

ARTWORK DESIGN STANDARD ETIKET



Date of use: 01/07/2025
(DD-MM-YYYY)

VALDIMEX 10 INJEKSI LOGO HALAL

Size (L x W) 30 x 28 mm

Material	Packsizes/Primary	Primary	No. Sertifikat Halal	No. Reg
Sticker High Gloss Paper S1010 BG 40 WH	5 ampul @ 2 mL	Ampoule Amber 2 mL	ID00310000202761021	DPL0433305743A1

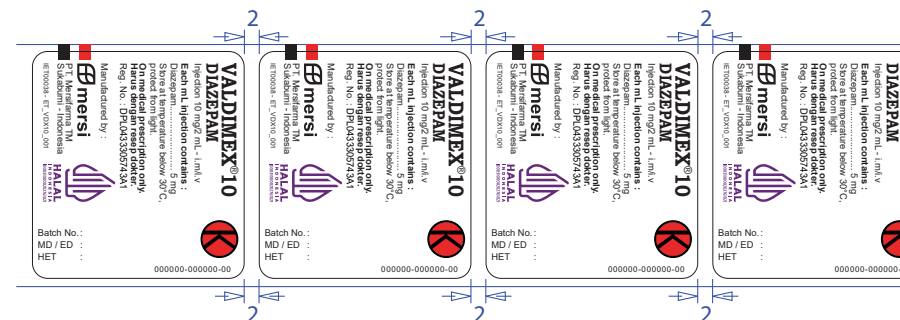
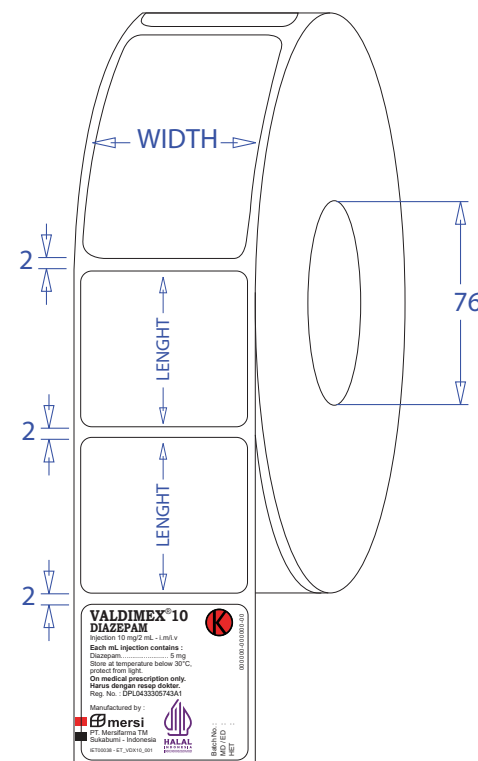
Front / Rear Panel

Type Font

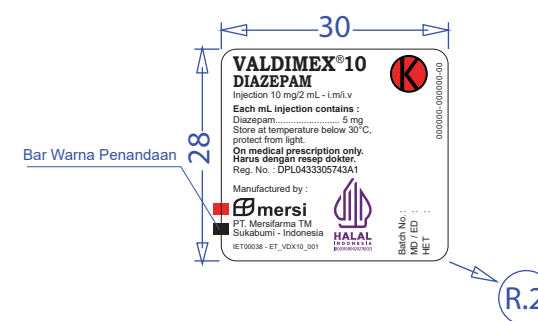
Product Name	Active Ingredient	Another Font
Bookmand Old Style, Bold	Bookmand Old Style, Bold	Arial Regular / Bold
8pt	6.4pt	3.5pt

