

FORMENING®



Komposisi

Komposisi utama: Grup A, C, Y, W135 polisakarida meningokokus
Pengencer : Air steril untuk injeksi

Indikasi

Setelah vaksinasi, membuat tubuh memproduksi respon imun humoral untuk mencegah penyakit meningokokus yang disebabkan oleh *Neisseria meningitidis* serogrup epidemi A, C, Y, dan W135.

Kontraindikasi

Vaksin ini tidak boleh diberikan untuk penderita sebagai berikut :

1. Penderita epilepsi, kejang, kerusakan otak atau memiliki riwayat alergi.
2. Penderita dengan penyakit ginjal, jantung, TBC aktif.
3. Penderita dengan penyakit infeksi akut dan demam.

Studi kehamilan dan reproduksi pada hewan belum dilakukan dengan vaksin ini. Belum diketahui apakah produk ini dapat menyebabkan kerusakan janin jika diberikan kepada wanita hamil atau dapat mempengaruhi kapasitas reproduksi. Akibatnya, wanita hamil tidak dianjurkan untuk vaksinasi, terutama pada tiga bulan pertama.

Perhatian

1. Harus dilakukan pemeriksaan visual pada tiap wadah terhadap partikel dan perubahan warna sebelum diberikan. Jangan diberikan setelah kadaluarsa. Jika vial pecah atau kemasan tidak baik maka vaksin tidak boleh diberikan.
2. Vaksin harus diberikan setelah dibuka, apabila tidak diberikan segera maka waktu pemberian tidak lebih dari 30 menit.
3. Perhatian khusus harus diberikan untuk menghindari vaksin disuntik secara intradermal, intramuscular dan intravena, selama tiga studi klinis tidak memberikan hasil yang aman dan efektif.
4. Karena endotoksin superposisi, tidak bisa diberikan bersamaan dengan vaksin pertusis dan vaksin tifoid.
5. Belum diketahui apakah vaksin diekresikan melalui air susu karena banyak obat yang diekresikan melalui air susu, hati-hati pemberian pada ibu menyusui.
6. Orang dengan immunosupresi, termasuk orang yang sedang menerima terapi immunosupresif, akan menimbulkan respon imun yang minim terhadap vaksin.
7. Vaksin tidak diindikasikan untuk pengobatan infeksi meningokokus, tidak bisa melindungi dari meningokokus kelompok B, tidak memberikan pencegahan jangka pendek untuk bayi dan anak-anak dibawah 2 tahun tetapi dapat memberikan perlindungan jangka pendek selama 3 bulan atau lebih dari meningokokus kelompok A, sama seperti vaksin lain yang tidak mampu memberi perlindungan 100 % untuk populasi yang mudah terinfeksi.
8. Obat-obat yang harus tersedia misalnya epinefrin atau obat lain, untuk mengelola kemungkinan terjadi reaksi anafilaksis setelah pemberian vaksin. Pengamatan harus dilakukan 30 menit setelah pemberian vaksin.

Dosis dan Posologi

1. Vaksin harus dilarutkan dengan mencampurkan pelarut yang disediakan, kocok sampai larut. Berikan segera setelah dilarutkan.
2. Vaksin harus diberikan secara intramuskular, diluar aspek deltoid.
3. Vaksinasi sekali suntik 0,5 ml. Vaksinasi dilakukan sebelum terjadi epidemi serebrospinal meningitis di musim epidemik.

Efek Samping

Penelitian klinis pada vaksin ini, menunjukkan tidak ada efek samping lokal atau sistemik yang berat.

Reaksi di tempat suntikan : dalam waktu 24 jam setelah vaksinasi, kemungkinan terjadi sedikit rasa nyeri di tempat injeksi, efek samping jarang dilaporkan termasuk efek lokal, pembengkakan ringan, kemerahan dan gatal-gatal, biasanya itu dapat hilang dengan sendirinya dalam 1 - 2 hari.

