dexa group
Serempak Bergerak
Sinergi untuk masa depan

Dexa Medica
Expertise for the Promotion of Health

Label Tepat, Obat Selamat: Manajemen Risiko *Look Alike Sound Alike (LASA)* dari Hulu *(Upstream)*

- Perspective Industri Farmasi -

Apt. Evi Dwi Nofiarny Zulkarnain, Ssi, M.Biomed

PIT HISFARSI, 26 Juni 2026

Label Tepat, Obat Selamat: Manajemen Risiko LASA dari Hulu
- Perspective Industri Farmasi -

Outline:

- Background:
  - Facts Check
  - Medication Error – LASA
- Guidance & References: Mitigation of Medication Error
- Mitigasi dari Industri Farmasi
- Sinergi Industri dan Rumah Sakit
- Wrap-up / Take home messages

Cek Fakta: Keluhan LASA melalui Media Sosial

Ondansetron HCl Dihydrate 8 mg

Rocuronium Bromide 10 mg

Diclofenac Sodium 50 mg

Fenofibrate 300 mg

Gabapentin 300 mg

Spironolactone 25 mg

Spironolactone 100 mg

Propranolol 10 mg

Pioglitazone HCl 30 mg

Gliquidone 30 mg

Glimepiride 4 mg

Atorvastatin Calcium Trihydrate 20 mg

Pioglitazone HCl 30 mg

Dexa Medica

dexa group
Serempak Bergerak
Sinergi untuk masa depan

Medication Error

"Any **preventable event** that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer"

**The National Coordinating Council for Medication Error Reporting and Prevention*.

Jenis-jenis medication error (kesalahan pengobatan) meliputi:

- kesalahan peresepan (**prescribing error**)
- kesalahan menyalin resep (**transcribing error**)
- kesalahan penyiapan obat (**dispensing error**)
- dan kesalahan pemberian obat (**administration error**).

LASA
Look-alike, sound-alike

Medication errors that occur when medicines have **similar-looking or similar-sounding** names, and/or **shared features** of products or packaging are called **LASA errors.**

European Journal of Clinical Pharmacology (2018) 74:985–993
https://doi.org/10.1007/s00228-018-2471-z

REVIEW

A systematic literature review on strategies to avoid look-alike errors of labels

Karin H. M. Larmené-Beld[1,2] · E. Kim Alting[2] · Katja Taxis[2]

Received: 8 January 2018 / Accepted: 25 April 2018 / Published online: 12 May 2018

Abstract

Purpose Unclear labeling has been recognized as an important cause of look-alike medication errors. The aim of this literature review is to systematically evaluate the current evidence on strategies to minimize medication errors due to look-alike labels.

Methods A literature search of PubMed and EMBASE for all available years was performed independently by two reviewers. Original studies assessing strategies to minimize medication errors due to look-alike labels focusing on readability of labels by health professionals or consumers were included. Data were analyzed descriptively due to the variability of study methods.

Results Sixteen studies were included. Thirteen studies were performed in a laboratory and three in a healthcare setting. Eleven studies evaluated Tall Man lettering, i.e., capitalizing parts of the drug name, two color-coding, and three studies other strategies. In six studies, lower error rates were found for the Tall Man letter strategy; one showed significantly higher error rates. Effects of Tall Man lettering on response time were more varied. A study in the hospital setting did not show an effect on the potential look-alike sound-alike error rate by introducing Tall Man lettering. Color-coding had no effect on the prevention of syringe-swaps in one study.

Conclusions Studies performed in laboratory settings showed that Tall Man lettering contributed to a better readability of medication labels. Only few studies evaluated other strategies such as color-coding. More evidence, especially from real-life setting is needed to support safe labeling strategies.

Keywords Look-alike · Label · Tall Man · Color coding · Medication

Tall Man Lettering (TML)

- Enam (6) studi menunjukkan tingkat kesalahan yang lebih rendah dengan strategi TML.
- Studi laboratorium mengonfirmasi bahwa TML berkontribusi pada keterbacaan label yang lebih baik.