SKETCHES

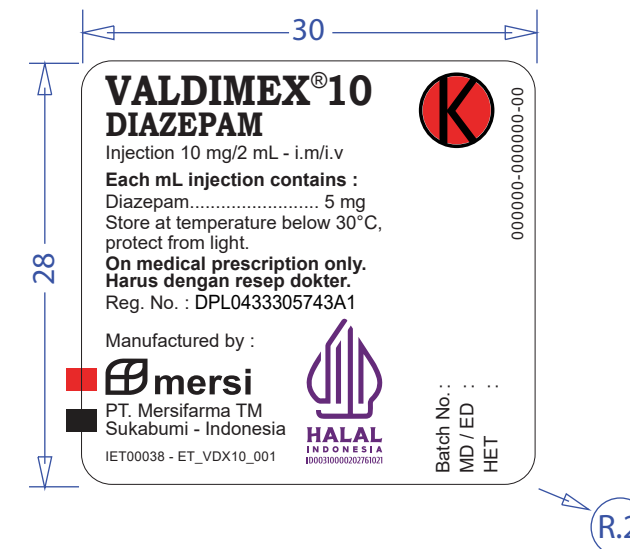
**ROLL PRINTED ETIKET
GAP ~ DIE CUT**



Preview Gap Roll



Actual size - Scale 100 %



Preview 200 %

						Material Code	Design Code	Finishing
Ø5mm	9.6 x 2.4mm (LxH)	5 x 9.5mm (LxH)	PURPLE TC 2316	RED TC 1315	Black	IET00038	VDX10_001	Full Varnish Waterbase

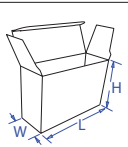
ARTWORK DESIGN STANDARD FOLDING BOX



PT. MERSIFARMA TIRMAKU MERCUSANA
DEPARTEMEN DESIGN & PACKAGING

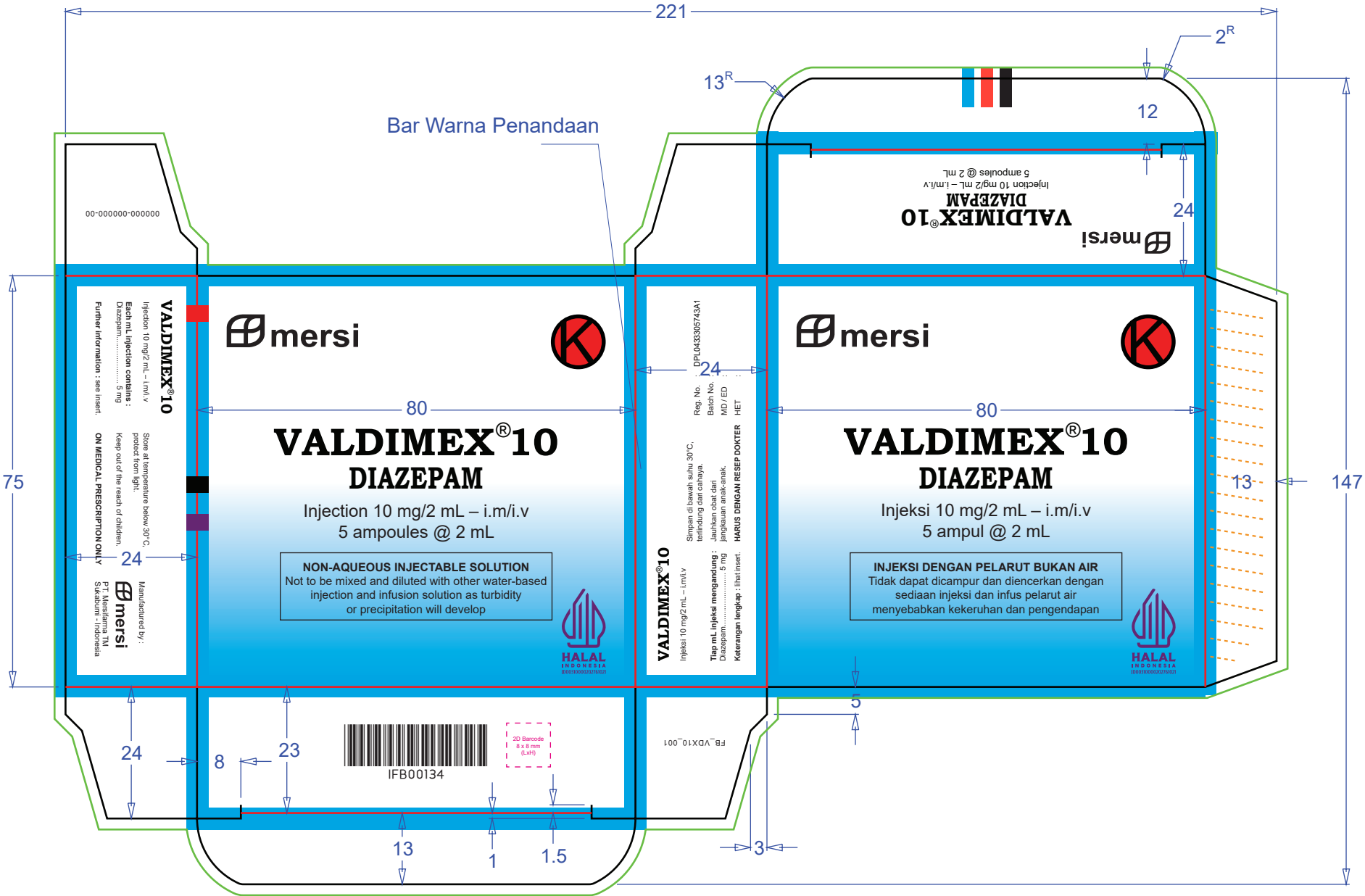
Date of use: 01/07/2025
(DD-MM-YYYY)

