KEMENTERIAN KESIHATAN MALAYSIA
HOSPITAL SEGAMAT

PERSATUAN FARMASI SEGAMAT

BULETIN FARMASI

Bil. 1/25

Hospital Segamat

Medication Error(ME) & ME Reporting

ME & ADR Analysis 2024

LASA Medications

Brand Changes

Pindaan Formulari Hospital

Pindaan FUKKM

NPRA Safety

Pharmacy Activities

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MEDICATION ERRORS

DEFINITION

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

Actual error: Medication errors that reached to patient

Near miss error: Potential to cause harm but did not reach patient by chance or intercepted in medication use process

TYPES OF MEDICATION ERROR

prescribing error	Incorrect drug product selection (based on indications, contraindications, known allergies, existing drug therapy, and other factors), dose, dosage form, quantity, route of administration, concentration, rate of administration, or instructions for use of a drug product ordered or authorized by physician (or other legitimate prescriber); illegible prescriptions or medication orders that lead to errors.
Omission error	The failure to administer an ordered dose to a patient before the next scheduled dose or failure to prescribe a drug product that is indicated for the patient. The failure to administer an ordered dose excludes patient's refusal and clinical decision or other valid reason not to administer
Wrong time error	Administration of medication outside a predefined time interval from its scheduled administration time (this interval should be established by each individual healthcare facility)
Unauthorised drug error	Dispensing or administration to the patient of medication not authorised by a legitimate prescriber.
Dose error	Dispensing or administration to the patient of a dose that is greater than or less than the amount ordered by the prescriber or administration of multiple doses to the patient, i.e. one or more dosage units in addition to those that were ordered.
Dosage form error	Dispensing or administration to the patient of a drug product in a different dosage form than that ordered by the prescriber.
Drug preparation error	Drug product incorrectly formulated or manipulated before dispensing or administration
Route of administration error	Wrong route of administration of the correct drug.
Administration technique error	Inappropriate procedure or improper technique in the administration of a drug other than wrong route.
Deteriorated drug error	Dispensing or administration of a drug that has expired or for which the physical or chemical dosage-form integrity has been compromised.
Monitoring error	Failure to review a prescribed regimen for appropriateness and detection of problems, or failure to use appropriate clinical or laboratory data for adequate assessment of patient response to prescribed therapy
Compliance error	Inappropriate patient behavior regarding adherence to a prescribed medication regimen
Other medication error	Any medication error that does not fall into one of the above predefined types.

CLASSIFICATION OF MEDICATION ERROR SEVERITY

NO ERROR	
Category A	Potential error, circumstances/events that have the potential to cause incident.

ERROR, NO HARM	
Category B	An error occurred but the error did not reach the patient (an 'error of omission' does reach the patient).
Category C	An error occurred that reached the patient but did not cause patient harm.
Category D	An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm.

ERROR, HARM	
Category E	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention.
Category F	An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalisation.
Category G	An error occurred that may have contributed to or resulted in permanent patient harm.
Category H	An error occurred that required intervention necessary to sustain life.

ERROR, DEATH	
Category I	An error occurred that may have contributed to or resulted in the patient's death.

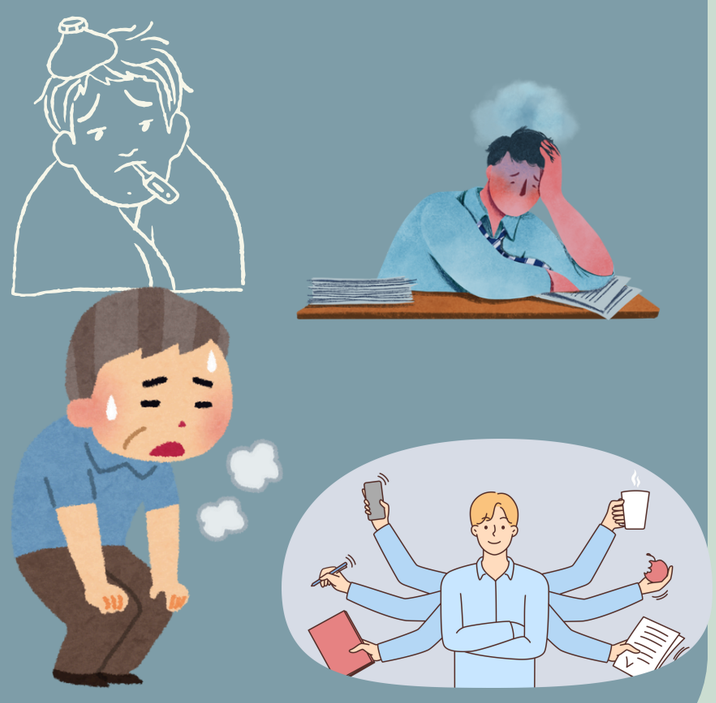
Malaysian Patient Safety Goals 2.0

- **Goal no.3 , KPI 5: Number of Medication Error Related to Severe Harm or Death**
- **Target: Zero Case of Error Leading to Severe Harm or Death (category F to I)**

FACTORS CONTRIBUTING TO MEDICATION ERRORS

Human factors

- illnesses
- stress
- fatigue
- multitasking
- inadequate knowledge



Medication related factors

- multiple strengths
- dosage forms
- LASA
- HAMs

Seleginine
5 mg VS
Verapamil
40 mg

Systemic factors

- poor work flow
- disorganised workplace
- noise
- confined space
- poor lighting

IMPORTANCE OF REPORTING MEDICATION ERRORS

Patient Safety

- Medication errors can lead to serious harm, disability, or even death.
- Reporting errors helps identify and address underlying issues in the medication use system, ultimately improving patient safety.
- By analyzing reports, healthcare organizations can implement strategies to prevent similar errors from occurring in the future.

Cost Reduction

- Medication errors can lead to increased healthcare costs, including longer hospital stays, readmissions, and treatment of adverse drug events.
- By preventing errors, healthcare organizations can reduce these costs and improve resource utilization.

Root Cause Analysis

- Medication error reports provide valuable data for conducting root cause analysis, helping to determine why errors occurred.
- By understanding the root causes, healthcare organizations can implement targeted interventions to address the underlying problems.

Data Collection and Trend Analysis

- Reporting errors allows for the collection of data on medication errors, which can be used to identify trends and patterns.
- This data can be used to track the effectiveness of interventions and to identify areas where further improvements are needed.

System Improvement

- Reporting errors allows healthcare organizations to identify weaknesses in their processes and systems
- This information can be used to develop and implement interventions to improve medication safety, such as better training, standardized procedures, or improved communication protocols.
- A culture of open reporting encourages continuous learning and improvement in medication safety practices.

GENERAL GUIDE ON MEDICATION ERROR AND INCIDENT REPORTING

1. All medication errors must be reported through incident reporting reporting form AND medication error form. Types of errors can be referred in both MER form and IR form
2. Kindly fill the forms thoroughly and as complete as you can including all evidences
3. All forms will be passed to Unit Kualiti, Hospital Segamat for further action

SULIT

MINISTRY OF HEALTH MALAYSIA
PATIENT SAFETY INCIDENT REPORTING FORM

IR 2.0/2017

DATE OF REPORTING:____/____/ _____

*Borang boleh diisi dalam ***Bahasa Malaysia***

SECTION A: TO BE COMPLETED BY THE REPORTER OF THE INCIDENT

INCIDENT DESCRIPTION (Please fill in the blanks)

1.	**NAME OF FACILITY/ INSTITUTION**		**PATIENT'S NAME**	
2.	**DATE OF INCIDENT**	☐☐ / ☐☐ / ☐☐☐☐	**IF UNCERTAIN** APPROXIMATE DATE:____/____/____	
3.	**TIME OF INCIDENT**	☐☐ : ☐☐ AM/ PM	**IF UNCERTAIN** APPROXIMATE TIME:____:____AM /PM	
4.	**PATIENT'S RN/ OTHER INDENTIFICATION NUMBER** :_____ **AGE**:_____ **ETHNIC**: _____ **GENDER** : MALE / FEMALE / UNKNOWN (please circle) **STATUS** : ALIVE / DECEASED **LANGUAGE BARRIER**: YES / NO **DIAGNOSIS** : _____			
5.	**TYPE OF PATIENT** (please tick one) ☐ INPATIENT ☐ DAY CARE ☐ OUTPATIENT ☐ OTHERS: SPECIFY ☐ A&E ---------- **LOCATION/ WARD / CLINIC** : _____	**DEPARTMENT(S) INVOLVED** (please tick) ☐ MEDICAL ☐ O&G ☐ ONCOLOGY ☐ SURGICAL ☐ PHARMACY ☐ GERIATRIC ☐ ORTHOPAEDIC ☐ RADIOLOGY & IMAGING ☐ REHABILITATION ☐ PAEDIATRIC ☐ A&E ☐ ICU/ CCU ☐ LABORATORY ☐ PSYCHIATRY ☐ OTHERS: SPECIFY _____		

6. **TYPE OF INCIDENT** (please tick one) ☐ **Actual** ☐ **Near Miss**

Examples of incidents that need to be reported: (Note that this list is not exhaustive)

☐	i.	Wrong surgery/procedure –wrong site, side or patient
☐	ii.	Unintended retained foreign body in patient after an operation/procedure
☐	iii.	Error in transfusion of blood/blood products
☐	vi.	Medication error (please fill in MERS form as well)
☐	v.	Patient fall in the facility
☐	vi.	Obstetric related incidents
☐	vii.	Adverse outcome of clinical procedure
☐	viii.	Pre-hospital care and ambulance service related incident
☐	ix.	Radiotherapy related incident
☐	x.	Patient suicide / attempted suicide
☐	xi.	Patient discharged to wrong family members / next-of -kin
☐	xii.	Assault/ battery of patient
☐	xiii.	Unanticipated Fire – Fire, flame, or unanticipated smoke, heat, or flashes occurring in the facility
☐	xiv.	**Others type of incident** :_____

7. **BRIEF DESCRIPTION OF WHAT HAPPENED** (Please fill in the blanks)
The description should explain what happen prior and during the incident and how it occurred. Do include any additional information which you think may lead to the incident.