Keterbatasan:

- Dampak terhadap waktu respons bervariasi.
- Satu studi di rumah sakit **tidak menunjukkan efek signifikan** dalam mengurangi potensi tingkat kesalahan *look-alike sound-alike*.

Kode Warna:

- Bukti pendukung sangat sedikit.
- Satu studi menunjukkan **kode warna tidak efektif** mencegah pertukaran spuit (*syringe-swaps*).

Strategi Lain (Simbol):

- Penggunaan simbol pada label menunjukkan peningkatan identifikasi obat yang benar pada pasien lansia.

- **Latar belakang label yang kontras** (putih vs transparan) meningkatkan skor pembacaan yang benar.

doi: 10.1016/j.bja.2021.09.030
Advance Access Publication Date: 2 November 2021

Non-standardised colour coding of anaesthetic ampoule labelling: a dangerous practice?

James R. Skelly*, Darragh O'Reilly and Vandan Ward

St. Vincent's University Hospital Group, Department of Anaesthesia, Critical Care and Pain Medicine, Dublin, Ireland

*Corresponding author. E-mail: jamesrichardskelly@gmail.com

Keywords: ampoule labelling; anaesthetic drugs; colour coding; medication safety; patient safety; vial labelling

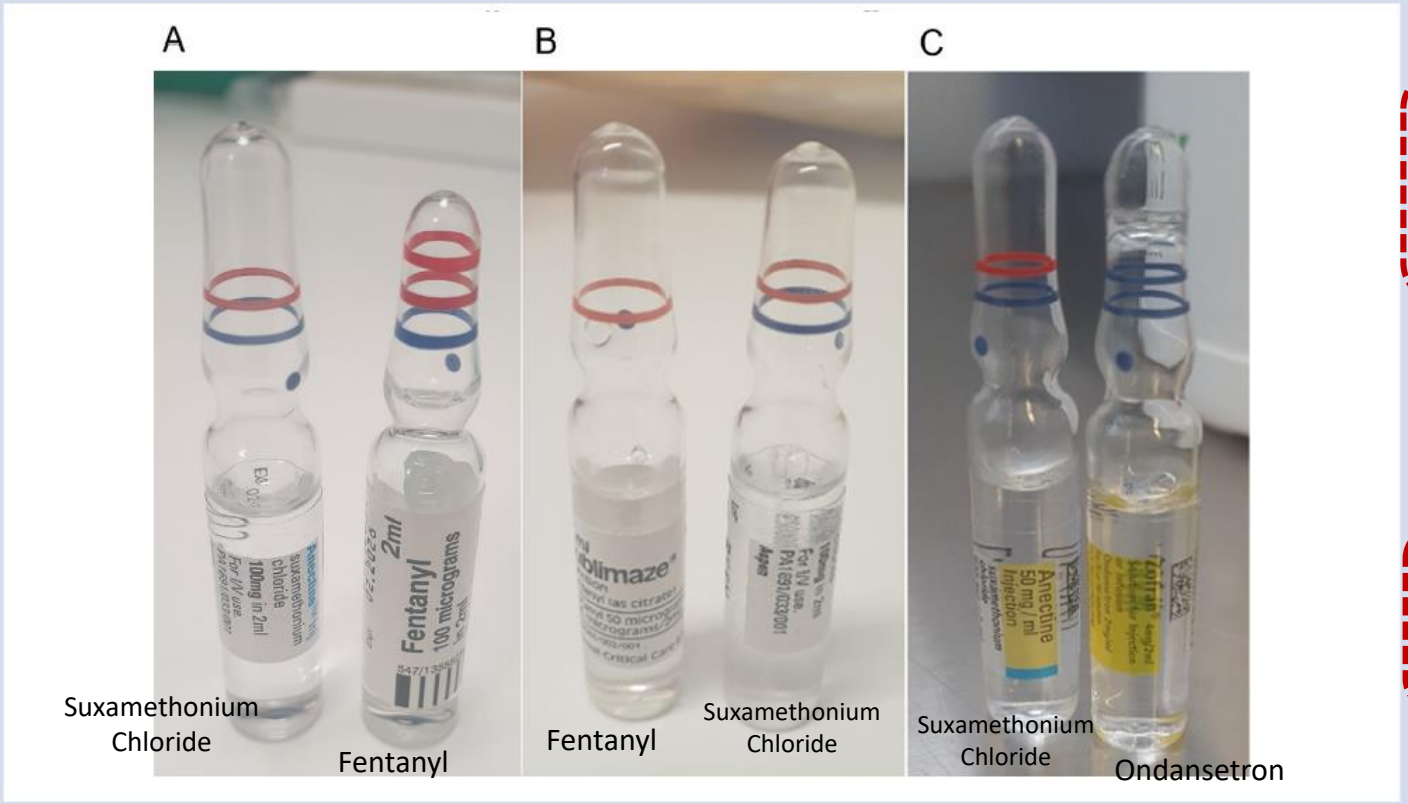


Fig 1. Look-alike medication: accidental commonality of colours between medication classes. (a) Suxamethonium chloride on the left and fentanyl on the right. (b) Fentanyl on the left and suxamethonium chloride on the right. (c) Suxamethonium chloride on the left and ondansetron on the right. 592×396 mm (130×130 DPI).

- Companies apply **painted rings to the top of ampoules**, which would seem the perfect opportunity to add the colour coding system. The markings are indeed applied to facilitate recognition of the contents of the ampoule, however, these are **not for the benefit of the end user.** Rather, they are provided to aid recognition **by scanning machines during the manufacturing process**.

- There is a need to make established safety mechanisms as robust as possible.

- As human factors typically favor **multimodal safety approaches that do not rely on a single strategy,** barcode-based identification of medications is an important and complementary safety strategy that should also be incorporated.

Guidance & References

