

Specification Packaging Material

E-63578-00, LABEL FONKOZOMIB LYOPHILIZED POWDER FOR INJECTION 3.5 MG MALAYSIA

Author(s):

14.10.2024, Helen Fransiska Manurung, Artwork Management Officer - BTR,

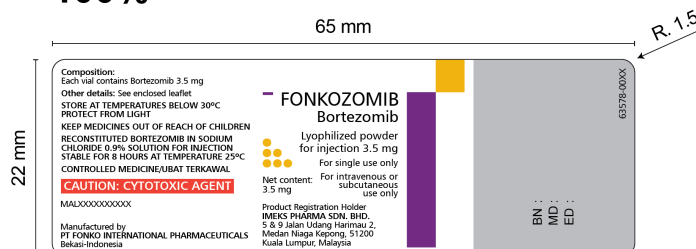
Reviewed by:

15.10.2024, Riski Amanda Tambunan, Supervisor Packaging Design,

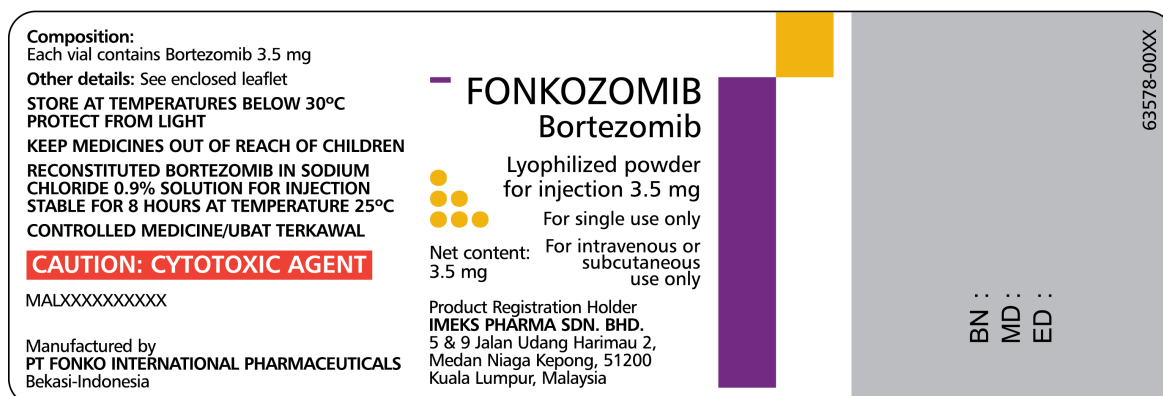
Approved by:

15.10.2024, RA Officer 03, Regulatory Affairs Officer,

100%



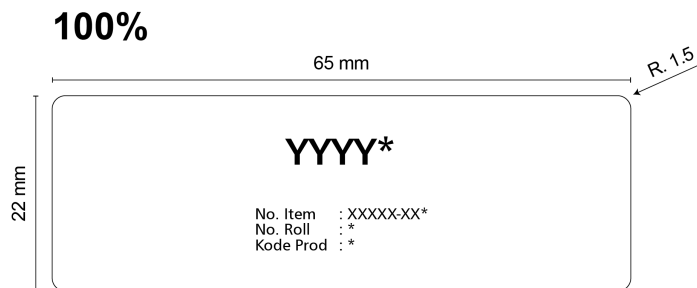
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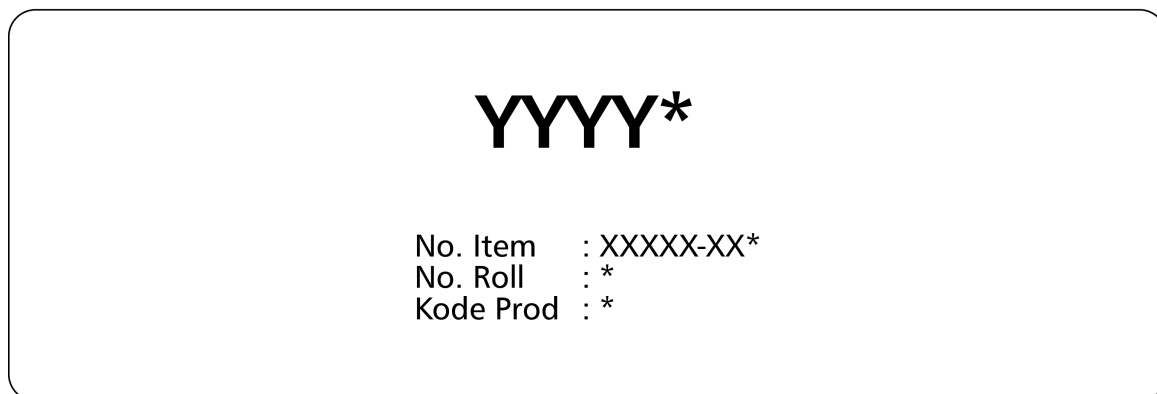
BN :
MD :
ED :

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.