INCIDENT REPORTING FORM

Mandatory Root Cause Analysis: *1) Incident with Severe or Death outcome* *2) Other incident/near miss based on the Risk Manager/ Quality Manager assessment* *3) Directive from State Health Department / Ministry.*	☐ "PRESCRIPTION SLIP" ☐ MONITOR THE TREND FIRST ☐ RCA ☐ MIRCA (Multi-incident Root Cause Analysis) Additional comments :
2. **e-IR SUBMITTED?** Please submit to e-IR **within 5 days** from the date of the incident.	Date of Submission:_____-_____-_____
3. **RISK MANAGER/ QUALITY MANAGER OF HOSPITAL**	(please fill in the blanks) NAME: SIGNATURE: DESIGNATION: DATE:

MEDICATION ERROR (ME) REPORT FORM

Pharmaceutical Services Programme
Ministry of Health Malaysia
www.pharmacy.gov.my
Tel: 03-78413200 Fax: 79682268

Reporters do not necessarily have to provide any individual identifiable health information, including names of practitioners, names of patients, names of healthcare facilities, or dates of birth (age is acceptable)

MERS reference no: ME/ref/

1 **Date of event:** ☐☐☐☐☐☐ dd/mm/yy

2 **Time of event:** ☐☐☐☐ hh/mm (24 hr)

3 **Type of Facility:** *Government/ Private

☐ Hospital ☐ Clinic ☐ Pharmacy

☐ Others: _____

4 **Location of event:**

☐ Ward (Please specify: Medical/Pead/Ortho/.....
☐ Clinic (Please specify: Outpatient/Specialist/Dental/.....
☐ Pharmacy (Please specify: Inpatient/Outpatient/Satellite/A&E/.....
☐ A&E
☐ Others (Please specify:.....

5 Please describe the error. Include description/ sequence of events and work environment (e.g. change of shift, short staffing, during peak hours) If more space is needed, please attach a separate page.

6 In which process did the error occur?

☐ Prescribing ☐ Data Entry System
☐ Filling ☐ Labelling
☐ Dispensing ☐ Administration
☐ Others (Please specify) :
_____

7 Did the error reach the patient? ☐ YES ☐ NO

8 Was the incorrect medication, dose or dosage form administered to or taken by the patient? ☐ YES ☐ NO

9 Describe the direct result on the patient (e.g. death, type of harm, additional patient monitoring e.g. BP, HR, glucose level etc.).

10 Please tick the appropriate Error Outcome Category (Select one)

☐ A Potential Error, circumstances/ events have potential to cause incident
☐ B Actual Error – did not reach patient (near miss)
☐ C Actual Error - caused no harm
☐ D Additional monitoring required - caused no harm
☐ E Treatment/ intervention required - caused temporary harm
☐ F Initial/ prolonged hospitalization - caused temporary harm
☐ G Caused permanent harm
☐ H Near death event
☐ I Death

Reference: © 2001 National Coordinating Council for Medication Error Reporting and Preventi

11 Indicate the possible error cause(s) and contributing factor(s).

☐ **Staff factors**
- ☐ Inexperienced personnel
- ☐ Inadequate knowledge
- ☐ Distraction

☐ **Medication related**
- ☐ Sound alike medication
- ☐ Look alike medication
- ☐ Look alike packaging

☐ **Task and technology**
- ☐ Failure to adhere to work procedure
- ☐ Use of abbreviations
- ☐ Illegible prescriptions
- ☐ Patient information/ record unavailable/ inaccurate
- ☐ Wrong labeling/ instruction on dispensing envelope or bottle/ container
- ☐ Incorrect computer entry

☐ **Work and environment**
- ☐ Heavy workload
- ☐ Peak hour
- ☐ Stock arrangements/ storage probler

☐ **Others (please specify):**
.....
.....

For question 12-14, please fill each box with one of the following option.

a. Specialist
b. Medical Officer (MO)
c. Houseman Medical Officer (HMO)
d. Pharmacist
e. Provisional Registered Pharmacist (PRP)
f. Nurse
g. Nurse (Trainee)
h. Assistant Medical Officer (AMO)
i. Assistant Medical Officer (AMO Trainee)
j. Pharmacist Assistant
k. Pharmacist Assistant (Trainee)
l. Patient/ Caregiver
m. Dentist
n. Others (Please specify:
.....

12 Which category made the initial error? ☐

13 Other category also involved in the error? ☐

14 Which category discovered the error or recognised the potential error? ☐

15 If available, please provide patient's particulars (Do not provide any patient identifiers).

Age: ☐☐ *years/ months/ days **Gender:** ☐ Male ☐ Female **Diagnosis:** _____

16 **Product Details:** Please complete the following for the product(s) involved. Kindly attach a separate page for additional products.

Product Description	Product # 1 (intended)	Product # 1(error)
16.1 Generic Name (Active Ingredient)		
16.2 Brand / Product Name		
16.3 Dosage Form		
16.4 Dose, frequency, duration, route		

If error involved similar product packaging, please fill in 16.5-16.7.

Product Description	Product # 1 (intended)	Product # 1(error)
16.5 Manufacturer		
16.6 Strength / Concentration		
16.7 Type and Size of Container		

* Please delete where not applicable

or describe policies or procedure
revent future similar errors. If ava
rt e.g. Root Cause Analysis (RC

For official use :

Date report receive ☐☐☐☐☐☐

Ref. No. ☐☐☐

ME Type ☐

ME Category ☐

MEDICATION ERROR FORM

Medication Safety

Is Everyone's Responsibility

MEDICATION ERROR REPORTING SYSTEM (MERS)

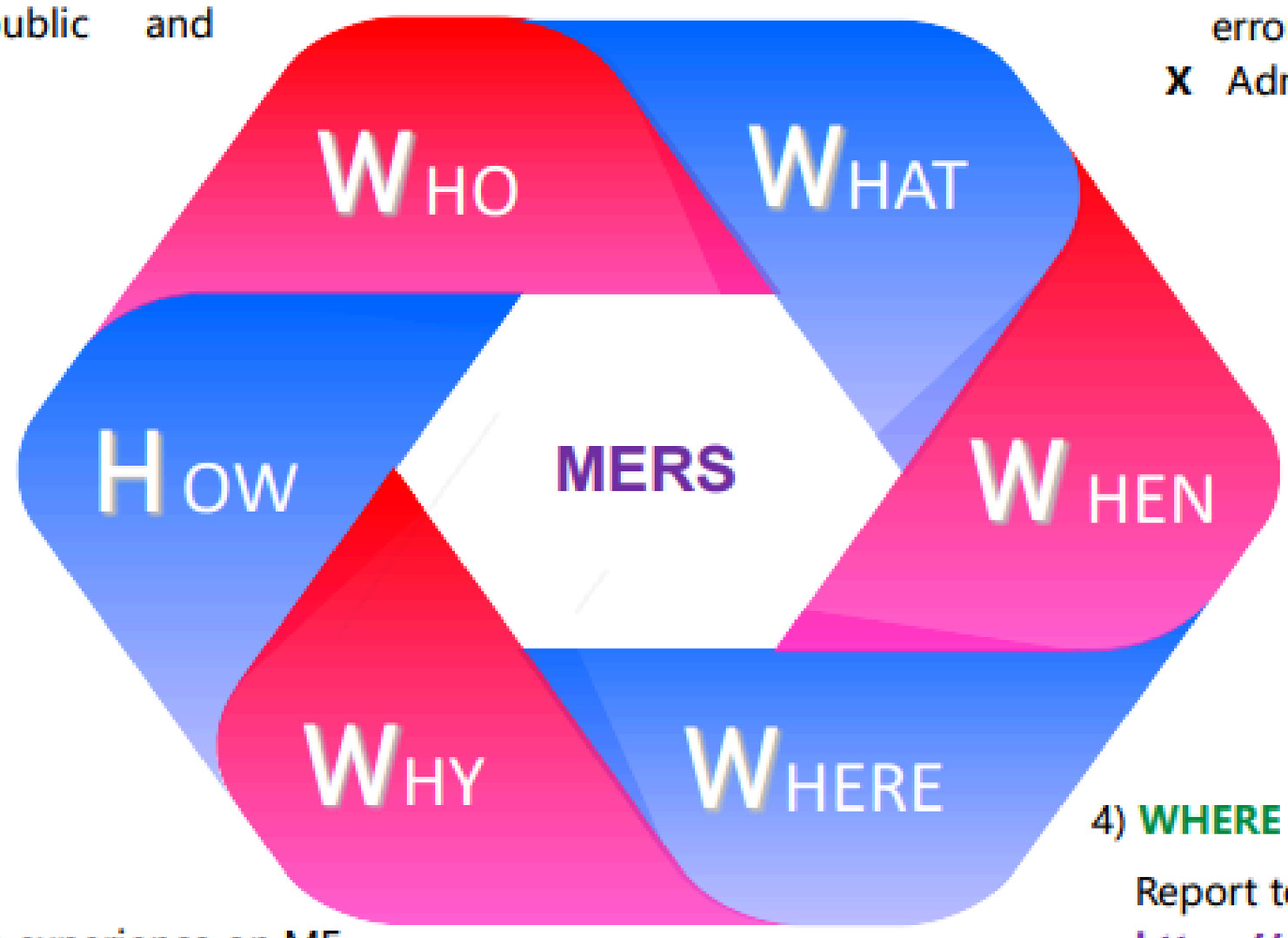
1) **WHO** can report?

All healthcare providers, both in public and private sector.

2) **WHAT** to report?

√ All medication error (actual error and near misses)

X Administrative error



3) **WHEN** to report?

Anytime when detected an error.

6) **HOW** to report?

Log in MERS.
Refer to Guideline on Medication Error Reporting 2019.