1. **Medication without harm, Policy brief,** World Health Organization 2023 (https://www.who.int/publications/i/item/9789240062764)
2. **Medication safety for look-alike, sound-alike medicines**, World Health Organization 2023 (https://www.who.int/publications/i/item/9789240058897)
3. Safety Considerations for **Product Design to Minimize Medication Errors** - Guidance for Industry, USFDA Center for Drug Evaluation and Research (CDER), April 2016
4. Safety Considerations for **Container Labels and Carton Labeling** Design to Minimize Medication Errors, Guidance for Industry, USFDA Center for Drug Evaluation and Research (CDER), May 2022

WHO's third Global Patient Safety Challenge: Medication without harm

Strategies to address LASA errors are considered below:

Medicines: Medicines as products;

Patients and the public:

Role of patients and family members in preventing LASA errors;

Health care professionals:

Role of health and care workers in preventing LASA errors;

Systems and practices of medication:

Health care systems and practices to be addressed.

https://www.who.int/initiatives/medication-without-harm

Medication safety for look-alike, sound-alike medicines, World Health Organization 2023

Stages of medication use at which LASA errors can occur:

Prescribing

- **Illegible or poorly legible** handwritten prescriptions
- Verbal and telephone orders: **sound alike**
- Inappropriate use of **error-prone abbreviations**

Transcribing or documenting

- **Incorrect transcription** of a LASA medicine name
- **inappropriate abbreviations** in transcribing,
- Incorrect interpretation of **sound-alike** LASA

Dispensing

- **Storage** of LASA medicines on the **same shelf** next to each other
- **Changing the appearance** or packaging of medicines, making them similar to other products;
- **Failure to double-check** accurately during dispensing due to time pressure

Administering

- **Unfamiliarity with medicines**, leading to selection of a look-alike product
- Selection of a product according to **familiarity with the packaging or strength** rather than confirming and double-checking the medicine name and the dose;

Monitoring

- **Failure to monitor outcomes** of medication by relevant clinical observations or biochemistry.