Reaksi sistemik : umumnya demam dapat terjadi setelah vaksinasi, sebagian besar adalah respon demam ringan (di bawah 37,5°C), biasanya setelah 1 - 2 hari hilang tanpa pengobatan. Bagi penderita yang telah menderita demam lebih dari 48 jam, perawatan simptomatik diperlukan. Reaksi yang merugikan sangat jarang dilaporkan adalah reaksi demam serius yang perlu segera diobati untuk mencegah kejang. Selain itu, demam, kelelahan, mengantuk, mialgia, nyeri perut. Hilangnya nafsu makan, mudah marah dan diare dapat terjadi setelah vaksinasi, efek samping yang sangat sedikit dilaporkan adalah muntah dan ruam, hal ini bisa diatasi dalam keadaan normal, atau perawatan gejala yang diperlukan sesuai dengan keadaan spesifik.

Persentase Efek Samping (%)

Kelompok Test (N=600)

Efek Samping	Jarang %	Ringan %	Berat %
Lokal	30.0	2.0	0.16
Sistemik			
Demam	21.67	7.33	0.33
Sakit kepala	6.67	0.5	0
Lelah	4.50	0.17	0
Mengantuk	3.17	0	0.17
Myalgia	2.00	0.17	0
Sakit pada bagian perut	2.17	0	0
Kehilangan nafsu makan	1.83	0	0
Iritabilitas	1.33	0.33	0
Diare	1.33	0.17	0
Muntah	0.33	0.17	0
Kulit kemerahan	0.17	0	0.17

Ringan: 37.1-37.5 °C, Sedang: 37.6-39.0 °C, Berat: >39.0 °C

Suhu Penyimpanan

Simpan pada suhu 2°C - 8°C, terlindung dari cahaya.
Jauhkan obat dari jangkauan anak-anak.

Kemasan dan Nomor Registrasi

Box, 1 Vial @ 200 µg & 1 Vial Pelarut @ 0,5 ml FORMENING Vaksin,
No. Reg : XXXXXXXXXXXXXXXXXX

Diproduksi oleh

Yuxi Walvax Biotechnology Co., Ltd.

Add : No. 83 South Dongfeng Road, Yuxi, Yunnan Province, China

Diimport & Didistribusikan oleh

PT. Mersi

PT. Mersifarma TM

Sukabumi - Indonesia

FORMENING®**Composition**

Major composition: Group A, C, Y, W135 meningococcal polysaccharide
Diluents: Sterile water for injection

Indication

After vaccination, it can make the body to produce humoral immune response to prevent meningococcal disease caused by epidemic *Neisseria meningitidis* serogroups A, C, Y, and W135.

Contraindications

This vaccine should not be administered to subjects as follows:

1. Subjects with known epilepsy, convulsion, brain disorder or allergic history.
2. Subjects with kidney and heart disease, active tuberculosis.
3. Subjects with acute infectious disease and fever.
4. Pregnancy and animal reproduction studies have not been conducted with this vaccine. It is also not known whether this product can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. As a result, pregnant women are not recommended for vaccination, especially in the first three months.

Warnings & Precautions

1. It should be inspected visually for container integrity, particulate matter and discoloration prior to administration. Do not use after the expiration date. If the vial is broken or any abnormal appearance of the package exists, the vaccine should not be administered.
2. The vaccine should be administered immediately once opened, if it's not used immediately, placing time should not be exceeded over 30 minutes.
3. Pay special attention to avoid the vaccine is injected into intradermal, intramuscular and intravenous ways, since these three clinical studies have not been determined to be safe and effective.
4. Because of endotoxin superposition, this vaccine may not be associated with pertussis vaccine and typhoid bacteria cell vaccine injection at the same time.
5. It is not known whether this vaccine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when vaccine is administered to a nursing woman.
6. Persons who are immunosuppressed, including persons receiving immunosuppressive therapy, may have a diminished immune response to vaccine.
7. It is not indicated for treatment of meningococcal infections, not be able to protect from group B meningococcal, do not provide short-term prevention for infants and children under 2 years old, but can provide short-term protection for 3 months and older children from group A meningococcal, the same as other vaccines which are not be able to provide 100% protection for susceptible populations.
8. Appropriate medical treatment for example epinephrine or other drugs must be available to manage possible anaphylactic reactions following administration of the vaccine, objects after injection should be observed for at least 30 minutes.

Posology/Dosage

1. The vaccine must be reconstituted by mixing the supplied diluents and shaken properly. Administer immediately once reconstituted.
2. The vaccine should be administered intramuscularly in the outer aspect of the deltoid.
3. Vaccinated once with dose of 0.5 ml per person. Vaccination should be completed before epidemic cerebrospinal meningitis epidemic season.