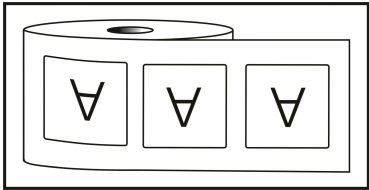
Color :		Font type : Humnst777 BT	
	Black	Font size (Product name) : 6 pt	
	P 124 C	(Generic name) : 5 pt	
	P Red 032 C	(Strength) : -	
	P 2603 C	(Redactional) : 2.8 pt	



200%



Color :	Keterangan:
■ Black	1. YYYY : Running no. dimulai dari angka terbesar
Font type : Humnst777 BT	2. XXXXX-XX : Diisi sesuai dengan no. Item kemasan jika item kemasan adalah E-63578-00; maka "No. Item" pada bagian belakang label adalah 63578-00
Font size : 12 pt	3. * : Diisi oleh supplier

No.	Parameters	Specification
1.	Material	Fasson Fascoat 2/S2420/BG40 Blue Imp SW7324 atau/or Fasson Fascoat/S2420/BG40 White Imp SW7325 (Lihat CoA / See CoA)
2.	Dimensi Panjang / <i>Length Dimension</i> (mm)	64 – 66 mm
3.	Dimensi Lebar / <i>Width Dimension</i> (mm)	21 – 23 mm
4.	Jumlah per roll / <i>Quantity per-roll</i> (pcs)	4,750 – 5,250 pcs (optional)
5.	Tebal total / <i>Total thickness</i> (mcm)	126 – 154 mcm (Lihat CoA / See CoA)
6.	Arah gulungan / <i>Roll direction</i>	
7.	Diameter core / <i>Core diameter</i>	72.39 – 80.01 mm (optional)
8.	Jarak antar label / <i>Gap between the label</i>	1.5 mm - 3.0 mm
9.	Penomoran back paper / <i>Numbering back paper</i>	Terdapat redaksional pada bagian belakang label / <i>There are redactional on the backpaper of label</i> (Lihat proof print / <i>See proof print</i>) Urutan angka terbesar pada bagian belakang label ada pada bagian terluar (angka 1 ada di bagian dalam) / <i>The biggest number on the backpaper of label is on the outside (number 1 on the inside)</i>
10.	Warna / <i>Colour</i>	Lihat proof print / <i>See proof print</i>
11.	Redaksional / <i>Redactional</i>	Lihat proof print / <i>See proof print</i>
12.	Karakter spesifik / <i>Specific character</i>	Jari-jari (R) / Radius: 1.5 mm (optional) Sambungan disatukan dengan selotip bening (harus kuat) dan ditandai dengan selotip berwarna gelap / <i>Joining extension with transparent celotape and marked by darkcelotape.</i>

HISTORY

Revision No.	Revision Date	Details	Reason
00	-	Dokumen baru / <i>New Document</i>	CMCOTHRec078494/1
01	26 Sep 2023	Penambahan keterangan “Manufacturing Date”	CMCOTHRec109764/1
02	10 Jan 2024	- Perubahan kotak sekunder untuk menghindari LASA di Site - Delete angka strength “3,5”	CMCOTHRec115328
03	26 Feb 2024	- Penambahan klim in use stabilitas - Penambahan alamat lengkap reg holder	CMCOTHRec117834
04	29 Mei 2024	Perubahan “Warning: Cytotoxic drug” menjadi “Warning: Cytotoxic agent”	CMCOTHRec122425
05	10 Okt 2024	- Penambahan klim “For intravenous or subcutaneous only” - Penambahan klim “For single use only” - Perbesaran ukuran font “Caution: Cytotoxic Agent” dan informasi lain diside panel lebih besar dari ket manufaktur dan PRH - Perubahan warna font informasi lain diside panel menjadi hitam selain “Caution: Cytotoxic Agent”	CMCOTHRec129646 CMCOTHRec129649