Medication safety for look-alike, sound-alike medicines, World Health Organization 2023

Actions Suggested For Reducing LASA Errors

Actions on medicines as products

1. Use **"tall man" lettering (TML)** to label medicines with which a risk has been identified.
2. **Segregate storage** of identified LASA medicine pairs or groups.
3. Develop and use tools and skills to identify LASA medicine pairs to prevent registration of such products, minimize approval of several strengths of the same medicine, and approve only dosage forms and strengths with different appearances and packaging.
4. **Identify LASA medicines** when including them in formularies and during purchase for institutions and countries.
5. **Prioritize LASA errors involving high-risk medicines** with greater potential for severe harm.
6. Label all raw and processed T&CM products including the botanical names of plants

Actions by patients, families and caregivers

1. **Know each medicine** prescribed, dispensed and administered, including the name, indication, strengths of medicines dispensed and the dose to be used.
2. Be **aware of potential errors** with LASA medicines, and be vigilant about such errors.
3. Learn to **label and store medicines appropriately at home** to avoid LASA errors with the medicines dispensed to the patient.
4. **Check with the health care provider if in doubt**, about a prescribed, dispensed or administer LASA medicine.

Actions by health and care workers

1. Educate themselves and the patients about the LASA medicines **that are prone to errors**, and address them in practice.
2. **Pay attention to LASA medicines** when prescribing, dispensing and administering medicines and during medication reconciliation at transitions of care.
3. **Use generic names** during prescribing and transcribing to minimize errors due to brand name confusion.
4. **Write legibly** when prescribing and transcribing.
5. Attach clear **labels for LASA medicines**, **with TML for medicines that could be confused**.

Actions by health care facilities, institutions and countries

1. Promote a just, **trusting culture** in facilities so that staff are at ease in discussing and reporting LASA medication errors and near misses.
2. **Identify the most common pairs of LASA medicines** in the country or organization, and update the list regularly.
3. **Label clearly, use TML, and segregate storage of LASA medicines**.
4. Take measures **to avoid interrupting and distracting** health and care workers while they are dispensing and administering medicines.
5. **Include technology based solutions,** such as CPOE and barcoded dispensing, to avoid LASA errors.
6. Apply **quality control measures** to ensure proper use of authentic herbal medicines.

Medication safety for look-alike, sound-alike medicines, World Health Organization 2023

Some LASA Medicine Names Recommended For “Tall Man” Lettering

Established name	Recommended “tall man” lettering
Acetohexamide Acetazolamide	acetoHEXAMIDE acetaZOLAMIDE
Bupropion Buspirone	buPROPion busPIRone
Chlorpromazine Chlorpropamide	chlorproMAZINE chlorproPAMIDE
Clomiphene Clomipramine	clomiPHENE clomiPRAMINE
Cyclosporine Cycloserine	cycloSPORINE cycloSERINE
Daunorubicin Doxorubicin	DAUNOrubicin DOXOrubicin
Hydralazine Hydroxyzine	hydrALAZINE hydrOXYzine
Hydromorphone	HYDROmorphone
Medroxyprogesterone	medroxyPROGESTERone
Methylprednisolone Methyltestosterone	methylPREDNISolone methylTESTOSTERone

Source: Food and Drug Administration *(5)* and ISMP *(6)*.

