

Specification Packaging Material

E-67913-01, DOOS MEDIXON POWDER FOR INJECTION
500 MG 1 VIAL + 1 AMPOULE TOLL BERNOFARM
MALAYSIA

Author(s):

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Reviewed by:

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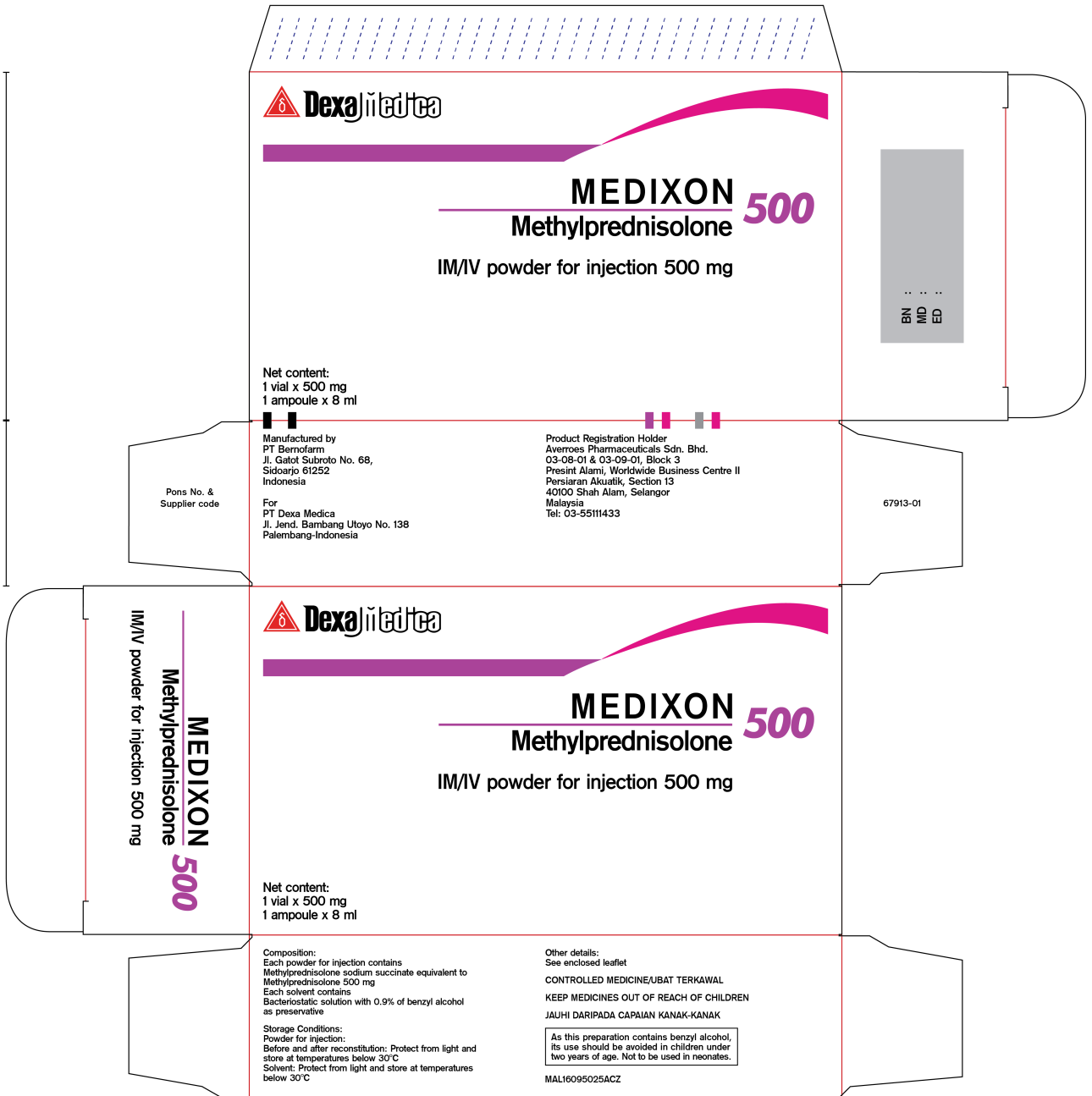
Approved by:

21.09.2023, RA Officer 03, Regulatory Affairs Officer,

107 mm

63 mm

30 mm



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 219 C	Black (50%)	Font type : Gothic 725 Bold BT
	P 485 C	P Purple C		Font size (Product name) : 18 pt
				Font size (Generic name) : 14.4 pt

No.	Parameters	Specification
1.	Material	Dupleks / <i>Duplex</i> (Lihat CoA / <i>See CoA</i>)
2.	Gramatur / <i>Grammature</i> (gsm)	243 – 297 gsm
3.	Dimensi Panjang / <i>Length Dimension</i> (mm)	106 - 108 mm
4.	Dimensi Lebar / <i>Width Dimension</i> (mm)	62 - 64 mm
5.	Dimensi Tinggi / <i>Height Dimension</i> (mm)	29 - 31 mm
6.	Varnish	Waterbase
7.	Warna / <i>Colour</i>	Lihat proof print / <i>See proof print</i>
8.	Redaksional / <i>Redactional</i>	Lihat proof print / <i>See proof print</i>

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-67913-01 - 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) - Revisi penulisan net content (manual terupdate) - Revisi penulisan komposisi - Update penulisan Controlled medicine/Ubat terkawal; Keep medicines out of reach of children; Jauhi daripada capaian kanak-kanak - Perubahan 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 	CMCOthRec083483/1
03	20 Sept 2023	<ul style="list-style-type: none"> - Perubahan storage condition 	CMCOthRec109500/1