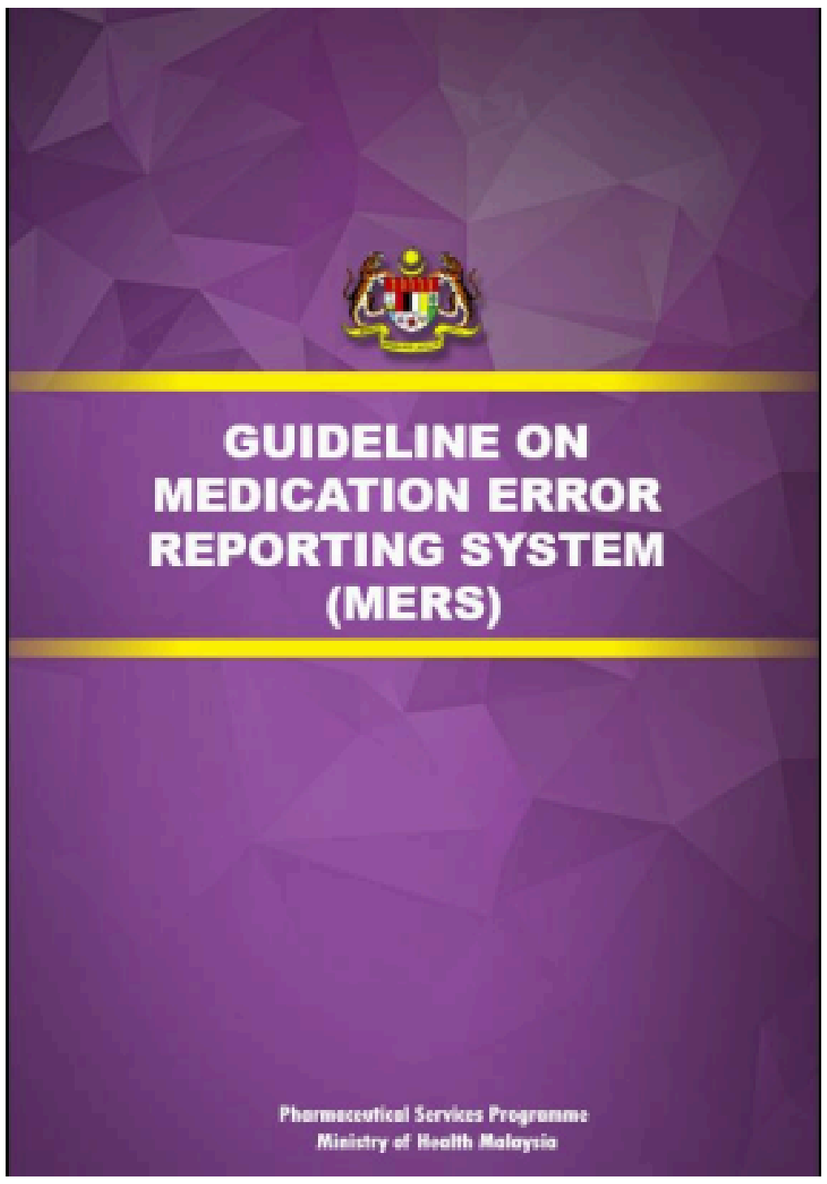
4) **WHERE** to report?

Report to MERS Online
https://mers.pharmacy.gov.my

5) **WHY** report?

✓ To learn and share experience on ME.
✓ To disseminate info on ME.
✓ To formulate risk reduction strategies.
✓ To improve **PATIENT SAFETY**.

Guideline on Medication Error Reporting System (MERS)



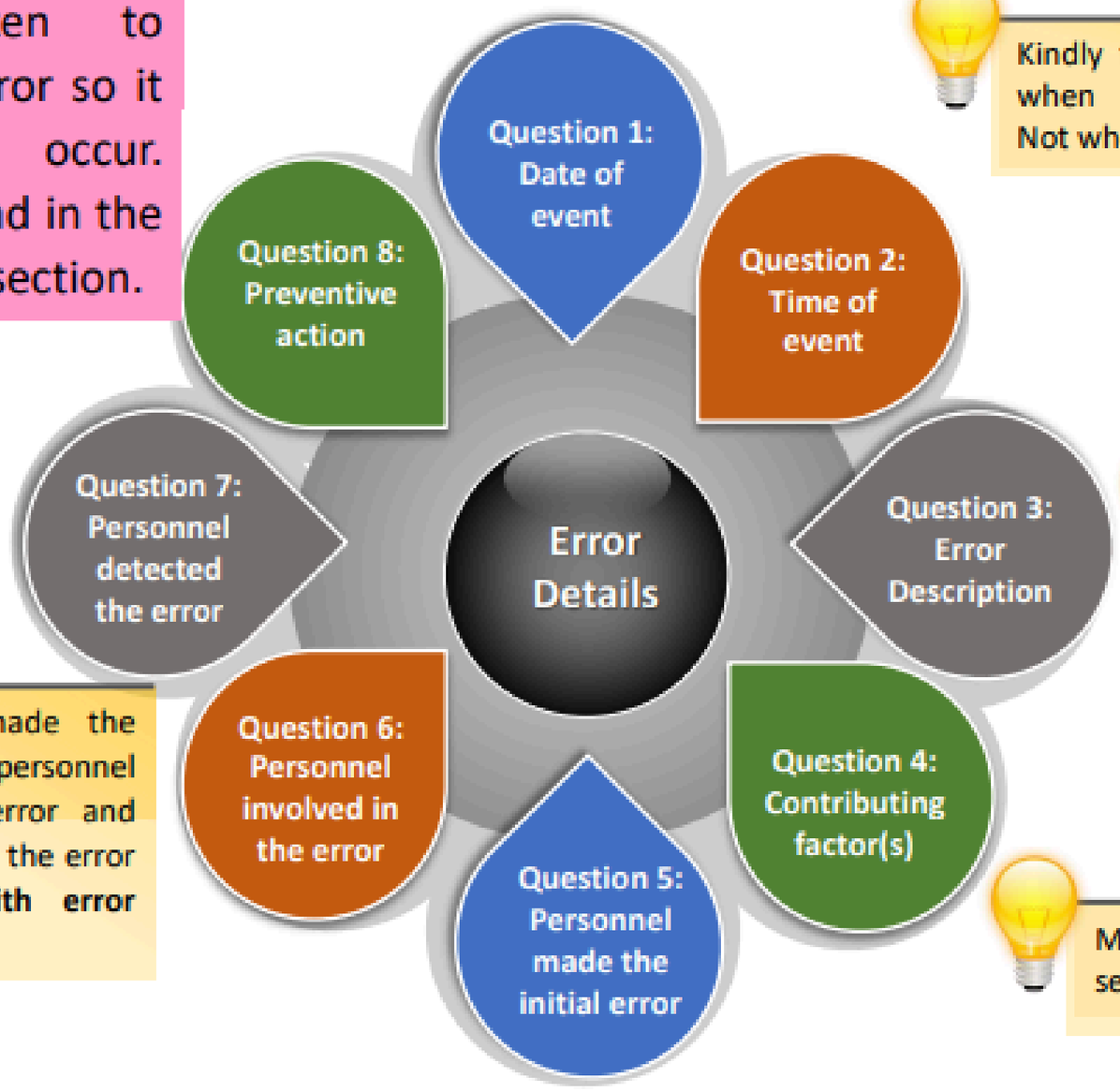
This guideline describes the management of medication error and the step-by-step process on how to fill and submit report to the Medication Error Reporting System (MERS). Available at www.pharmacy.gov.my

"Medication Safety is Everyone's Responsibility"

Part 1: Error Details

Action taken to avoid the error so it would not occur. Can be upload in the Attachment section.

Kindly fill in the date and time when the error occurred. Not when you report the error.



No need to include the name of the personnel who did the error / patient's information.

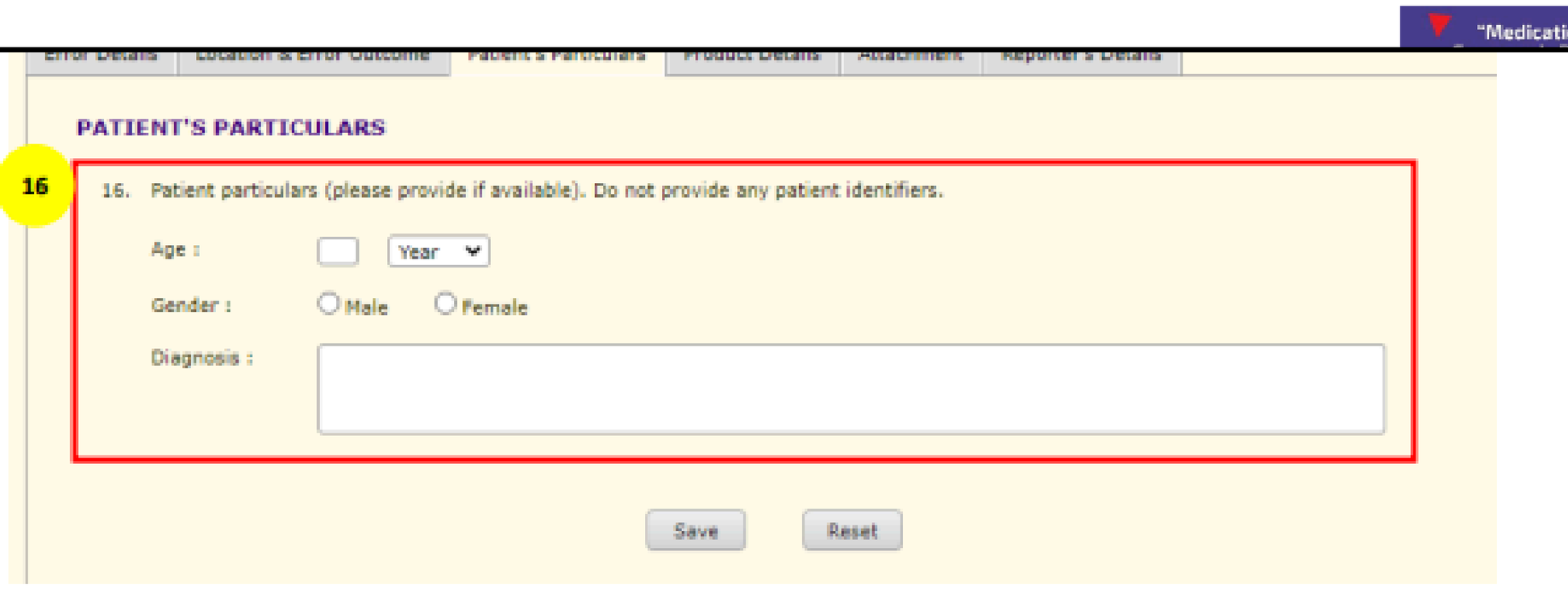
Personnel who made the initial error, personnel involved in the error and personnel detected the error should **match with error description.**

More than one options may be selected.

"Medication Safety is Everyone's Responsibility"

Part 2: Location & Error Outcome

Part 3: Patient's Particulars



Part 4: Product Details

Error Details | Location & Error Outcome | Patient's Particulars | Product Details | Attachment | Reporter's Details

Submit

PRODUCT DETAILS

17

Summary of Product(s) Involved

No	Product	Generic name	Brand name	Dosage form	Dose, frequency, duration, route	Similar packaging involved?
1	Intended	-	-	-	-	-
	Error	-	-	-	-	-

Fields marked with * are compulsory fields.

17. *Product(s) involved

Product Description	Product #1 (intended)	Product #2 (error)
☐ Generic Name	Search Generic Name...	Search Generic Name...
☐ Brand Name	Search Brand Name...	Search Brand Name...
Dosage Form		
Dose, Frequency, Duration, Route		

17.5 Similar packaging involved? ○ Yes ○ No

Save Reset

Part 5: Attachment

Submit

ATTACHMENT

18. Reports are most useful when relevant materials such as product label, copy of prescription/ order, etc., can be reviewed. Can these materials be provided?