Huruf atau Suku kata **Awal** dan **Akhir** nya **SAMA**

Medication safety for look-alike, sound-alike medicines, World Health Organization 2023

The guidance recommendations include:

- Tablets and other oral dosage forms should have **distinct and legible imprint codes** so healthcare providers and consumers can verify the drug product and strength.
- Oral syringes and other dosing devices co-packaged with a liquid oral dosage form should be appropriate for **the doses to be measured**.
  - **Dosing errors** have been reported when an oral syringe is labeled in milligrams but the dose is prescribed in milliliters.
- The **package design should protect the consumer against incorrect use.**
  - Medications applied to the skin (topical) should not be packaged in **containers that look like** the containers usually associated with eye, ear, nasal, or oral products.
  - **Similar looking containers** have resulted in people putting a topical product in the eye, ear, nose, and mouth.

Safety Considerations for Product Design to Minimize Medication Errors

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

April 2016
Drug Safety

Safety by Design: A Systems Approach to Medication Error Prevention

Premarketing Risk assessment

Drug product design features that predispose end users to medication errors **may not always be overcome** by product labeling or health care provider or patient education.

Medication errors can be minimized by conducting **premarketing risk assessments to evaluate how users will interact with the drug product within various environments** of use within the medication use system.

Change, CAPA & QRM Management

Error prevention in manufacturing is not a new concept. Corrective and Preventive Action, Change Control, and Quality Risk Management are well-recognized elements of **current good manufacturing practice (CGMP)** for drug products that focus on investigating, understanding, and correcting identified risks and managing the changes necessary for correction to prevent their recurrence while preventing unintended consequences.

Safety Considerations for Product Design to Minimize Medication Errors - Guidance for Industry, USFDA

Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

May 2022
Drug Safety

GENERAL CONSIDERATIONS

A. **Poor Design** of Product Container Labels and Carton Labeling Can **Obscure Critical Safety Information**.

B. **Risk Assessment** During the Design Stage Can Reduce the Risk of Medication Errors.

C. Critical Product Information Should Appear on the **Principal Display Panel**.

D. Container Labels and Carton Labeling Should be **Legible, Readable, and Understandable**. ❤

E. **Avoid** Look-Alike Container Labels and Carton Labeling. ❤

Please check USFDA website for full information: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-considerations-container-labels-and-carton-labeling-design-minimize-medication-errors

Container Labels & Carton Labeling Should be Legible, Readable, & Understandable

1. Container **Label Size**:
    - **The size** of the container label greatly influences the overall container label design.
2. Text **Size and Style**:
    - should choose **fonts** that are **not lightweight** (i.e., thin font) or **condensed** such that legibility is compromised.
3. **Contrast** of Text and Background Color
    - should be chosen to afford adequate legibility of the text.
4. Information **Crowding and Visual Clutter**
    - When container labels or carton labeling are crowded, text size and prominence are generally decreased, and important information may be difficult to read or easily overlooked.
5. **Error-Prone** Abbreviations, Acronyms, and Symbols
    - Certain abbreviations, acronyms, and symbols should not be used on container labels or carton labeling because they are frequently misinterpreted and can lead to medication errors that result in patient harm.

Avoid Look-Alike Container Labels and Carton Labeling

General Consideration:

1. ***Corporate Trade Dress***
   - Dapat menggunakan warna **khusus Company** untuk membedakan dari produk Farmasi lainnya.
   - Tetap harus memastikan: **Label terlihat jelas, terbaca,** dan tidak menimbulkan kebingungan.

2. ***Use of Color***
   - Perhatian pada: nama produk, kekuatan/strength, & peringatan atau perhatian khusus.
   - Harus tetap diingat:
     - Warna dapat dipersepsi berbeda oleh tiap orang, termasuk ada yang color vision deficiency;
     - Identifikasi produk berdasarkan warna **dapat menggantikan keharusan membaca** label dengan seksama, sehingga **harus dihindari**.
     - **Keterbatasan ketersediaan jenis warna.**
     - Warna tergantung kondisi pencahayaan.
   - Cara lainnya: cetak tebal/bold, pemberian tanda box/garis, & jenis font.

Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors, USFDA May 2022

dexa group

Serempak Bergerak

Sinergi untuk masa depan

- ≥ 1500 products HALAL certified (99.9%)

HALAL INDONESIA

State-of-the-Art Facilities

dexa group
Serempak Bergerak
Sinergi untuk masa depan

R&D Centers:

Dexa Development Center
Cikarang

Dexa Laboratories of Biomolecular Sciences
Cikarang

Manufacturing Facilities:

Solid and Cephalosporin Production
PT Dexa Medica
Palembang

Oral Solid & Syrup Production
PT Beta Pharmacon
Karawang

Solid, Liquid, Injectables and API Production
PT Ferron Par Pharmaceuticals
Cikarang

API OMAI (Herbal/ Protein) and Oral Solid FG OMAI
Cikarang

Oncology Injectables Production
PT Fonko International Pharmaceuticals
Cikarang

Oral Solid Pharma and Oral Liquid OMAI
PT Anugrah Amartha Global
Bogor

Expertise for The Promotion of Health

Medical Device Production
PT Deca Metric Medica
Cikarang

Distribution Facilities:

National Distribution Center
PT Anugrah Argon Medica
Cikarang

Certifications:

Journey of Dexa Group Packaging Design

Corporate Design:

Objective:
To create good Pharma Packaging

Clear, patient-centric, readable, intuitive, consistent, digital-friendly

Runs efficiently across multiple sites, reduces changeovers

Protects the drug, manufacturable, compliant, reduces errors, sustainable

Differentiated, trusted, user-friendly, cost-competitive, scalable, strong brand block across SKUs

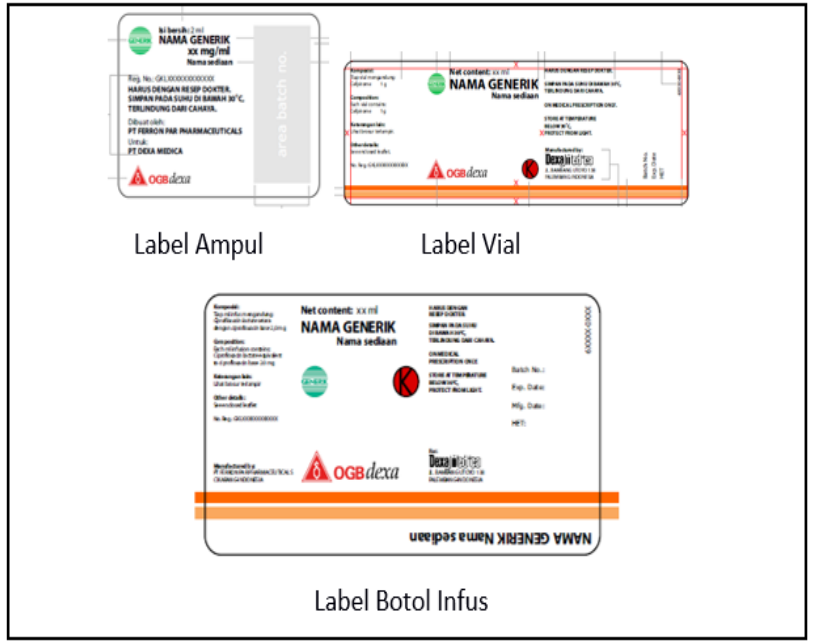
Design the Product Label & Packaging that:

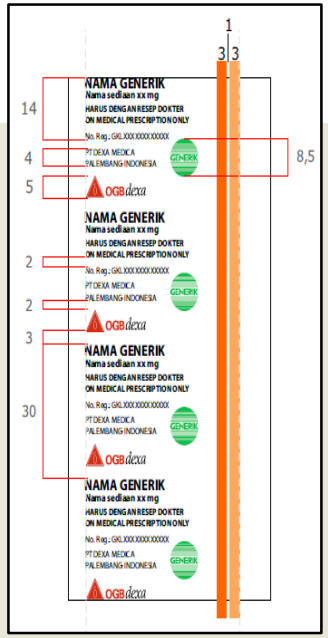
- ✓ Meet BPOM/Health Authorities and Halal/BPJS requirements.
- ✓ Have specific Corporate Trade Dress: **RED**
- ✓ Have Security Features to mitigate falsified products
- ✓ Avoid LASA: i.e. Design arrangement, Font type & size
- ✓ Support ESG Green Pharmacy: Recycle & Recyclable

