

Specification Packaging Material

E-61926-01, LABEL DEXAMEDICA MEROPENEM POWDER FOR INJECTION 0.5 G MALAYSIA

Author(s):

06.03.2025, Ayu Vidya Kartika, Artwork Management Officer

Reviewed by:

10.03.2025, Riski Amanda Tambunan, Artwork Management Manager

Approved by:

10.03.2025, RA Officer 03, Regulatory Affairs Officer

Effective date: 10.03.2025

SpecPacGen002901/7
CONFIDENTIAL

100%

85 mm

30 mm

Composition:
Each vial contains Meropenem trihydrate equivalent to 0.5 g Meropenem

Other details:
See enclosed leaflet

**STORE AT TEMPERATURE BELOW 30°C
PROTECT FROM LIGHT**

KEEP MEDICINES OUT OF REACH OF CHILDREN

JAUHI DARIPADA CAPAIAN KANAK-KANAK

1 vial x 0.5 g

DexaMedica
Meropenem
Powder for Injection
Meropenem 0.5 g

IV injection or infusion

The reconstituted solution should be used immediately. If not used immediately, it must be stored for no longer than 3 hours at 25°C or 16 hours at 5°C when diluted in water for injection and no longer than 3 hours at 25°C or 15 hours at 5°C when diluted in 0.9% sodium chloride. Meropenem shows lower stability in 5% dextrose compared to other solutions; therefore it should be freshly prepared

Both the vial before reconstitution and the reconstituted solution should not be frozen

MAL16065047AZ

**CONTROLLED MEDICINE/
UBAT TERKAWAL**

Product Registration Holder
Averroes Pharmaceuticals Sdn. Bhd.
3-08-01 & 3-09-01, Block 3
Presint Alam, Worldwide Business Centre II
Persiaran Akuatik, Section 13
40100 Shah Alam, Selangor
Malaysia
Tel: 03-55111433

Manufactured by

DexaMedica

Jl. Jenderal Bambang Utuyo No. 138
Palembang-Indonesia

BN :
MD :
ED :

R³

61926-01XX

200%

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BN :
MD :
ED :

61926-01XX

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 485 C

P 635 C

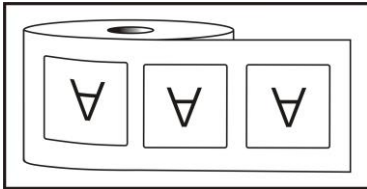
P 232 C

Font type : Aller

Font size (Product name) : 8 pt

(Generic name) : 6.4 pt

(Redactional) : 3 pt

No.	Parameters	Specification
1.	Material	Fasson LW 60/S2090/BG 40 White Imp (Lihat CoA / <i>See CoA</i>)
2.	Dimensi Panjang / <i>Length Dimension</i> (mm)	84 - 86 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)	103.5 – 126.5 mcm (Lihat CoA / <i>See CoA</i>)
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) / Radius: 3 mm Sambungan disatukan dengan selotip bening (harus kuat) dan ditandai dengan selotip berwarna gelap / <i>Joining extension with transparent celotape and marked by dark celotape</i> (optional)

HISTORY

Revision No.	Revision Date	Details	Reason
00	-	Dokumen baru	Email RA tanggal 9-Des-2016 Email RA tanggal 21-Des-2016
01	05 Agustus 2021	- Perubahan branded menjadi OGB yaitu Meropenem - Perubahan packsize dari 1 vial menjadi Box, 10 vial	CMCOthRec075867/1 (Email RA)
02	23 Agustus 2022	- Perubahan desain kemasan mengikuti acuan manual terupdate - Perubahan nama brand	CMCOthRec090571/1 CMCOthRec090572/1
03	05 Oktober 2022	- Penambahan Route of administration "IV injection or infusion" - Penambahan keterangan "1 vial" menjadi "1 vial x 0.5 g" - Revisi brand name Dexamedica Meropenem" menjadi "DexaMedica Meropenem"	CMCOthRec092616/1 CMCOthRec092617/1
04	27 Sep 2023	- Perubahan dokumen menjadi general use - Penghilangan BN, MD dan ED untuk area coding - Penambahan approval site	CMCOthRec109812/1
05	28 Jan 2025	- Revisi item number menjadi E-61926-01 - Perubahan warna brand menjadi P635C - Perubahan redaksional klim in use sesuai acuan PI - Update desain sesuai manual DIB Branded terbaru: Penambahan warna TC P232C	CMCOthRec133851/1 CMCOthRec133850/1 CMCOthRec136224/1
06	06 Mar 2025	Penambahan MD pada gray area untuk akomodir regulasi NPRA Malaysia	Menyesuaikan dengan regulasi NPRA Malaysia