VALDIMEX 10 INJEKSI LOGO HALAL				
Dimension (L x W x H) 80 x 24 x 75 mm				
Material	Packsize/Primary	Primary	No. Sertifikat Halal	No. Reg.
Carton Duplex 250g	5 ampoules @ 2 mL	Ampoule Amber 2mL	00140096650719	DPL0433305743A1



Front / Rear Panel			Left / Right Side Panel		Top Closure Panel		
Type Font			Type Font		Type Font		
Product Name	Active Ingredient	Another Font	Product Name	Another Font	Product Name	Active Ingredient	Another Font
Bookmand Old Style, Bold	Bookmand Old Style, Bold	Arial	Bookmand Old Style, Bold	Arial	Bookmand Old Style, Bold	Bookmand Old Style, Bold	Arial
20pt	16pt	9pt	8pt	4pt	12pt	9.6pt	5pt

SKETCHES



Actual size - Size in mm

	Cut									Material Code	Design Code	
	Crease											
	Outside Bleed											
	Glue Flap											
		Ø10mm	8 x 15.5mm (LxH)	24 x 6mm (LxH) 12 x 3 mm, 16 x 4mm (LxH)	Gradient TC 3604 to White	SKY BLUE TC 3604	RED TC 1315	PURPLE TC 2316	Black	 IFB00134	FB_VDX10_001	
Finishing : Full Varnish Water Base												

ARTWORK DESIGN STANDARD INSERT



PT. MERSIFARMA TIRMAKU MERCUSANA
DEPARTEMEN DESIGN & PACKAGING

Date of use: 03/07/2025

(DD-MM-YYYY)

VALDIMEX 10 INJEKSI

Size (L x W) 100 x 220 mm

Material
HVS Paper 60g
Packsize/Primary
5 ampoules @ 2 ml
Primary
Ampoule
No. Reg
DPL0433305743A1

Front / Back	
Type Font	
Product Name	Another Font
Bookmand Old Style, Bold	Arial Regular / Bold
8pt	6pt

16 x 4mm (LxH)	TEXT Black
Material Code	Design Code
IIN00128	IN_VDX10_001

Note:

CHECKED & APPROVED BY				
R&D		RA		
Tgl:	Tgl:	Tgl:	Tgl:	Tgl:
Staff/SPV	Manager	Staff/SPV	Manager	Dir. Bus. Dev

VALDIMEX®10
Injection i.m/i.v

DRUG DESCRIPTION

Clear liquid, colorless, sterile in 2 mL ampoule amber.

COMPOSITION

Each mL VALDIMEX 10 injection contains Diazepam 5 mg

EXCIPIENTS

Benzoic Acid, Sodium Benzoate, Benzyl Alcohol, Propylene Glycol, Alcohol.

ACTIONS

Diazepam is a Benzodiazepine derivative. Primary mode of action is potentiation to neuron inhibition in central neuro system with gamma-aminobutyrate (GABA) as a mediator in central neuro system. Diazepam is metabolized to the active metabolites N-desmethyldiazepam and Oxazepam. Peak plasma concentration is reached within 1-2 hours after administration orally. Half-life varies between 20-70 hours, while the half-life of Desmethyldiazepam varies up to 100 hours, depending on patient's age and liver function.