dexa group Serempak Bergerak
Sinergi untuk masa depan

RIWAYAT PERUBAHAN KEMASAN OGB DEXA GROUP

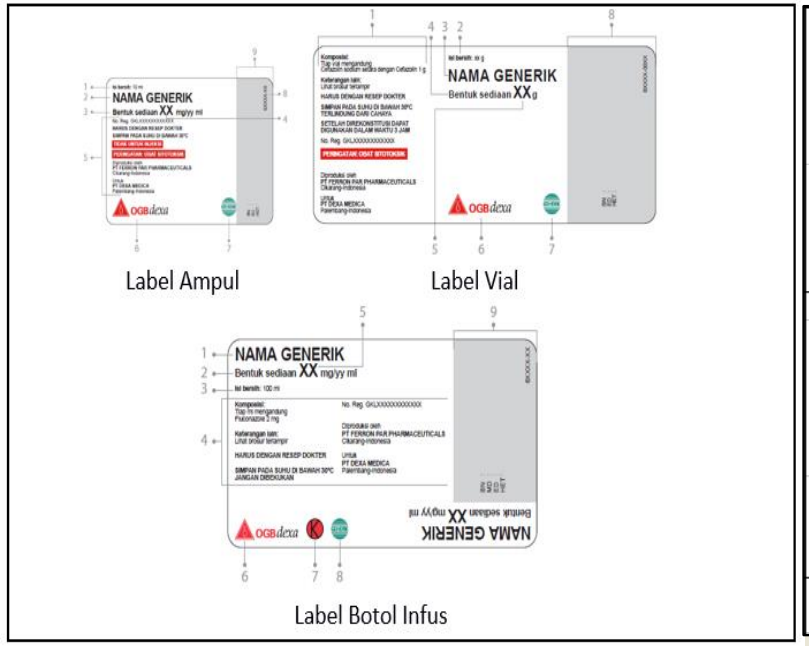
1991-2015: Desain Konsep warna

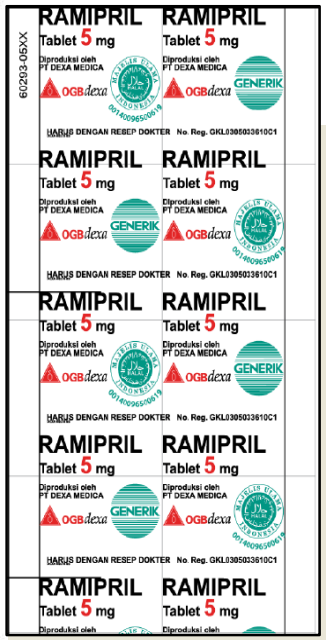




- Berdasarkan SK Menkes tahun 1990
- Pengajuan kombinasi lis warna ke BPOM

2016- 2022: Desain polos





- Kemasan polos, hanya 3 warna dasar (hitam-nama produk, merah- logo OGB dan obat keras, hijau-logo halal dan generik)

Note: JKN dimulai Januari 2014

OGB*dexa*

Segitiga Merahnya, Bikin Hemat

PT Dexa Medica berkomitmen untuk menjaga kenyamanan dalam penggunaan produk OGB*dexa* termasuk selalu berupaya memperbaiki desain kemasan produk OGB*dexa* dengan menitikberatkan pada **kejelasan dan keterbacaan** untuk menghindari dan mencegah potensi LASA dengan detil sebagai berikut:

a. Desain warna merah

Perubahan dilakukan untuk desain yang sebelumnya **polos menjadi warna merah** dengan tujuan untuk **mencegah kemiripan rupa (*look alike*)** OGB*dexa* dengan **obat generik yang lain**.