Side Effects

Through clinical research observation of this vaccine, no severe local or systemic adverse reactions are found.

Injection site reactions: within 24 hours after vaccination, slightly pain at injection site may appear, less commonly reported adverse reactions including local, mild swelling, redness and itching, normally it can be resolved spontaneously in 1-2 days.

Systemic reactions: in general fever may be occurred after vaccination, most of which are mild fever response (below 37.5°C), normally it lasts 1-2 days can be relieved, no need for treatment. For those people who have been suffered from fever more than 48 hours, symptomatic treatments are required. Very rare adverse reactions reported as severe fever reactions which need to be treated immediately to prevent fever convulsion. In addition, fever, fatigue, drowsiness, myalgia, abdominal pain. Loss of appetite, irritability and diarrhea may be occurred after vaccination, very few adverse reactions reported are vomiting and rash, it can be relieved under normal circumstances, or symptomatic treatments are required according to the specific circumstances.

The percentage of adverse events (%)

Test group (N=600)

Adverse reactions	Any %	Mild %	Severe %
Local	30.0	2.0	0.16
Systemic			
Fever	21.67	7.33	0.33
Headache	6.67	0.5	0
Fatigue	4.50	0.17	0
Drowsiness	3.17	0	0.17
Myalgia	2.00	0.17	0
Abdominal pain	2.17	0	0
Loss of appetite	1.83	0	0
Irritability	1.33	0.33	0
Diarrhea	1.33	0.17	0
Vomiting	0.33	0.17	0
Rash	0.17	0	0.17

Light: 37.1-37.5°C, Moderate: 37.6-39.0°C, Severe: >39.0°C

Storage

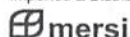
Store at temperature 2°C - 8°C, protect from light.
Keep out of the reach of children.

Package and Registration Number

Box, 1 Vial @ 200 µg & 1 Vial Solvent @ 0.5 ml of FORMENING Vaccine,
Reg. No: XXXXXXXXXXXXXXXXXX

Manufactured by

Yuxi Walvax Biotechnology Co., Ltd.
Add: No. 83 South Dongfeng Road, Yuxi, Yunnan Province, China
Imported & Distributed by



PT. Mersifarma TM
Sukabumi - Indonesia

0000-000000-00

UN4INF2008

ARTWORK DESIGN STANDARD INSERT

FORMENING

Size (L x W) 180 x 200 mm

Material	
HVS Paper 60g	
Packs/size/Primary	
Vial @ 0.5 ml	
Primary	
Vial	
No. Reg	

Font / Back	
Type Font	
Product Name	Another Font
Helvetica Narrow, Bold	Helvetica Narrow
10pt	7pt

mersi	
16 x 4mm (LxH)	TEXT Black
Material Code	
UN4INF72008	



PT. MERISABRITA TRIMAYU PERKUSANA
DEPARTMENT DESIGN & PACKAGING

Date of use: 14/01/2015
(DD-MM-YYYY)

180

FORMENING®

Composition
Major components: Glass A, C, Y, W125, non-aqueous polyacrylate
Dispersant: Emulsifier, stabilizer, surfactant
Initiator: Peroxide, cross-linker, stabilizer, surfactant
Preservative: Antimicrobial, stabilizer, surfactant
Packaging: Glass A, C, Y, W125, non-aqueous polyacrylate

Contraindications

This vaccine should not be administered to subjects at following:
1. Subjects with known hypersensitivity, including but not limited to egg, gelatin, or any other component of the vaccine.
2. Subjects with a history of severe allergic reaction to any component of the vaccine.
3. Subjects with a history of severe allergic reaction to any component of the vaccine.
4. Subjects with a history of severe allergic reaction to any component of the vaccine.
5. Subjects with a history of severe allergic reaction to any component of the vaccine.

Warnings & Precautions

1. It is essential to inspect the vaccine vial for any visible particles, discoloration, or other signs of contamination. Do not use the vaccine if any of these signs are present.
2. The vaccine should be administered immediately after receipt, if it is not used immediately, it should be stored in a cool, dry place.
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Precautions/Contraindications

1. The vaccine must be administered by using the supplied diluent and vial.
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Side Effects
Through clinical research observation of this vaccine, no severe local or systemic adverse reactions were observed. The most common side effects observed were mild to moderate fever, headache, and muscle pain. These side effects were usually self-limiting and resolved within 24 hours.