○ Yes ○ No

19. Attachment for Error Description. (Include description/ sequence of events and work environment (e.g. change of shift, short staffing, during peak hours)

Choose File No file chosen

20. Attachment for recommendations or describe policies or procedures you instituted or plan to institute to prevent future similar errors. If available, kindly attach investigational report e.g. Root Cause Analysis (RCA).

Choose File No file chosen

Part 6: Reporter's Details

1. Reporter

- Reporter's Name
- Profession

2. Facility

- State
- Type of facility (Government- MOH, Government- non-MOH, private)
- Facility name
- Address
- Telephone Number
- Fax Number

3. Contacts

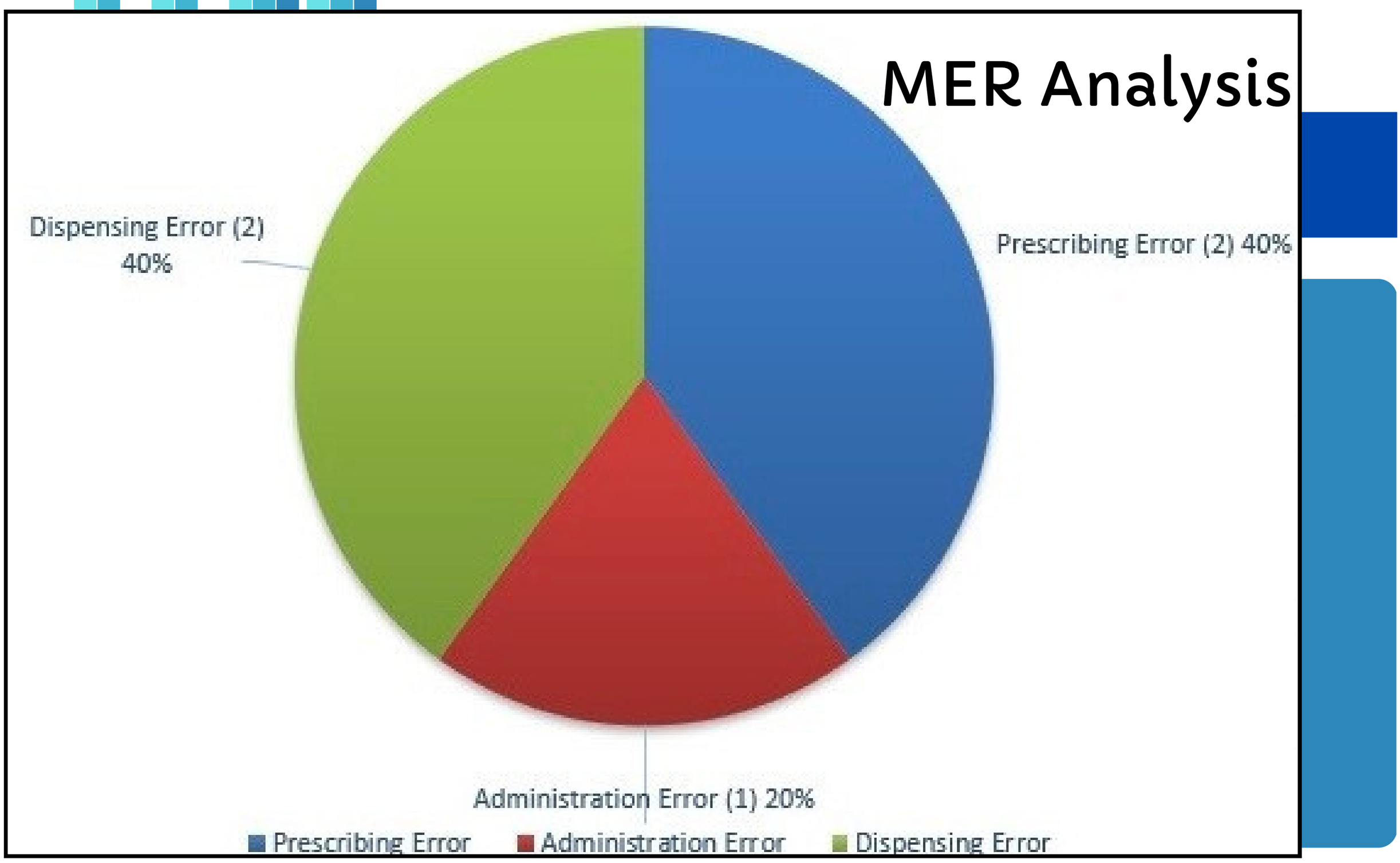
- E-mail
- Telephone number

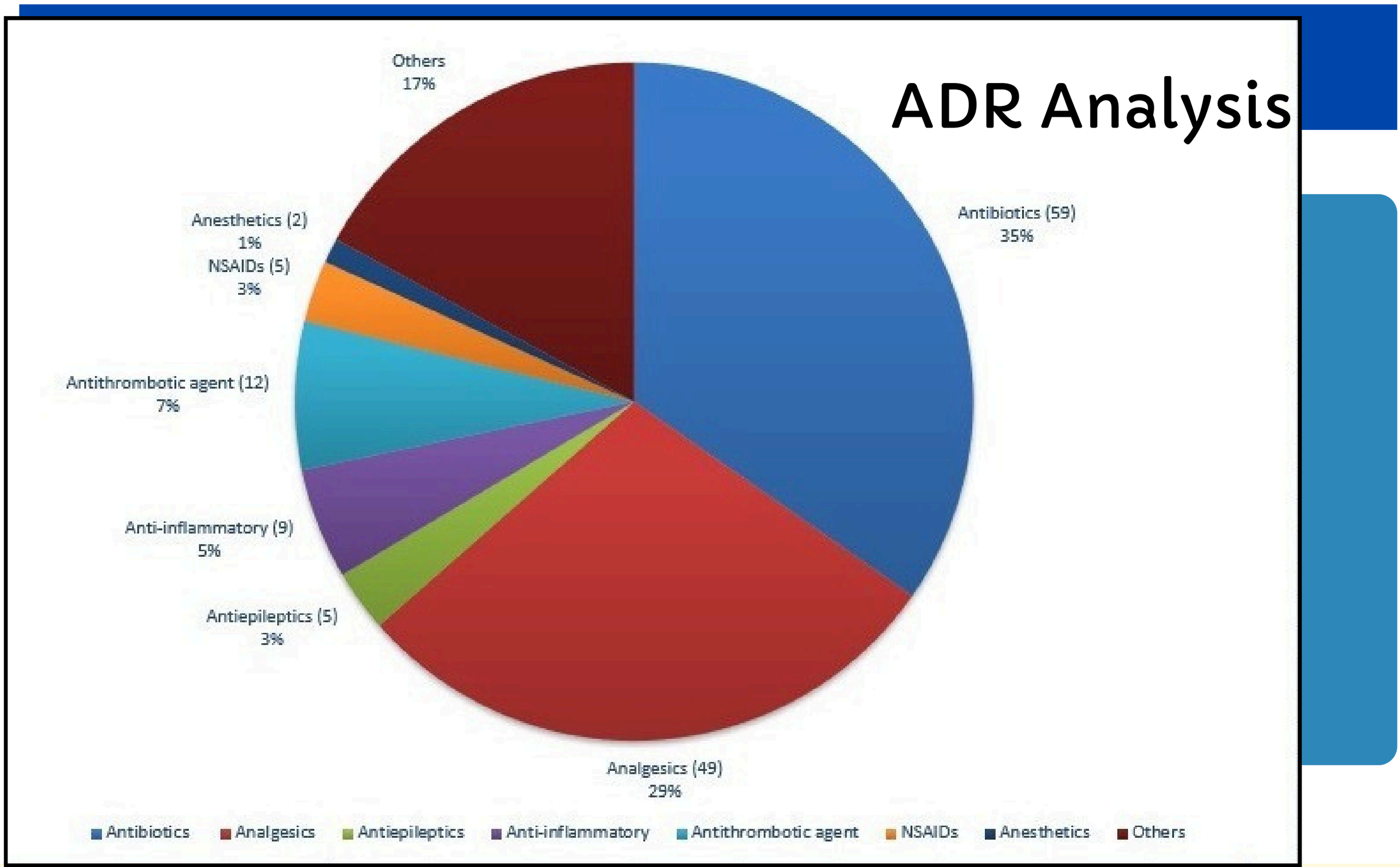
* This details is important if the administrator need further clarification from the reporter. Kindly provide a valid e-mail / telephone number.

Reminder

1. Reporter's details will be auto-filled if reporter choose "own facility" in the first pop-up message.
2. Facility's details will be auto-filled once selected the facility from the drop-down list. Reporter can edit the details filled.

MER & ADR Analysis 2024





SENARAI UBAT-UBATAN LASA

Look Alike Sound Alike

Hydrocortisone Sodium Succinate 100 mg
VS
Streptomycin Sulphate 1 g

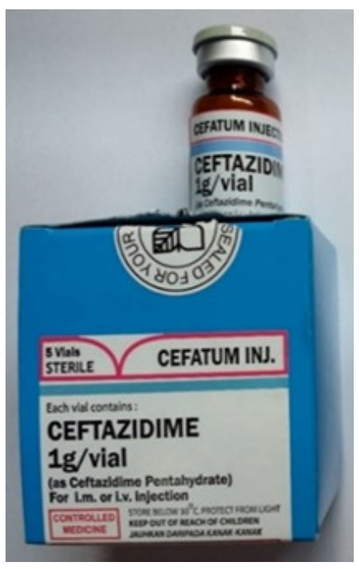
Neostigmine Methylsulphate 2.5 mg/mL
VS
Nalbuphine HCL 10 mg/mL
VS
Hyoscine N-Butylbromide 20 mg/mL

Cefotaxime 500 mg
VS
Cefotaxime 1000 mg

Midazolam HCL 15 mg/3mL
VS
Midazolam HCL 5 mg/mL

Morphine Sulphate BP 10 mg/mL
VS
Pethidine HCL 50 mg/mL
VS
Pethidine HCL 100 mg/2mL