b. Keterbacaan Nama Produk dan Kekuatan (*strength*)

- Perubahan **ukuran huruf (*font*)** baik untuk nama produk dan kekuatan dengan *font* **yang lebih besar agar lebih jelas terbaca**.
- Pemberian ***background* putih dengan tulisan hitam** pada **Nama Produk** agar **lebih jelas terbaca.**
- Pemberian ***background* putih dengan tulisan berwarna** untuk membedakan **Kekuatan (*strength*)** produk agar lebih jelas terbaca.

Change Management

Dilakukan sesuai Regulasi, CPOB dan bertahap

- **Identifikasi dan Dokumentasi Usulan Perubahan**: alasan perubahan, deskripsi rinci, dan potensi dampaknya terhadap kualitas produk, peraturan, dan status validasi.
- **Peninjauan dan Analisis Dampak**: tim multidisiplin yang kompeten untuk menganalisis potensi risiko dan dampaknya terhadap proses dan produk yang sudah tervalidasi.
- **Persetujuan**: persetujuan dari yang berwenang: BPOM dan Jaminan Mutu (Quality Assurance).
- **Perencanaan Implementasi**: jadwal, tanggung jawab personel, kebutuhan pelatihan, dan pembaruan dokumen terkait.
- **Validasi dan Verifikasi**: Jika perubahan signifikan memengaruhi kualitas produk, proses yang diubah mungkin memerlukan validasi atau verifikasi tambahan.
- **Sosialisasi dan Pelatihan**: dilatih dan disosialisasikan mengenai prosedur baru sebelum perubahan diimplementasikan.
- **Evaluasi Pasca-Implementasi (Tindak Lanjut)**: memastikan perubahan berjalan efektif, tidak menimbulkan masalah baru, dan tujuan perubahan tercapai.
- **Penyimpanan Dokumentasi**: Seluruh dokumentasi terkait proses manajemen perubahan, harus disimpan dengan tertib dan mudah ditelusuri.

Manajemen perubahan dalam GMP bertujuan untuk mempertahankan kondisi terkendali (***state of control***) di seluruh aspek produksi dan memastikan kualitas produk tetap terjamin.

Wrap-up

1. Solusi pencegahan Kesalahan Pengobatan (Medication errors) akibat LASA perlu **pendekatan dari berbagai faktor** dan belum ada solusi tunggal yang robust.
2. Kesalahan Pengobatan **dapat dicegah dengan dukungan dan kerjasama** dari berbagai pihak (BPOM/Regulator – Nakes/Pelayanan Kesehatan – Industri Farmasi – Pasien/Masyarakat)
3. Industri Farmasi lakukan upaya pencegahan kesalahan pengobatan dengan menerapkan prinsip ***Good Manufacturing Practices*, dan *Safety by Design***.
4. Kemasan **OGBdexa berwarna merah** dan kemasan dirancang untuk membantu **Keterbacaan Nama Produk dan Kekuatan (*strength*)** dengan lebih baik.
5. Implementasi perubahan perlu mengikuti Regulasi yang berlaku dengan mempertimbangkan efisiensi produksi dan kontinuitas ketersediaan obat di masyarakat, serta dilakukan evaluasi efektivitas perubahan.


beta pharmacon
Fonko
Dexa Medica
PT FERRON PAR PHARMACEUTICALS
dexa group
Terima kasih
Jutaan cara inovasi dilakukan
Ratusan ribu dosis obat telah diformulasi
Demi pastikan ribuan produk kami berkhasiat, aman, halal dan terpercaya
Karena kami percaya, 1 DETIK berhargamu takkan terulang
Dexa #CerminanKualitas