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Warnings & Precautions

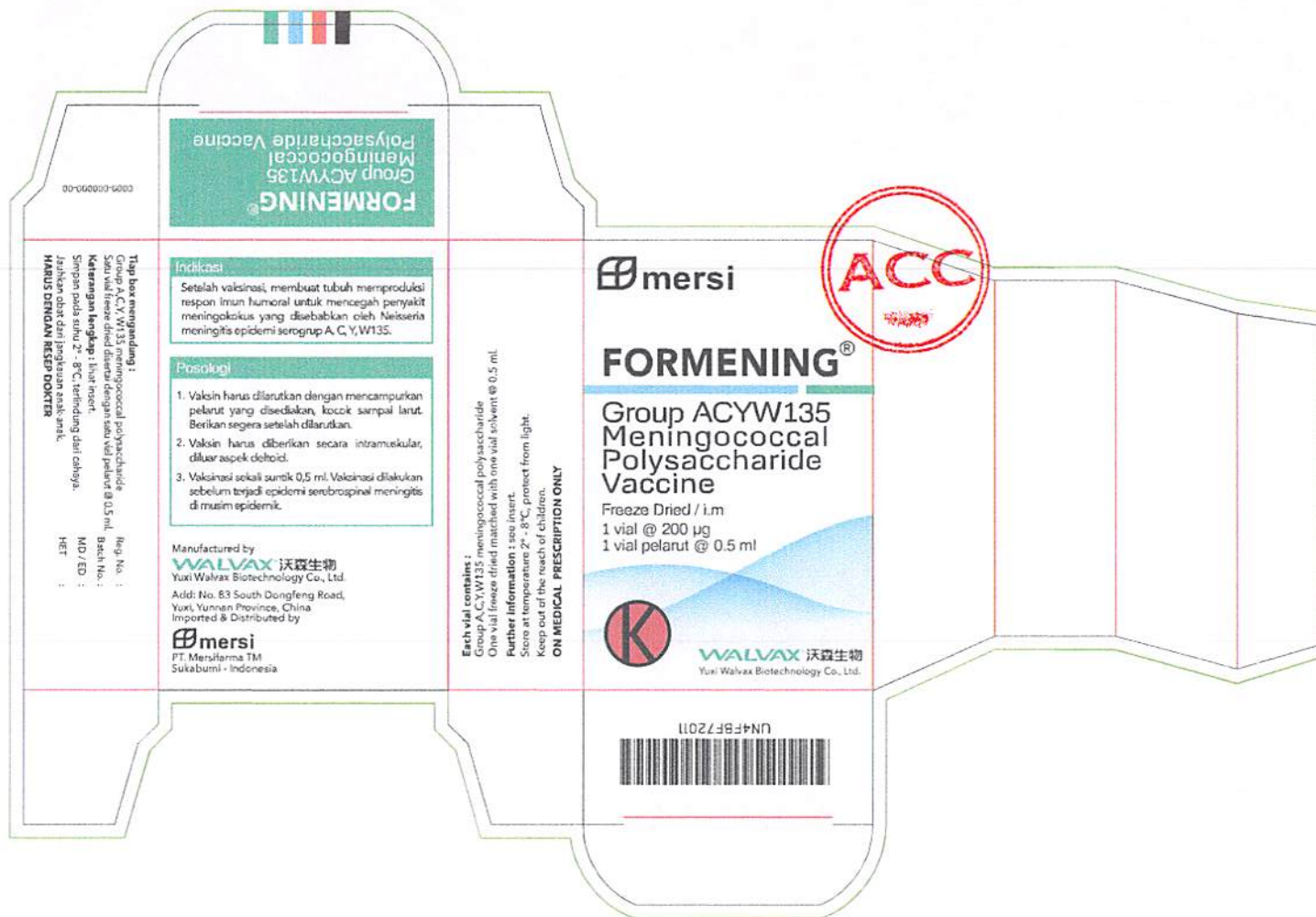
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Not at scale - Size in mm

STANDARD SECONDARY 2013



ARTWORK DESIGN STANDARD FOLDING BOX



PT. MERSIFARMA TRIAMKU MERCUSANA
DEPARTMENTEN DESIGN & PACKAGING

Date of use: 14/01/2015

(AUA-777-00)