Ceftazidime 1 g
VS
Ceftriaxone 1000 mg

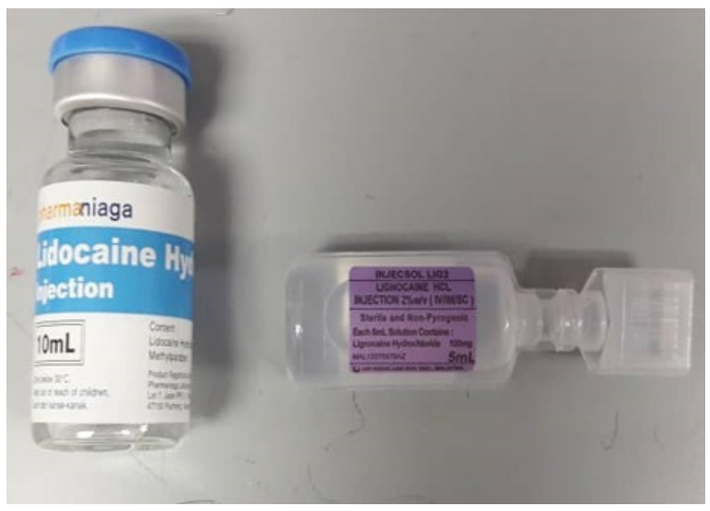


SENARAI UBAT-UBATAN LASA

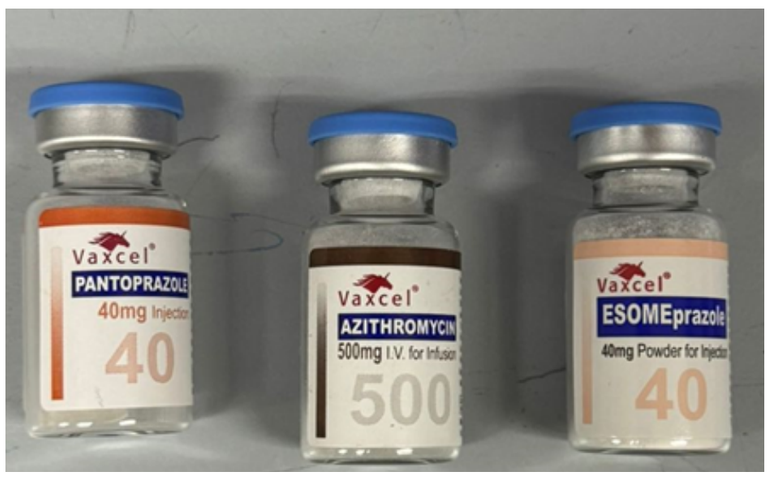
Look Alike Sound Alike

Heparin 5000 iU/mL
VS
Heparin Saline 10 iU/mL

Lignocaine HCL 2 %
VS
Lignocaine HCL 20 mg/mL



Inj Pantoprazole 40 mg
VS
Inj Azithromycin 500 mg
VS
Inj Esomeprazole 40 mg



Vitamin K 10 mg/mL
VS
Vitamin K 1 mg/mL

Glyceryl Trinitrate 50 mg/10mL
VS
Noradrenaline 4 mg/4mL

Neb Ipratropium Bromide 500 mcg/2mL
VS
Neb Ipratropium Bromide/Salbutamol 0.5 mg/2.5mg

SENARAI UBAT-UBATAN LASA

Look Alike Sound Alike

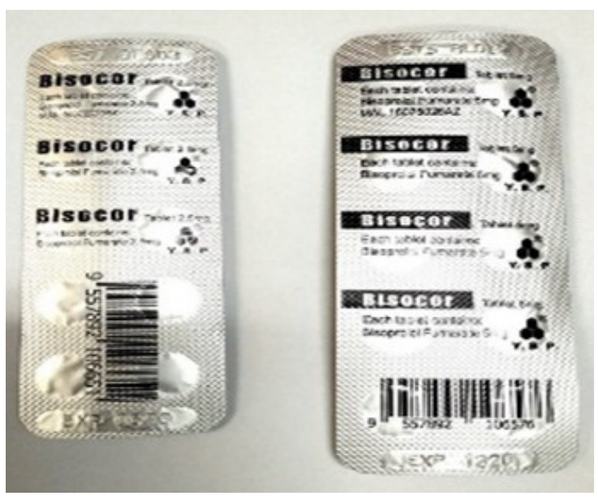
Seleginine 5 mg
VS
Verapamil 40 mg

Magnesium Sulphate 2.47 g/5mL
VS
Potassium Dihydrogen Phosphate 1.361g/10mL

Chloramphenicol Eye Drops
VS
Chloramphenicol Ear Drops

Warfarin 1 mg Tablet
vs
Warfarin 2mg Tablet
vs
Warfarin 5 mg Tablet

Bisoprolol 2.5 mg
VS
Bisoprolol 5 mg

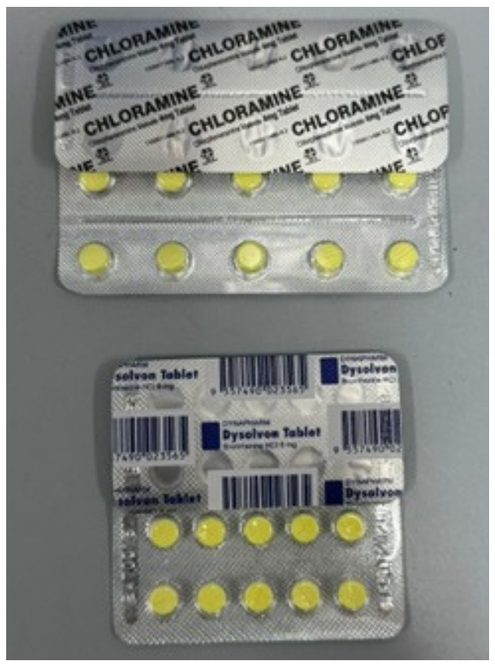


Trimetazidine 20 mg
VS
Medroxyprogesterone 5 mg

SENARAI UBAT-UBATAN LASA

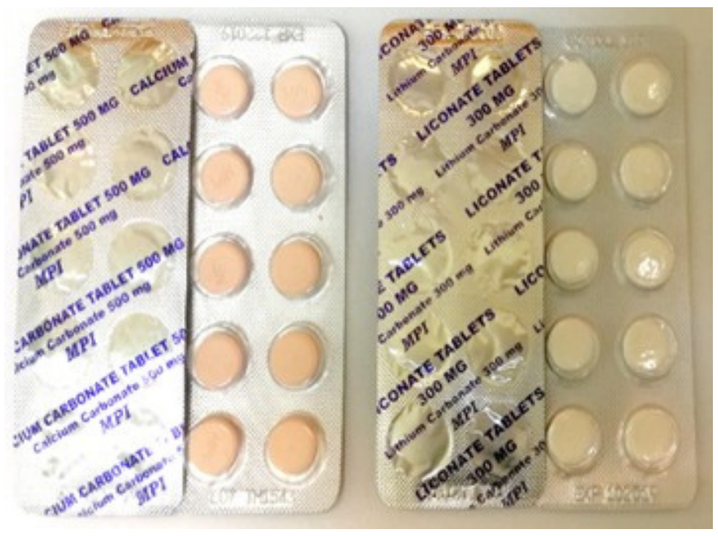
Look Alike Sound Alike

T. Chlorpheniramine 4 mg
VS
T. Bromhexine 8 mg

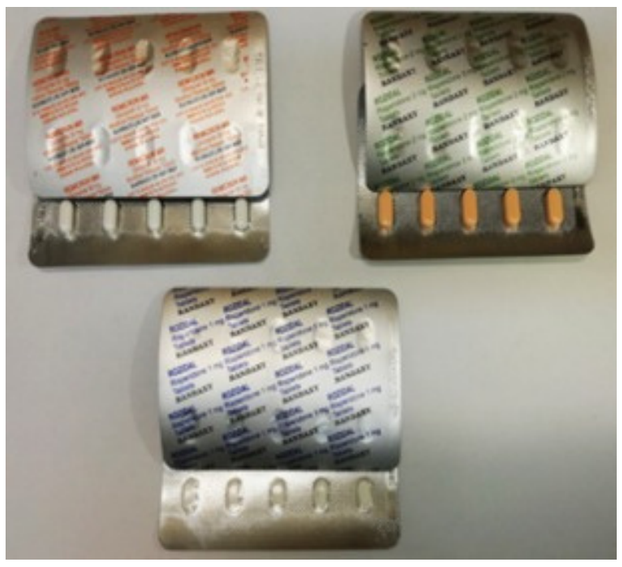


Paliperidone 3 mg
VS
Paliperidone 6 mg

Calcium Carbonate 500 mg
VS
Lithium Carbonate 300 mg



Gliclazide MR 30mg
VS
Risperidone 2mg
VS
Risperidone 1mg



Clozapine 100 mg
VS
Clozapine 25 mg

Olanzapine 10 mg
VS
Omeprazole 20 mg

SENARAI UBAT-UBATAN LASA

Look Alike Sound Alike

Quaitipine IR 50 mg
VS
Quaitipine IR 200 mg
VS
Quaitipine IR 400 mg

Tacrolimus 0.5 mg
VS
Tacrolimus 1 mg

TALL-MAN LETTERING OF SOUND ALIKE MEDICATION

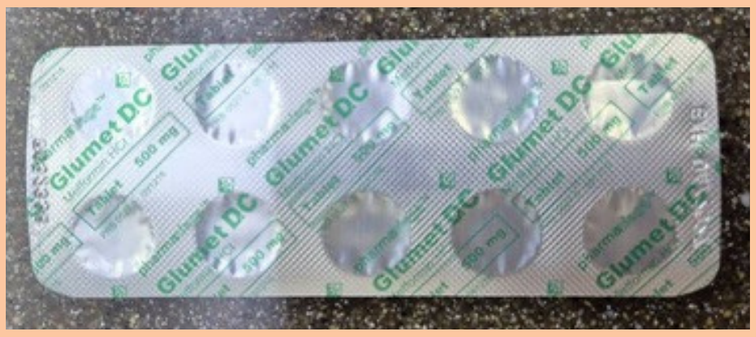
No.	Medication name	Confused With
1	ALPRAZolam	MIDAZolam, cloBAZam
2	AMLOdipine	FELOdipine,NIFEdipine, NICARdipine
3	amPIcillin	amOXIcillin, CLOXAcillin, PENIcillin V
4	ATORvastatin	PRAvastatin, SIMvastatin
5	AZITHROmycin	CLINDAmycin, ERYTHROmycin
6	BISOprolol	METOprolol, LABEtalol, ATEnolol, PROPRAnolol
7	BUPIvacaine	LIGNOcaine, ROPIvacaine
8	carBAMAZepine	carBIMazole
9	cefOTAXime	cefUROXime, cefTAZIDime, cefTRIAXone, ceFAZolin, cefEPime, cefoPERAZone
10	chlorproMAZINE	chlorproPAMIDE

