour of solution	100494-2	colourless	colourless
Average volume in container	100229-2	nlt 10,0 ml	10,5 ml
Volume in cont.	100229-2	10,0 - 11,0 ml	10,5 ml
Partic.matter, presence of visib. partic	100473-2	practically no particles	practically no particles
Clarity of solution	100493-2	clear	clear
pH	100432-2	4,0 - 6,0	4,4
Ident., atipamezole HCl, HPLC	100643-3	positive	positive
Ident., methyl parahydroxybenzoate, HPLC	100643-3	positive	positive
Assay, atipamezole HCl, %	100643-3	95,0 - 105,0 %	102,1 %
Assay, methyl parahydroxybenzoate, %	100643-3	90,0 - 110,0 %	98,2 %
Related substances	100643-3	nmt 1,0 %	<0,1 %
Test for sterility	113205-1	sterile	sterile
Bacterial endotoxins.	120383-1	nmt 10 EU/ml	nmt 10 EU/ml

Quality control site : Orion Corporation, Espoo plant Oriontie 1 FI-02200 ESPOO  
Certificate of GMP Compliance: FIMEA/2020/001590  
Authorisation number: FIMEA/2019/000732

Electronically approved 03.02.2021 13:29:57 by a Qualified Person Hanna Strand

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Orion Corporation

Manufacturing license number FIMEA/2019/000732

ORION PHARMA

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CERTIFICATE OF CONFORMITY

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Marketing authorisation number: 3286/1/13 UP/1-322-05/13-01/856 0022-1920-04.01.2013 323-01-00101-19-002 NP/V/0019/001

Manufacturing site: Orion Corporation, Espoo plant Orionintie 1 FI - 02200 ESPOO  
Certificate of GMP Compliance: FIMEA/2020/001590  
Authorisation number: FIMEA/2019/000732

Packaging site: Orion Corporation, Espoo plant Orionintie 1 FI - 02200 ESPOO  
Certificate of GMP Compliance: FIMEA/2020/001590  
Authorisation number: FIMEA/2019/000732

API: ATIPAMEZOLE HYDROCHLORIDE  
API batch number: 1909263  
API manufacturing site: Fermion Oy, Oulu plant , Lääketehtaantie 2 , FI - 90660 Oulu , Finland

API: ATIPAMEZOLE HYDROCHLORIDE  
API batch number: 1912801  
API manufacturing site: Fermion Oy, Oulu plant , Lääketehtaantie 2 , FI - 90660 Oulu , Finland

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 03.02.2021 13:29:57 by a Qualified Person Hanna Strand

133981\_2036256\_COC\_08.02.2021\_11:48:12\_HASTRA

Orion Corporation

Manufacturing license number: FIMEA/2019/000732

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