Front / Rear Panel		Left / Right Side Panel		Top Closure Panel		Back / Rear Panel	
Type Font		Type Font		Type Font		Type Font	
Product Name	Another Font	Another Font	Product Name	Active Ingredient	Another Font	Another Font	Another Font
Avenir, Bold	Avenir Next	Avenir, Regular	Avenir, Bold	Foodbar Pro, Bold	Avenir, Bold	Foodbar Pro, Bold	Avenir, Regular
16pt	12 8pt	5pt	10pt	8pt			5pt

FORMENING		
Dimension (L x W x H) 43 x 20 x 67 mm		
Material	Packsize/Primary	Primary
Ivory 300g	1 vial @ 200 µg & 1 Vial pelarut @ 0.5ml	Vial @ 0.5ml

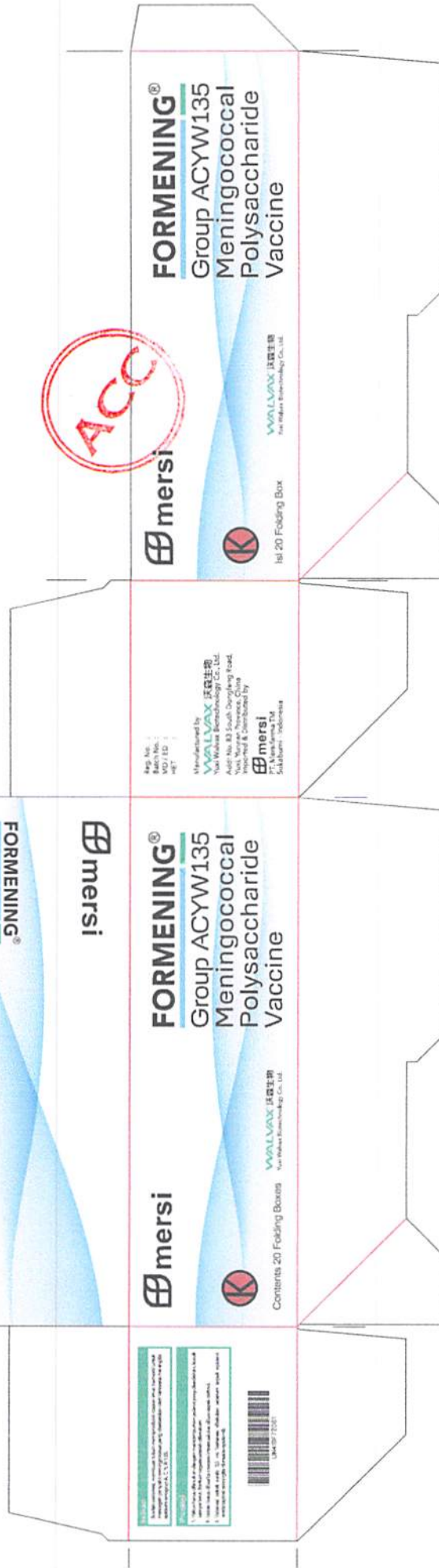
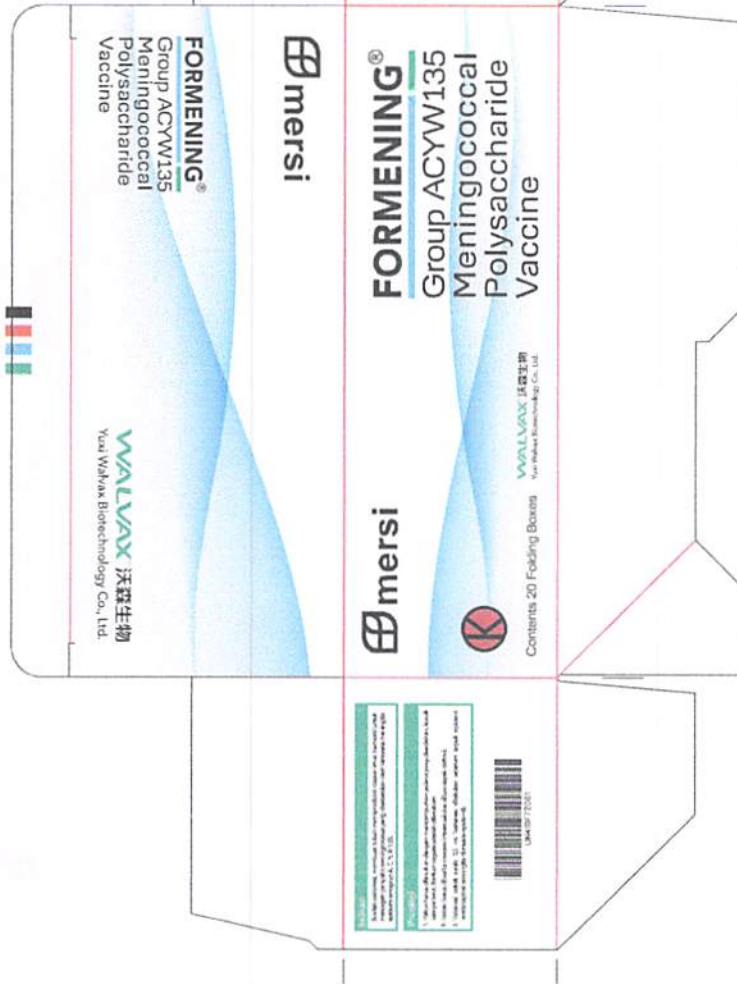