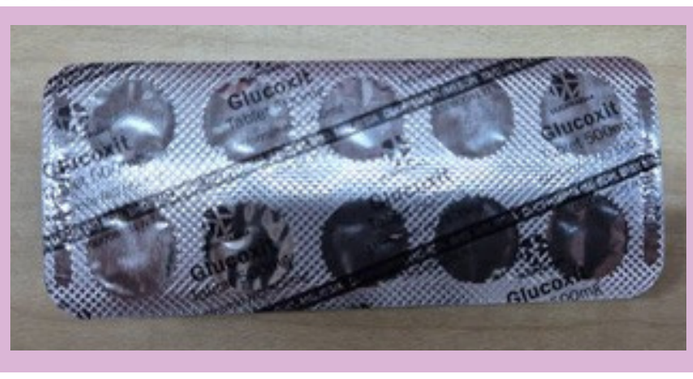
BRAND CHANGES

PREVIOUS VERSION

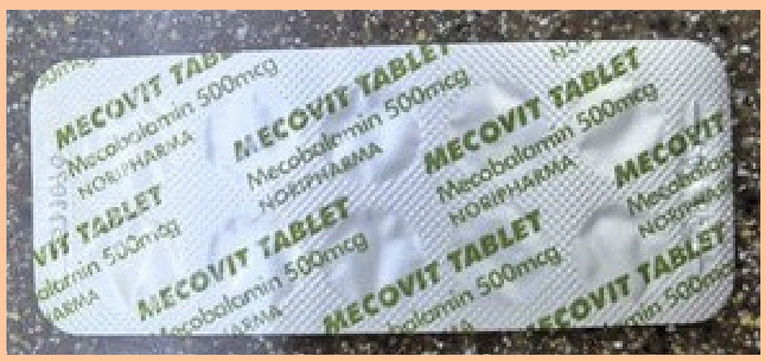
NEW VERSION

METFORMIN 500MG TAB

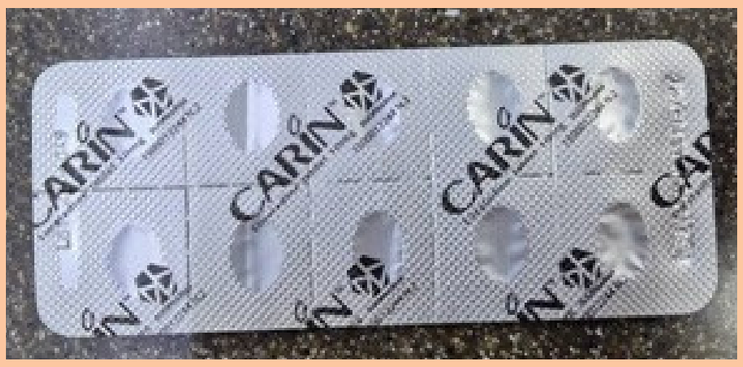


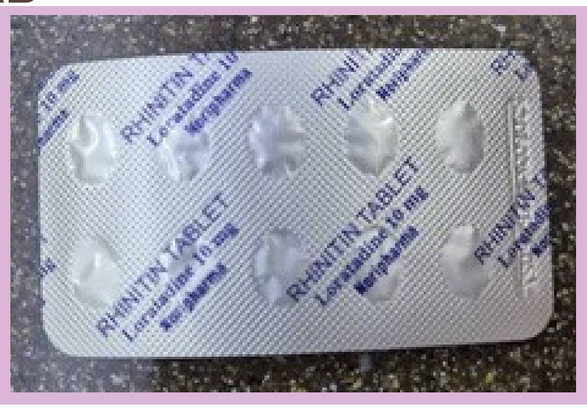


MECOBALAMIN 500MCG TAB

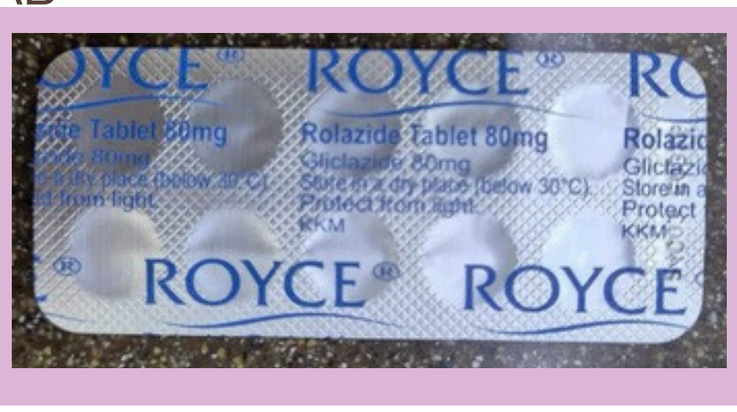


LORATADINE 10MG TAB

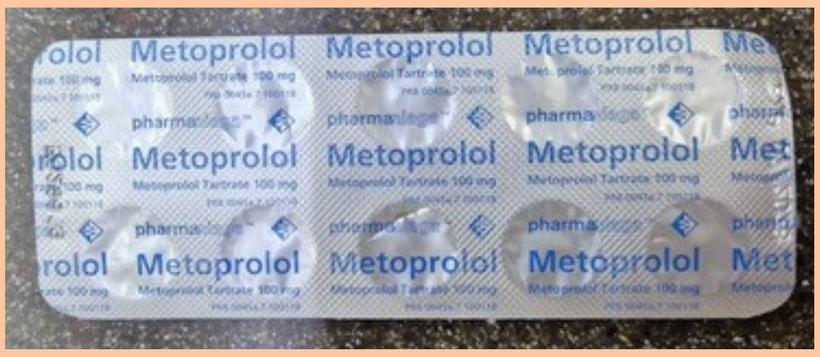


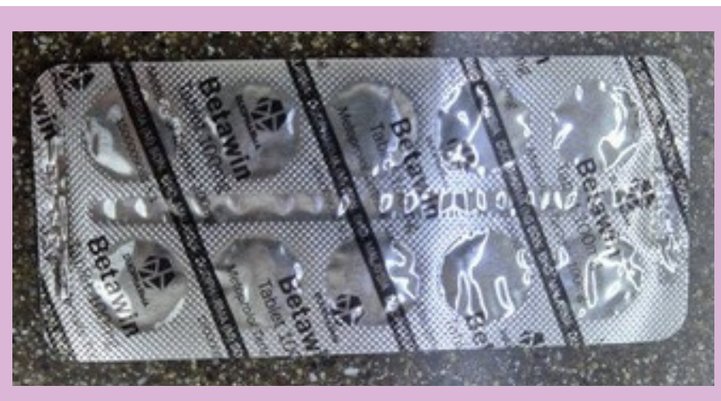


GLICLAZIDE 80MG TAB

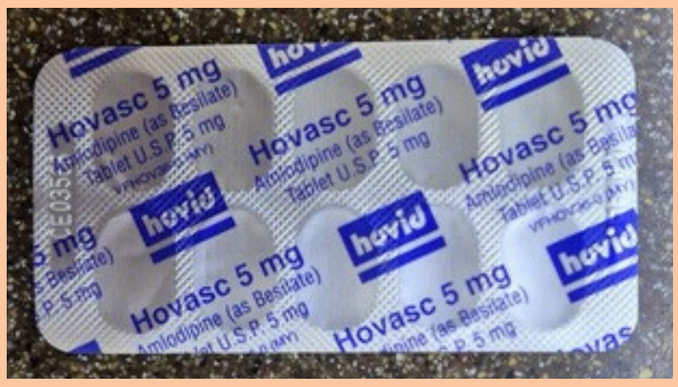


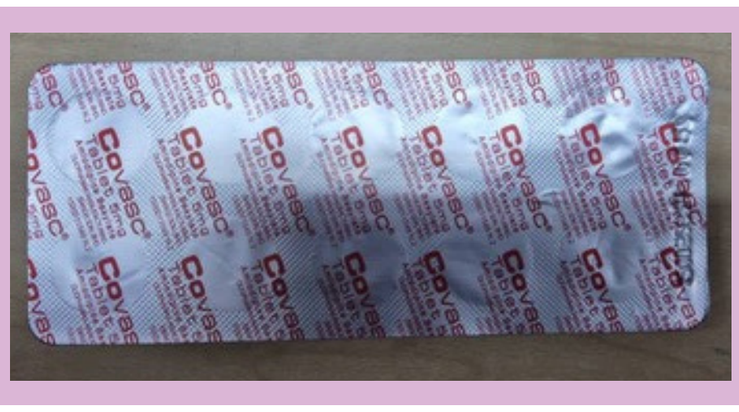
METOPROLOL 100MG TAB



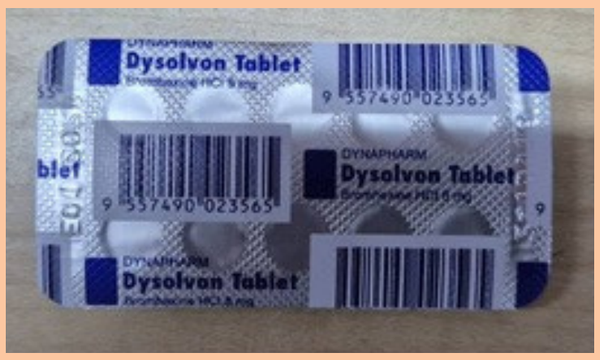


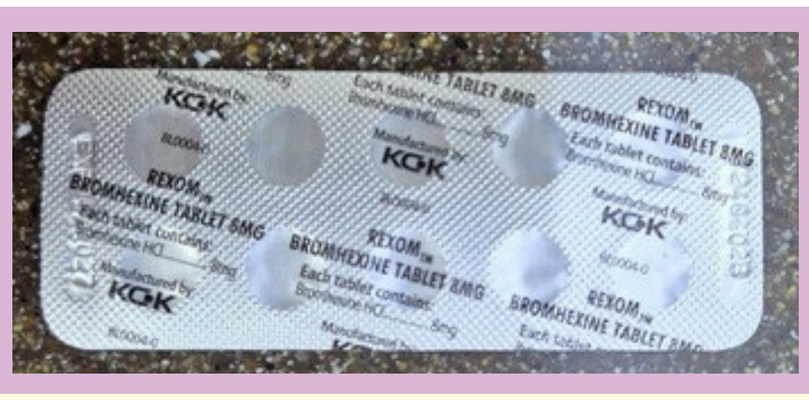
AMLODIPINE 5MG TAB





BROMHEXINE 8MG TAB



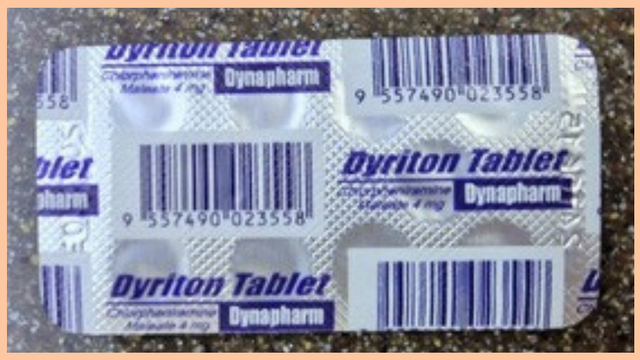


BRAND SWITCHING

PREVIOUS VERSION

NEW VERSION

CHLORPHENIRAMINE MALEATE 4MG TAB

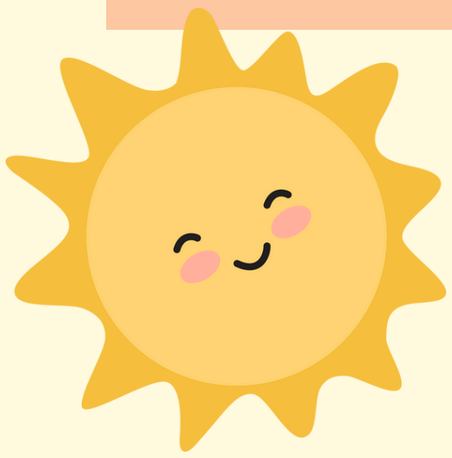


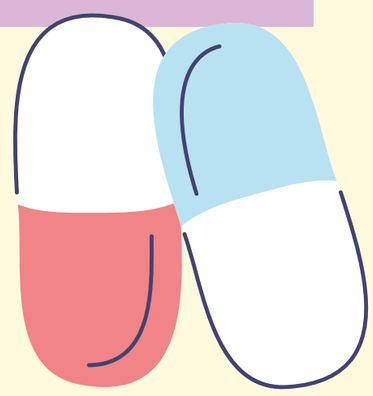
DIPHENHYDRAMINE HCL EXPECTORANT (ADULT)

