

DELTANIL 10MG/ML RÁÖNT. OLD. 2,5L
Gysz: 87XY/308702 Lej: 2026-02-28
Kisz: 1X Me: Darab
SZÉKELY KFT részére

Szállító:
Medimpex Gy. Zrt.
1158 Budapest
Rákospalotaihatárút2
Tel: +36-1-414-6476
e-mail: qa@mpx.hu



**Certificat d'analyse / Analysis certificate
Certificat de libération / Release certificate**

PRODUIT / PRODUCT : DELTANIL FLEXIBAG 2,5L VBI
Code produit / Code product : 308702
Date de fabrication / Manufacturing date : March 2021

LOT N° / BATCH N° : 87XY
Quantité / Quantity : 375 P
Date de validité / Expiry date : February 2026

Date d'édition / printed on :
April 15, 2021

Lot informatique / IT batch number 2564661

ANALYSES / ANALYSIS	RESULTATS / RESULTS	NORMES / STANDARDS
CHARACTERS		
Appearance of product	Passed	Slightly yellowish clear oily solution
Appearance of packaging	Passed	aluminium-coloured flexible pouches 2,5L equipped by a screw cap and a transfer device
Density	0.949 g/ml	0.940 to 0.960 g/ml
Water content	0 %	Max. 1 %
Extractable volume for pouches	Passed	Min 2500 ml
IDENTIFICATIONS		
Deltamethrin (HPLC/UV)	Passed	RT and UV identical to reference
TESTS		
TMAC	<10	Max 100 CFU/g
TYMC	<10	Max 10 CFU/g
Pseudomonas aeruginosa	Passed	Absence/1g
Staphylococcus aureus	Passed	Absence/1g
ASSAYS		
Deltamethrin (HPLC)	1.02 g/100ml	0.95 to 1.05 g/100ml

Je certifie que ces informations sont exactes et authentiques. Ce lot a été fabriqué, y compris l'emballage / étiquetage et le contrôle qualité, en conformité avec les BPF en vigueur. Dans le cas d'un produit avec une autorisation de mise sur le marché, je certifie que toutes les étapes de fabrication de ce lot sont conformes aux spécifications de l'AMM du (ou des) pays de destination.

I hereby certify that all this information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control in full compliance with the applicable GMP requirements. In case of product with marketing authorization, I certify that all manufacturing steps of this batch are in compliance with the marketing authorization specifications of the importing country(ies).

Date de libération/Release date

15 AVR. 2021

Personne qualifiée/Qualified person

A. CHAUTARD

Signature

Virbac

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Siège social - 1^{ère} avenue 2065 m - LID - 06516 Carros - société anonyme au capital de 10.572.500 euros - 417 350 311 RCS Grasse

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BATCH RELEASE CERTIFICATE

CODE	308702
QUANTITY	375 P
FINAL DECISION	Accepted

NAME OF PRODUCT	DELTANIL FLEXIBAG 2,5L VBI
COUNTRIES FOR WHICH THE PRODUCT HAS A MARKETING AUTHORIZATION	ATBECYCZDEDKEEESFRGBGRHUIELTLVNLPLPTRO
MARKETING AUTHORISATION NUMBER	0022-2123-104478045-28725/18/2
STRENGTH/POTENCY	Cf CoA
PHARMACEUTICAL FORM	Liquid preparations for cutaneous application
PACKAGE SIZE / TYPE	Cf CoA
BATCH NUMBER	87XY
DATE OF MANUFACTURE	03 / 2021
EXPIRY DATE	02 / 2026
ALL MANUFACTURING & QUALITY CONTROL SITES	VIRBAC 1 ^{ère} avenue - 2065 m 06516 CARROS CEDEX (FR)
CERTIFICATE OF GMP COMPLIANCE OF ALL SITES LISTED UNDER 10	V 0296/79
RESULTS OF ANALYSIS	Cf CoA
COMMENTS / REMARKS	

Printed on : 15/04/21

14. CERTIFICATION STATEMENT

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control, at the above mentioned site in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country. The batch processing, packaging, and analysis records have been reviewed and found to be in compliance with GMP.

Release date

15 AVR. 2021

Qualified person

A. CHAUTARD

Signature

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