SKETCHES



Actual Size - Size in mm

	Cut				 WALVAX (株式会社) The Kansai Breaching Co., Ltd.					Material Code  UH418/2231
	Crease									
	Outside Bleed	Ø10mm	20 x 5mm (LxH)	12 x 3mm (LxH)	24 x 4mm (LxH)	GREEN TC 3814	GRADIENT/BLUE TC 3502	RED TC 1315	Black	
	Glue Flap	Finishing : Full Varnish Type Water Base								



ARTWORK DESIGN STANDARD ETIKET

FORMENING (Liquid - Powder)

Size (L x W) 42 x 14 mm

Material
Sticker High Gloss Paper S1010 BG 40 WH1

Packsize/Primary
Vial @ 0.5 ml

Primary

No. Reg

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Type Font	
Product Name	Another Font
Avenir, Bold	Footbar Pro
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3.5pt	3.5pt



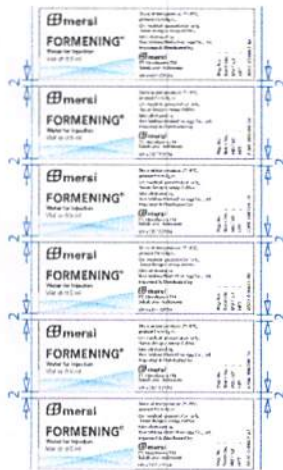
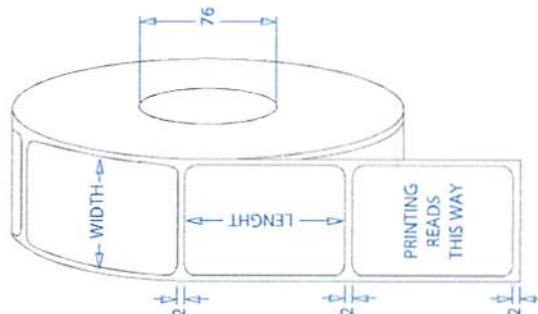
PT. MERISAPARMA TIRIKAU MERISIDANA
ENTERPRISE DESIGN & PACKAGING

Date of use: 14/01/2015

(DD-MM-YYYY)

SKETCHES

ROLL PRINTED ETIKET GAP ~ DIE CUT



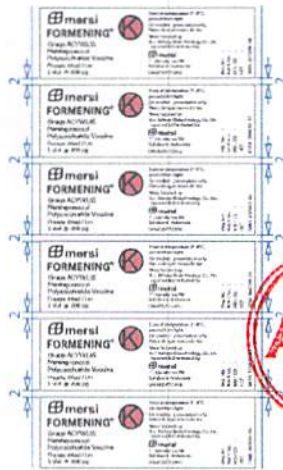
Liquid



Powder



Preview Gap Roll



ACC



Preview 200 %

Actual size - Scale 100 %

	Ø6mm	9.6 x 2.4mm (LxH)	BLUE TC 3502	RED TC 1315	GREEN TC 4206	Black	Material Code (Etiket Liquid)	UN4EDF72004	Material Code (Etiket Powder)	UN4EDF72005	Finishing	Full Varnish Waterbase
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ARTWORK DESIGN STANDARD INNER BOX



