

Specification Packaging Material

E-67914-01, LABEL MEDIXON POWDER FOR INJECTION
500 MG TOLL BERNOFARM MALAYSIA

Author(s):

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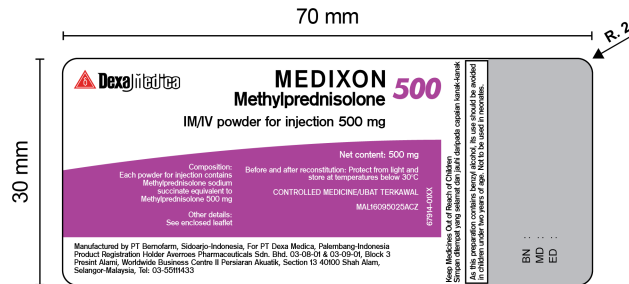
Reviewed by:

21.09.2023, Riski Amanda Tambunan, Supervisor Packaging Design,

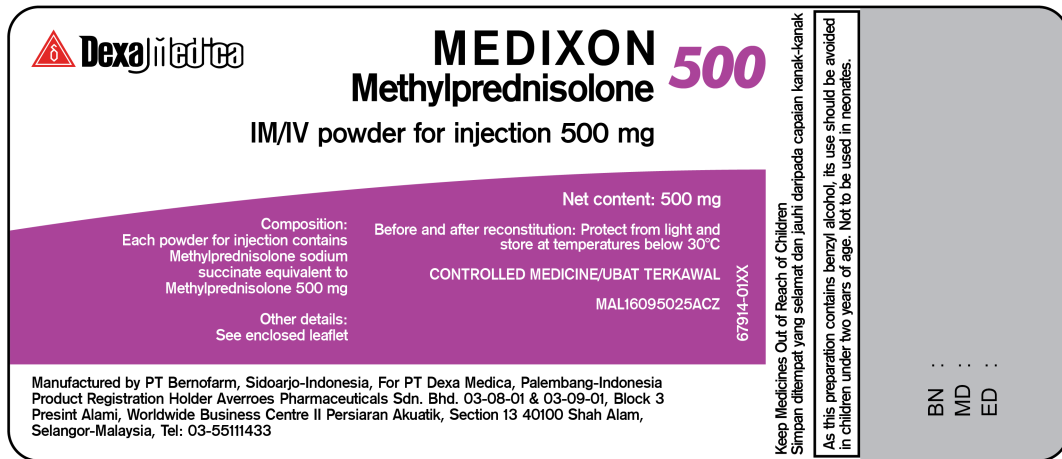
Approved by:

21.09.2023, RA Officer 03, Regulatory Affairs Officer,

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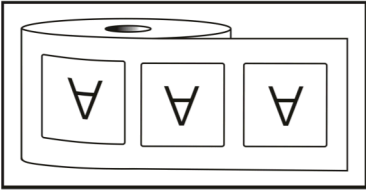


BN :
MD :
ED :

Grey area is a block area for inserting batch number (BN); manufacturing date (MD); expiry date (ED); during manufacturing process, it will not appear in commercial packaging.

Color :
 Black
 P Purple C
 P 485 C

Font type : Gothic725 Bd BT
 Font size (Product name) : 9 pt
 (Generic name) : 7.2 pt

No.	Parameters	Specification
1.	Material	Fasson Fascoat 2/S2420/BG40 Blue Imp SW7324 atau / or Fasson Fascoat 2/S2420/BG40 White Imp SW7325 (Lihat CoA / See CoA)
2.	Dimensi Panjang / <i>Length Dimension</i> (mm)	69 - 71 mm
3.	Dimensi Lebar / <i>Width Dimension</i> (mm)	29 - 31 mm
4.	Jumlah per roll / <i>Quantity per-roll</i> (pc)	4750 – 5250 pc (optional)
5.	Tebal total / <i>Total thickness</i> (mcm)	126 – 154 mcm
6.	Arah gulungan / <i>Roll direction</i>	
7.	Diameter core / <i>Core diameter</i> (mm)	72.39 – 80.01 mm (optional)
8.	Jarak antar label / <i>Gap between the label</i> (mm)	1.5 mm – 3.0 mm
9.	Warna / <i>Colour</i>	Lihat proof print / <i>See proof print</i>
10.	Redaksional / <i>Redactional</i>	Lihat proof print / <i>See proof print</i>
11.	Karakter spesifik / <i>Specific character</i>	Jari-jari (R) / <i>Radius</i> : 2 mm Sambungan disatukan dengan selotip bening (harus kuat) dan ditandai dengan selotip berwarna gelap / <i>Joining extension with transparent celotape and marked by darkcelotape.</i> (optional)

HISTORY

Revision No.	Revision Date	Details	Reason
00	-	Dokumen baru untuk implementasi general use	CMCOthRec040575
01	20 Sept 2021	<ul style="list-style-type: none"> - Revisi no item menjadi E-67914-01 - Revisi nama generik dari Methylprednisolone 500 mg menjadi Methylprednisolone (manual terupdate) - Revisi bentuk sediaan dari sterile powder for injection, IM/IV injection menjadi IM/IV powder for injection 500 mg (manual terupdate) - Update penulisan Controlled medicine/Ubat terkawal - Penambahan alamat Averroes 	CMCOthRec077679/1
02	02 Mar 2022	<ul style="list-style-type: none"> - Penambahan "After reconstitution: Stable for 48 hours below 30°C" - Revisi 'Imported by' menjadi 'Product Registration Holder' - Perubahan alamat manufactur PT Bernofarm - Penamban ket. MD diblok abu 	CMCOthRec083483/1
03	14 April 2022	<ul style="list-style-type: none"> - Revisi alamat Averrous menggunakan alamat lengkap 	CMCOthRec085356/1
04	20 Sept 2023	<ul style="list-style-type: none"> - Perubahan storage condition 	CMCOthRec109500/1