

COMFORION VET 100MG/ML INJEKCIÓ 10X100ML  
Gysz: 1120941AA Lej: 2023-10-31  
Kisz: 10x100ml Me: Doboz  
SZÉKELY KFT részére

Szállító:  
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CERTIFICATE OF CONFORMITY

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COMFORION VET 100 mg/ml Solution for injection 10x100ml

Product Number: 156927  
Orion Batch Number: 2055388  
Batch Number: 1120941AA  
Date of Manufacture: 20.11.2020  
Date of Expiration: 10.2023  
Strength/Potency: 100 mg/ml  
Dosage form: Solution for injection  
Package size: 10x100ml  
Package type: Vial  
Storage: Below +25 °C  
Country of destination: Hungary, Poland  
Marketing authorisation number: 2347/4/08 MGSZH ÁTI 1852/08

Manufacturing site: Richter Pharma AG Durisolstrasse 14 AT - 4600 Wels  
Certificate of GMP Compliance: 481035-0052  
Authorisation number: 481035

Packaging site: Richter Pharma AG Durisolstrasse 14 AT - 4600 Wels  
Certificate of GMP Compliance: 481035-0052  
Authorisation number: 481035

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 08.06.2021 08:53:00 by a Qualified Person Eero Mäki-Lohiluoma

156927\_2055388\_COC\_08.06.2021\_09:21:34\_EEROMAKI

Orion Corporation

Manufacturing license number: FIMEA/2019/000732

ORION PHARMA

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



## CERTIFICATE OF ANALYSIS

Page 1 of 2

## COMFORION VET 100 mg/ml Solution for injection 10x100ml

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TESTS	METHOD	REQUIREMENTS	RESULTS
Appearance clear, colourless to almost colourless or yellowish or brownish solution	visual	conforms	conforms
Clarity	Ph.Eur.	clear	clear
Colour not more than B6 – Y6 – BY6	Ph.Eur.	conforms	conforms
pH	Ph.Eur.	6,0 - 7,5	6,7
Density (g/cm <sup>3</sup> )	Ph.Eur.	1,038 - 1,048	1,044
Visible particles	visual	none	none
Filling volume	IPC	nit 100	>100
Identification, ketoprofen	HPLC	positive	positive
Ident., ketoprofen	TLC	positive	positive
Identification, benzyl alcohol	HPLC	positive	positive
Ident., benzyl alcohol	TLC	positive	positive
Identification, arginine	TLC	positive	positive
Impurities, ketoprofen imp. A	HPLC	nmt 0,50 %	<0,30 %
Impurities, single unknown impurity	HPLC	nmt 0,50 %	<0,30 %
Total impurities	HPLC	nmt 1,0 %	<0,3 %
Assay, ketoprofen	HPLC	95,0 - 105,0 mg/ml	99,0 mg/ml
Assay, benzyl alcohol	HPLC	9,0 - 11,0 mg/ml	9,9 mg/ml
Bacterial endotoxins	Ph.Eur.	nmt 150 EU/ml	<2 EU/ml
Sterility	Ph.Eur.	sterile	sterile

**Quality control site:** Richter Pharma AG, Durisolstrasse 14, AT - 4600 Weis, Austria  
**Certificate of GMP Compliance:** 481035-0052  
**Authorisation number:** 481035

**Quality control site:** AGES GmbH IMED, Beethovenstrasse 6, AT - 8010 Graz, Austria  
**Certificate of GMP Compliance:** 480687-0013  
**Authorisation number:** 480687

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Manufacturing license number: FIMEA/2019/000732

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Orion Batch Number: 2055388

Electronically approved 08.06.2021 08:53:00 by a Qualified Person Eero Mäki-Lohiluoma

156927\_2055388\_COA\_08.06.2021\_09:19:55\_EEROMAKI

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Manufacturing license number: FIMEA/2519/000732

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