PT. MERIDIUM TIRAMU MERUSANA
DEPARTEMEN DESIGN & PACKAGING

Date of use: 14/01/2015
(DD-MM-YYYY)

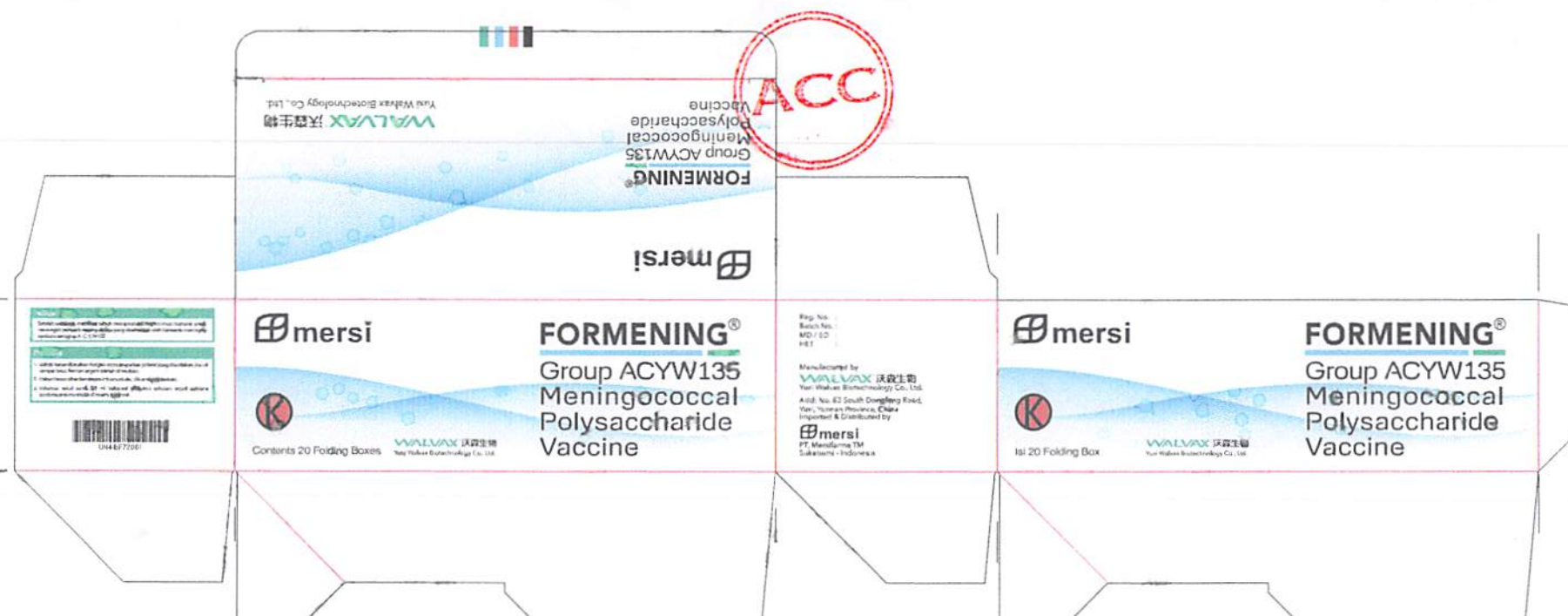
FORMENING

Dimension (L x W x H) 220 x 90 x 70 mm

Material	Packsize/Primary	Primary	No. Reg
Ivory 300g	20 Folding Box	Vial @ 0.5ml	

Front & Back / Rear Panel			Left / Right Side Panel	Top Closing Panel	
Type Font			Type Font	Type Font	
Product Name	Active Ingredient	Another Font	Another Font	Product Name	Active Ingredient
Avenir, Bold	Footbar Pro, Bold	Avenir Next	Avenir, Regular Bold	Avenir, Bold	Footbar Pro, Bold
35pt	28pt	15pt	8pt	10pt	8pt

SKETCHES



Not at scale - Size in mm

Cut	Crease	Outside Bleed	Glue Flap	Finishing : Full Varnish Type Water Base	Material Code
Ø15mm	47 x 11mm (LxH)	24 x 6mm (LxH)	70 x 12mm (LxH)	47 x 7.8mm (LxH)	41.5 x 7mm (LxH)
				GREEN TC 3914	GRADIENT/BLUE TC 3502
					RED TC 1315
					Black
					UM4-BF72001