INDICATIONS

For short-term therapy in anxiety symptoms.
Adjunct for the relief of muscle spasm due to inflammation or trauma and muscle hypertonicity (cerebral motoric disorders, paraplegia).
It is used also for the relief of acute Alcohol abstinence and pre-anesthetical medicament.

POSOLOGY AND METHOD OF ADMINISTRATION

Posology

- For anxiety and adjunct in muscle spasms : 2-10 mg, 2-4 times daily is depend on the severity.
- For relief of acute Alcohol abstinence : 10 mg, 3-4 times daily in the first 24 hours, followed by 5 mg, 3-4 times daily.
- In the elderly and weakness patients : Initial dose 1-2.5 mg, 3-4 times daily. If necessary and tolerable, the dose may be increased gradually.

Method of administration

The drug is given intramuscular/intravena.

CONTRAINDICATIONS

- Hypersensitivity patients.
- Baby under 6 months.
- Pregnant and lactating women.
- Breathing depression.
- Narrow angle glaucoma.
- Acute pulmonary insufficiency.
- Phobia condition.

SIDE EFFECTS

Drowsiness, ataxia, fatigue, skin eruption, edema, nausea and constipation, extrapyramidal symptoms, jaundice and liver dysfunction, change in libido, headache, amnesia, hypotension, blurred vision and urine retention.

WARNINGS AND PRECAUTIONS

- Do not drive or operate machinery when using this drug.
- Anxiety or common life-stress not necessary to be treated with anxiolytic.
- Efficacy in the long-term treatment (more than 4 months) has not yet been systematically established by clinical trial.
- In long-term treatment may cause drug dependence.
- In the elderly and weakness patients, minimum effective dose is recommended.
- Use with caution in patients with chronic pulmonary insufficiency, liver and renal dysfunction the dose should be reduced.
- Therapy should be stopped, if paradoxical reactions occur, e.g. Acute hyperexcitation, anxiety, hallucination and sleep disturbances.

Precautions : VALDIMEX 10 injections is a non-aqueous injectable solution. Accordingly, mixing or diluting with other water-based injections or infusion solutions is not allowed as it will cause turbidity or precipitation of the active substance.

DRUG INTERACTIONS

Concomitant use with CNS depressant or Alcohol may increase depressant effects.
Cimetidine and Omeprazole may reduce Benzodiazepine clearance.
Rifampicin may increase Benzodiazepine clearance.

STORAGE

Store at temperature below 30°C, protect from light.
Keep out of the reach of children.

PRESENTATION AND REGISTRATION NUMBER

Box, 5 ampoules @ 2 mL injection of VALDIMEX 10, Reg. No. DPL0433305743A1

For reporting Side Effects and Product Complaints, please contact:

PT. Mersifarma Pharmacovigilance Team

Email : farmakovigilans@mersifarma.com

Telephone : 0818-8287-0825

ON MEDICAL PRESCRIPTION ONLY

Manufactured by :



PT Mersifarma TM
Sukabumi - Indonesia

000000-000000-00

IIN00128
IN_VDX10_001

VALDIMEX®10
Injeksi i.m/i.v

PEMERIAN OBAT

Cairan jernih, tidak berwarna, steril dalam ampul amber 2 mL.

KOMPOSISI

Tiap mL injeksi VALDIMEX 10 mengandung Diazepam 5 mg

ZAT TAMBAHAN

Benzoic Acid, Sodium Benzoate, Benzyl Alcohol, Propylene Glycol, Alcohol.

CARA KERJA

Diazepam merupakan turunan Benzodiazepine. Kerja utama Diazepam adalah potensiasi inhibisi neuron pada sistem saraf pusat dengan gamma-aminobutirat (GABA) sebagai mediator pada sistem saraf pusat. Diazepam mengalami metabolisme menjadi metabolit aktif yaitu N-desmetildiazepam dan Oxazepam. Kadar puncak dalam darah tercapai setelah 1-2 jam pemberian oral. Waktu paruh bervariasi antara 20-70 jam sedangkan waktu paruh Desmetildiazepam bervariasi hingga 100 jam, tergantung pada usia dan fungsi hati pasien.