PARACETAMOL 250MG/5ML SYRUP

GLYCERIN 25%, SODIUM CHLORIDE 15% ENEMA, 20ML (RAVIN)

EPHEDRINE HCL 30MG/ML INJECTION





PINDAAN FORMULARI HOSPITAL SEGAMAT BIL 1/2025

UBAT BARU YANG DILULUSKAN

- Everolimus 0.25mg tablet
- Ferrous Iron (elemental iron ≥ 100mg), vitamin & mineral Capsule
- Tenofovir Disoproxil Fumarate 300mg, Emtricitabine 200mg & Efavirenz 600mg Tablets (Fixed-dose combination)
- Rituximab 10mg/ml Injection
- Ceftazidime 2g & Avibactam 0.5g Injection
- Micafungin Sodium 50mg Injection
- Lignocaine (Lidocaine), Aluminium Acetate, Zinc Oxide and Hydrocortisone Suppository
- Budesonide 9mg Prolonged Release Tablets
- Acitretin 25mg Capsule
- Salicylic acid, Sulphur and Liquid Coal Tar Ointment (2% w/w / 4% w/w / 12% w/w)
- Prazosin HCl 5mg Tablet

PINDAAN FORMULARI HOSPITAL SEGAMAT BIL 1/2025

UBAT BARU YANG DILULUSKAN

- Clonidine HCl 0.025mg Tablet
- Levofloxacin 500mg Injection
- Phenylephrine 50mcg/ml Injection
- Permethrin 1% w/v Lotion.
- Venlafaxine HCl 150mg Extended Release Capsule
- Valbenazine 40mg capsule
- Perphenazine 4mg tablet
- Calamine Cream 30g
- Levetiracetam 100mg/ml Oral Solution
- Ethyl Chloride 100ml Spray
- Diclofenac Sodium 50mg Suppository

PINDAAN FORMULARI HOSPITAL SEGAMAT BIL 1/2025

UBAT BARU YANG DILULUSKAN

- Mirabegron 50mg Prolonged Release Tablet
- Piracetam 1.2g Tablet
- Clostridium botulinum Type A toxin haemaglutinin complex 500U/vial powder for injection
- Clostridium Botulinum Toxin Type A 100units

UBAT YANG DIKELUARKAN DARI FORMULARI

- Trimetazidine 20 mg Tablet
- Risperidone 25mg Injection
- Risperidone 37.5mg Injection
- Oxycodone 20mg Tablet
- Phenylephrine 10mg/ml Injection

Pindaan/Tambahan kepada Formulari Ubat KKM (FUKKM) Bil. 3 Tahun 2024

UBAT BAHARU YANG DILULUSKAN KE DALAM FUKKM

MAKLUMAT UBAT	KETERANGAN UBAT
Brexpiprazole 1mg, 2mg, 3mg and 4mg Film Coated Tablet MDC: 1mg: N05AX16-000-T32-03-001 2mg: N05AX16-000-T32-04-001 3mg: N05AX16-000-T32-05-001 4mg: N05AX16-000-T32-06-001 Kos/unit (RM): 1mg & 2mg: RM 12.50 / tablet 3mg & 4mg: RM 13.61 / tablet Kategori Preskriber: A*	Approved Indication(s): Use as an adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) Prescribing restriction(s): To be prescribed by Psychiatrists only Dose: The recommended starting dose as adjunctive treatment is 0.5 mg or 1 mg once daily. Dose titration to 1 mg/day and up to the target dose of 2 mg/day should occur at intervals of up to 1 week based on the patient's clinical response and tolerability. Doses up to 3 mg/day have been studied in clinical trials. Precaution(s): Increased mortality in elderly patients with dementia-related psychosis, cerebrovascular adverse reactions including stroke in elderly patients with dementia-related psychosis, suicidal risk, suicidal thoughts and behaviours in children, adolescents and young adults, neuroleptic malignant syndrome (NMS), tardive dyskinesia, metabolic changes (e.g. hyperglycemia and diabetes mellitus, dyslipidemia, weight gain), prolactin elevation, genitourinary, venous thromboembolism, immune hypersensitivity, cardiovascular disorders, leukopenia, neutropenia and agranulocytosis, orthostatic hypotension and syncope, QT interval, falls, seizures, body temperature regulation, dysphagia, pathological gambling and other compulsive behaviours, lactose, potential for cognitive and motor impairment Adverse reaction(s): Blurred vision, constipation, dry mouth, nasopharyngitis fatigue, weight increase, increased appetite, akathisia, somnolence, tremor, dizziness, restlessness, insomnia, anxiety. Contraindication(s): Hypersensitivity to the active substance or to any of the excipients. Reactions have included rash, facial swelling, urticaria, and anaphylaxis. Interaction(s): Strong CYP3A4 inhibitors (e.g. itraconazole, clarithromycin, ketoconazole), strong CYP2D6 inhibitors (e.g. paroxetine, fluoxetine, quinidine), strong CYP3A4 inducer (e.g. rifampin, St. John's wort)

PINDAAN KATEGORI PRESKRIBER YANG DILULUSKAN BAGI UBAT-UBATAN YANG TERSENARAI DALAM FUKKM

NAMA GENERIK	KETERANGAN PINDAAN
Noradrenaline Acid Tartrate (Norepinephrine Bitartrate) 1 mg/ml Injection	Change in the prescriber category from A to A/KK Indication(s): Septic shock and shock where peripheral vascular resistance is low Prescribing restriction(s): Use only for emergency cases in health clinic with Medical Officers (MO) upon consultation with Family Medicine Specialist (FMS)
Amiodarone 50mg/mL Injection	Change in the prescriber category from A* to A/KK Indication(s): Ventricular arrythmia (ventricular tachycardia and ventricular fibrillation) Prescribing restriction: Use only for emergency cases in health clinic with Medical Officers (MO) upon consultation with Family Medicine Specialist (FMS)
Donepezil 5mg & 10mg Tablet	Change in the prescriber category from A to A/KK Indication(s): Treatment of mild, moderate and severe dementia in Alzheimer's disease Prescribing restriction(s): Psychiatrists, Neurologists, Geriatricians, Family Medicine Specialists trained in Mental Health Disorders
Betamethasone 17-Valerate 0.1% Ointment	Change in the prescriber category from A to A/KK Indication(s): Potent topical corticosteroid indicated for adults, elderly and child over 1 year for relief of inflammatory and pruritic manifestation of steroid responsive dermatoses Prescribing restriction(s): None
Betamethasone 17-Valerate 0.1% Cream	Change in the prescriber category from A to A/KK Indication(s): Potent topical corticosteroid indicated for adults, elderly and child over 1 year for relief of inflammatory and pruritic manifestation of steroid responsive dermatoses Prescribing restriction(s): None

PENGEMASKINIAN MAKLUMAT UBAT DALAM FUKKM

Bil.	Nama Generik/Kategori Preskriber/Kaedah Perolehan	Maklumat Sedia Ada dalam FUKKM	Cadangan Pindaan Baharu (maklumat yang dipinda di-highlight BIRU)	Justifikasi Pengemaskinian
1.0 DERMATOLOGICALS				
1.	i. Mometasone Furoate 0.1% Cream ii. Mometasone Furoate 0.1% Ointment Kategori Preskriber: A* Kaedah Perolehan: LP	i. Mometasone Furoate 0.1% Cream ii. Mometasone Furoate 0.1% Ointment	TAMBAHAN BENTUK DOSEJ i. Mometasone Furoate 0.1% Cream ii. Mometasone Furoate 0.1% Ointment iii. Mometasone Furoate 0.1% Lotion	i. Sediaan lotion boleh digunakan pada kulit yang berbulu seperti kulit kepala kerana dapat menembusi kulit dengan lebih efektif. ii. Berbanding sediaan cream dan ointment, sediaan lotion didapati tidak oklusif dan tidak berminyak. iii. Memberi fleksibiliti rawatan kepada pesakit yang mengalami corticosteroid responsive dermatoses pada kulit kepala.
		INDIKASI Steroid responsive dermatosis and vitiligo. Used where a potent steroid is required for short duration not more than 6 weeks	PINDAAN INDIKASI For the relief of the inflammatory and pruritic manifestations of the corticosteroid responsive dermatoses	Untuk mengemas kini indikasi bagi semua sediaan Mometasone yang tersenarai dalam FUKKM selaras dengan indikasi berdaftar
2.	Acriflavine 0.1% Lotion Kategori Preskriber: C+ Kaedah Perolehan: APPL	Acriflavine 0.1% Lotion INDIKASI Infected skin, lesions, cuts, abrasions, wounds and burns.	TAMBAHAN BENTUK DOSEJ Acriflavine 0.1% Cream	Memberi fleksibiliti rawatan kepada pesakit yang memerlukan rawatan antiseptik pada kulit
2.0 MUSCULOSKELETAL SYSTEM				
2.	Febuxostat 80 mg tablet Kategori Preskriber: A* Kaedah Perolehan: LP	INDIKASI Treatment of chronic hyperuricaemia in adult patients, in conditions where urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis). PRESCRIBING RESTRICTIONS As second line for patients who are allergic or intolerant to allopurinol.	TAMBAHAN PRESCRIBING RESTRICTIONS As second line for patients who: i. are allergic or intolerant to allopurinol; or ii. fail to achieve serum uric acid target despite dose escalation and good compliance to allopurinol	Untuk mengemas kini prescribing restrictions dalam FUKKM agar selari dengan Malaysian CPG Management of Gout, second edition, 2021 iaitu: -If unable to tolerate allopurinol/failure to achieve SU target despite dose escalation and good compliance to treatment, consider: i. switching to febuxostat or uricosuric agent ii. addition of uricosuric agent
3.0 ANTI-INFECTIVES FOR SYSTEMIC USE				
1.	Cefuroxime Axetil 125 mg Tablet Kategori Preskriber: A/KK Kaedah Perolehan: LP	INDIKASI Upper and lower respiratory tract, genitourinary tract, skin & soft tissue and urinary tract infections (UTI) DOS ADULT: 250 mg twice daily; UTI: 125 mg twice daily. CHILD: 30 mg/kg/day in 2 divided doses, up to 500 mg daily	PINDAAN DOS ADULT Most infections: 250 mg twice daily Severe infections: 500mg twice daily CHILD Most infections: 125mg twice daily or 30 mg/kg/day in 2 divided doses, up to 500 mg daily Severe infections: 250mg twice daily Dosing is individualised and according to package insert	i. Untuk mengemas kini maklumat dos dalam FUKKM selaras dengan maklumat berdaftar ii. Cadangan pendosan baharu adalah berdasarkan maklumat berdaftar dalam sisip bungkusan bagi bentuk dosej tablet.
2	Cefuroxime Axetil 250 mg Tablet Kategori Preskriber: A/KK Kaedah Perolehan: APPL			
3	Cefuroxime Axetil 500 mg Tablet Kategori Preskriber: A/KK Kaedah Perolehan: LP			

