

LABEL SPECIFICATION COVER SHEET

Label ID #: DIL2501

Current Job #: 2567-003-21 RL #1

Original Job #: 2567-003-21 RL #1

Client Part #: N/A

Protocol: REMAP-CAP (FCS 73130)

Blinded Study: No

Label Package Integration: No

Client Name: Dimerix Limited

Created By: Terranova, Michael 4/28/2021 12:30:37 PM EST

Updated By: Lockamy, Nicholas 5/1/2021 9:35:41 AM EST

Project Manager Sign/Date: Terranova, Michael

Study Logistics

Description: Single Panel Bottle Label
Drug Name/Strength: DMX-200 (Repagermanium) 120mg
Container Type: Bottle Label
Languages: 2
Blinded Label: No
Last Coding Job: N/A
Variable Field Associations: (No F-Values Assigned)
Manufacture Quantity: 200
Internal PFI Quantity: 0

Colors

Content Color 1: Black
Content Color 2: N/A
Content Color 3: N/A
Label Color: White - (Material)
Special Instructions: N/A

Change Notices

N/A

Deviation Reports

N/A

Special Instructions

Size Reference: DWG# B10-230 (DIL2500).

Store: 15 - 25°C.

Label Application: Ambient

No write-in lines for the following:

Site Number:

Investigator:

Trial Subject ID:

Manufacturing Logistics

Design Program: In-Design
TCN#: TCN09748
Template ID #: 1.1250.5500.1250.6000
Label Type: Single
Open Direction: N/A
Overall Size: 1 1/4" x 5 1/2"
Repeat: 6"
Gen Strip: N/A
Backtape: N/A
Base Label Stock: Semi-Gloss Elite Fascover ES / Opaque / S246 / 50# SCK / Component Part # RLP00013
Booklet Stock: N/A
Over Laminate: N/A
Under Laminate: N/A
OSW Stock: N/A
Mfg Type: Manufacture New
Blank Stock: No
New Dies Req'd: Flexo: No Digital BK: No Digicon: No Onsert: No

Base Panel Inks/Varnishes

Print Station 1: Varnish - CTV00003
Print Station 2: N/A
Print Station 3: N/A
Print Station 4: N/A
Print Station 5: N/A

Finishing Operations

Process Type: Finished
Blinding Laminate: N/A
Apply Laminates To: N/A
Reorient: No
Press Roll: Yes **Core:** 6" **Max. Diam:** 12.75" **Unwind:** 4

CUSTOMER AUTHORIZATION

AUTHORIZED SIGNATURE

DATE

Customer approval applies to all sections of this label specification cover sheet and all associated label proofs.



#4

LEFT SIDE
OF COPY
DISPENSES
FIRSTfisher clinical
services

by Thermo Fisher Scientific

LABEL PROOF

Finished Web Direction

OVERPRINT VARNISH REQUIRED / 500 ANILOX

Trial Code / Onderzoekscodes: REIMAP CAP 2015-002340-14	
Batch No. / Charge nr.: 3193246	Expiry Date / Niet gebruiken na: AUG 2021
Site Number / Centrum nummer: DMX-200 (Fepagermanum) 120mg 30 capsules for oral use or via capsule dissolved in water for delivery via NG tube; see Study Administration Guide. Use as directed. Store: 15 - 25°C. For clinical trial use only. Keep out of reach of children. Sponsor: University Medical Center Utrecht, PO BOX 85500, 3504 GA Utrecht, The Netherlands. eu.remcap@uncutrecht.nl +31 (0) 6 277 444 77 Manufacturer: Dimerix Bioscience Pty Ltd	Trial Subject ID / Subject ID: Investigator / Onderzoeker: DMX-200 (Fepagermanum) 120mg 30 capsules for oral use or via capsule dissolved in water for delivery via NG tube; see Study Administration Guide. Use as directed. Store: 15 - 25°C. For clinical trial use only. Keep out of reach of children. Sponsor: University Medical Center Utrecht, PO BOX 85500, 3504 GA Utrecht, The Netherlands. eu.remcap@uncutrecht.nl +31 (0) 6 277 444 77 Manufacturer: Dimerix Bioscience Pty Ltd
DMX-200 (Fepagermanum) 120 mg 30 capsules voor oraal gebruik of door middel van een in water opgeloste capsule bij toediening via neussonde; zie Toedieningsgids voor het onderzoek. Gebruik volgens instructies. Bewaren bij 15 - 25°C. Uitsluitend voor gebruik in klinisch onderzoek. Buiten bereik van kinderen houden. Sponsor: Universitair Medisch Centrum Utrecht, Postbus 85500, 3504 GA Utrecht, Nederland. eu.remcap@uncutrecht.nl +31 (0) 6 277 444 77 Fabrikant: Dimerix Bioscience Pty Ltd	

Label Repeat = 6"

Label ID #: DIL2501

Label Designed By: Nick Lockamy

Label Updated By: N/A

Template ID#: 1.1250.5500.1250.6000

Client Approval: _____

IPI: SIGNATURE ON FILE