INDIKASI

Untuk pengobatan jangka pendek pada gejala-gejala ansietas.
Sebagai pembantu untuk meringankan spasme otot rangka karena inflamasi atau trauma dan hipertonisitas otot (kelainan motorik serebral, paraplegia).
Digunakan juga untuk meringankan gejala-gejala pada penghentian pemakaian Alkohol akut dan medikasi pra-anestesi.

POSOLOGI DAN CARA PEMBERIAN

Posologi

- Untuk ansietas dan sebagai pembantu penanganan spasme otot rangka : 2-10 mg, 2-4 kali sehari tergantung berat penyakit.
- Untuk gejala-gejala pada penghentian Alkohol akut : 10 mg, 3-4 kali sehari pada 24 jam pertama, selanjutnya 5 mg, 3-4 kali sehari.
- Usia lanjut atau penderita yang lemah : dosis awal 1-2,5 mg, 3-4 kali sehari. Bila diperlukan dan dapat ditoleransi, dosis dapat ditingkatkan bertahap.

Cara pemberian

Obat diberikan secara Intramuskular/Intravena.

KONTRAINDIKASI

- Penderita hipersensitif.
- Bayi dibawah 6 bulan.
- Wanita hamil dan menyusui.
- Depresi pernafasan.
- Glaukoma sudut sempit.
- Kelemahan pulmoner akut.
- Keadaan phobia.

EFEK SAMPING

Mengantuk, ataksia, kelelahan, erupsi pada kulit, edema, mual dan konstipasi, gejala-gejala ekstrapiramidal, sakit kuning dan disfungsi hati, perubahan libido, sakit kepala, amnesia, hipotensi, gangguan visual dan retensi urin.

PERINGATAN DAN PERHATIAN

- Jangan mengemudikan kendaraan bermotor atau menjalankan mesin selama minum obat ini.
- Ansietas atau biasa hidup stress tidak memerlukan pengobatan dengan ansiolitik.
- Efektifitas pada pengobatan jangka lama (lebih dari 4 bulan) belum diuji sistematis secara klinis.
- Penggunaan jangka lama dapat menyebabkan ketergantungan pada obat.
- Pada penderita lemah dan usia lanjut dianjurkan dengan dosis efektif terkecil.
- Hati-hati penggunaan pada penderita kelemahan pulmoner kronik, gangguan fungsi hati dan ginjal kronik : dosis dikurangi.
- Hentikan pengobatan jika terjadi reaksi-reaksi paradoksisal seperti keadaan hipereksitasi akut, ansietas, halusinasi dan gangguan tidur.

Perhatian : VALDIMEX 10 injeksi adalah injeksi dengan bahan pelarut bukan air. Karenanya, pencampuran atau pengenceran dengan injeksi atau cairan infus berbasis air tidak diperbolehkan karena akan timbul kekeruhan dan pengendapan zat aktifnya.

INTERAKSI OBAT

Penggunaan bersama obat-obat depresan SSP atau Alkohol dapat meningkatkan efek depresan.
Cimetidine dan Omeprazol mengurangi klirens Benzodiazepine.
Rifampicin dapat meningkatkan klirens Benzodiazepine.

CARA PENYIMPANAN

Simpan di bawah suhu 30°C, terlindung dari cahaya.
Jauhkan obat dari jangkauan anak-anak.

KEMASAN DAN NOMOR REGISTRASI

Dus, 5 ampul @ 2 mL injeksi VALDIMEX 10, No. Reg. DPL0433305743A1

Untuk pelaporan Efek Samping dan Keluhan Produk, dapat menghubungi:

Tim Farmakovigilans PT. Mersifarma

Email : farmakovigilans@mersifarma.com

Telepon : 0818-8287-0825

HARUS DENGAN RESEP DOKTER

Diproduksi oleh :



PT Mersifarma TM
Sukabumi - Indonesia

IN00128
N VDX10 001

PT Mersi
PT Mersifarma TM
Sukabumi - Indonesia