NPRA SAFETY UPDATE

ETHAMBUTOL: RISK OF DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS)

(Retrieved from NPRA safety updates, 21 February 2025.)

01 Overview

- Ethambutol is an antibiotic commonly used in combination with other drugs for the treatment of tuberculosis (TB) and Mycobacterium avium complex (MAC) infections. In Malaysia, there are currently 5 ethambutol-containing products (3 single ingredient and 2 combination products) registered with the Drug Control Authority (DCA).
- Drug reaction with eosinophilia and systemic symptoms (DRESS) is a rare but potentially life-threatening adverse reaction characterised by fever, rash, lymphadenopathy, eosinophilia, and internal organ involvement potentially affecting the liver, lungs, and kidneys. Symptoms of DRESS typically appear 2 to 8 weeks after starting the offending drug. The aetiology of DRESS is not fully understood but is believed to involve a complex interplay of factors, including delayed-type immunological reactions to drugs, genetic polymorphisms in drug-metabolising enzymes, genetic predisposition linked to human leukocyte antigen (HLA), herpes virus reactivation, and activated Janus kinase-sig
(JAK-STAT) pathway.

02 Background Of The Safety Issue

- Cases of DRESS in association with ethambutol treatment have been reported during post-market use. A Korean retrospective cohort study by Jung et al. (2019) examining antituberculosis (anti-TB) drugs reported a DRESS prevalence of 1.2% (15 cases) in 1,253 adult TB patients, of which ethambutol was the most frequently implicated drug (53.5%, 8 cases) in DRESS cases among first-line anti-TB drugs. Additionally, several case reports in the literature have identified ethambutol as a causative agent of DRESS, both as in single agent or in combination products.
- According to Jung et al. (2019), the median latency period for DRESS was 37 days from the start of ethambutol treatment. Among 8 cases where ethambutol was implicated, 3 also involved other causative anti-TB drugs. Six cases improved after sequential rechallenging (which involved stopping all anti-TB drugs and reintroducing them one by one), while 2 improved with sequential dechallenging (which involved removing drugs one by one with monitoring). The median time from DRESS onset to drug discontinuation was 17.5 days in sequential rechallenging and 56.5 days for sequential dechallenging.
- Identifying the causative anti-TB drug is often challenging due to the combined use of anti-TB drugs. Jung et al. (2019) highlighted that dechallenge and rechallenge require a proactive approach, as discontinuing first-line anti-TB drugs and switching to second-line regimens can reduce effectiveness, increase toxicity risks, and extend treatment to up to 2 years. Considering the long latency period of DRESS, it is recommended to immediately discontinue all anti-TB drugs followed by sequential rechallenging to identify the causative drug. Patch testing with anti-TB drugs may assist in the drug assessment before rechallenge.

03 Adverse Drug Reaction Reports

- The NPRA has received a total of 778 reports with 1,347 adverse events suspected to be related to ethambutol-containing products. Of these, 38 cases reported DRESS following the use of ethambutol. Four reports listed ethambutol as the single suspected drug, although 2 of these cases also reported concomitant use of other anti-TB drugs. Another 4 cases listed ethambutol as an interacting drug. In the remaining cases where ethambutol was suspected, all patients were simultaneously taking other anti-TB drugs and reported more than 1 suspected drug, including other anti-TB drugs and antibiotics.

- The reported time to onset ranged from days to 3 months. Of the 38 cases, 31 cases were reported to be recovering, while 3 had an unknown outcome at the time of reporting. Three cases reported a fatal outcome and 1 case had not recovered at the time of reporting,

04 Advice For Healthcare Professionals

- Be aware that DRESS is a severe skin adverse reaction that can occur with anti-TB drugs, including ethambutol.
- Be vigilant when starting anti-TB therapy, including ethambutol:
- Remind patients of the long latency period of DRESS (about 2–8 weeks).
- Educate patients to closely watch for delayed symptoms of DRESS, including generalised rash, fever, and enlarged lymph nodes.
- Advise patients to stop taking anti-TB drugs and seek immediate medical care if symptoms occur.
- If a patient presents with any signs and symptoms suggestive of DRESS, promptly discontinue anti-TB drugs, including ethambutol, and refer to a dermatologist for DRESS management.
- Sequential rechallenging with monitoring can help identify the causative drug. If ethambutol is identified as the causative drug, withdraw ethambutol and consider alternative treatment (as appropriate).
- Report all suspected adverse events associated with the use of anti-TB products, including ethambutol, to the NPRA.

ACTIVITIES

MAJLIS SANTAPAN MALAM JABATAN FARMASI

MAJLIS PERPISAHAN MISS JOSEPHINE

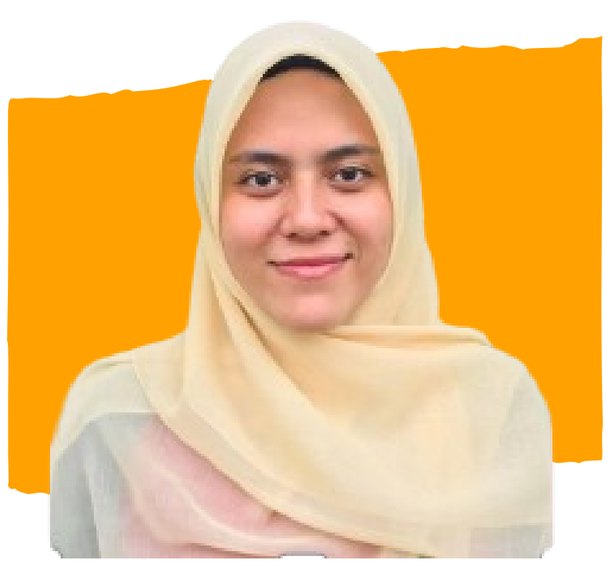
WELCOME TO HOSPITAL SEGAMAT

FUI HUEY PIN
PF UF13

MOHD ASYRAF BIN SAMSUDIN
PF UF10

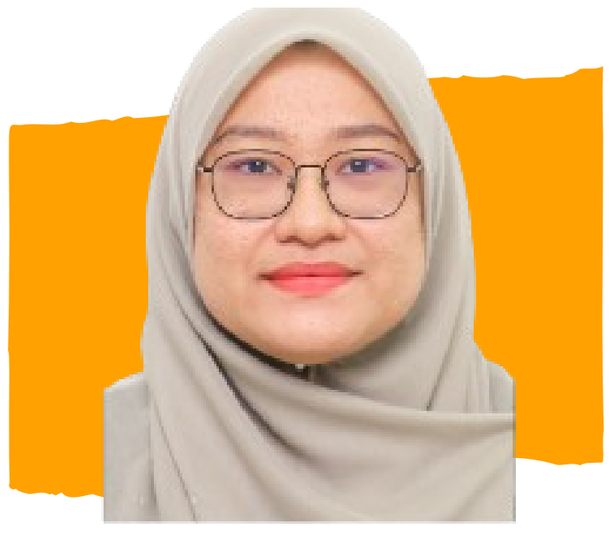
NURUL QISTINA BINTI MOHD SHABERI
PF UF9

NURAMALINA BINTI AFANDI
PF UF9



NURUL ATHIRAH BINTI RIDUAN
PF UF9

MUHAMMAD MUSTAQIM BIN MOHAMMAD ROSDI
PPF U5



INTAN NADZIRAH BINTI YUNOS
PPF U5

WELCOME TO HOSPITAL SEGAMAT

NEW PRPs

MUHAMMAD SIRAJUDDIN BIN AB RAHMAN

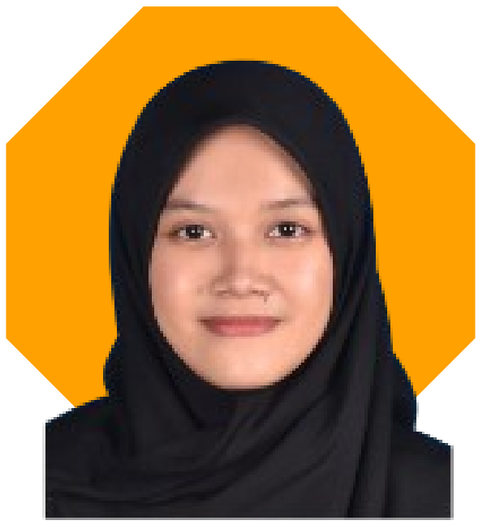
SAIFUL AMRI BIN HASNAN

HANNAN BINTI ABDUL RAZAK

SHAMIMI IRAWAYU BINTI SAMSUDIN

NURUL NASUHA BINTI ALMA ZA'ADI

NUR ALYANI BINTI MOHAMAD ASRI



NOR HIDAYATUL ALIA BINTI HARUN

NUR AYUNI SYAHIRAH BINTI ABDUL NAIDI

THANK YOU & FAREWELL,

CIK IZZATI, EN ADI, CIK SUHAILA, MS OOI WEN LI & MS JOSEPHINE