

PHARMACY BULLETIN

FIRST EDITION 2019

PHARMACY DEPARTMENT
HOSPITAL SERI MANJUNG

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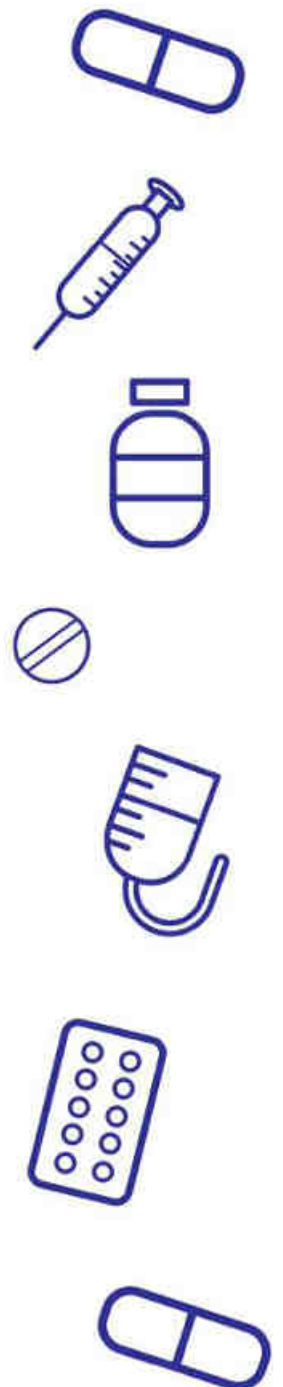
HIGH ALERT MEDICATIONS

by Cik Nur Qatrunnada bt Mohd Sukhairi, Cik Foo Yen Li

High Alert Medications are medications that bear a heightened risk of causing significant patient harm when these medications are used in error. Though medication mishaps with High Alert Medications may or may not be more common than other drugs, the consequences following an error with these drugs can be especially serious to the patient.

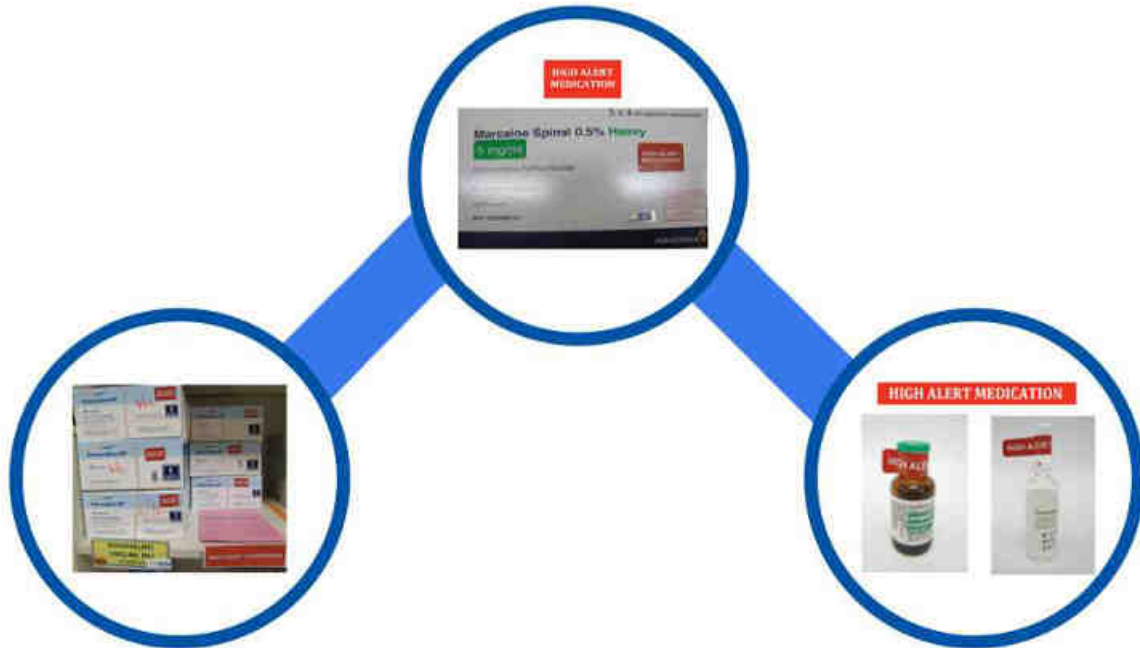
High Alert Medications Category

- 1 Adrenergic agonists, IV**
e.g. adrenaline, noradrenaline
- 2 Adrenergic antagonists, IV**
e.g. propranolol, labetalol
- 3 Anaesthetic agents, general, inhaled and IV**
e.g. propofol, ketamine, dexmedetomidine
- 4 Antiarrhythmias, IV**
e.g. lignocaine (lidocaine), amiodarone
- 5 Antifibrinolytics, hemostatic**
- 6 Antithrombotic agents**
e.g. warfarin, heparin, tenecteplase, streptokinase
- 7 Antivenom**
e.g. sea snake, cobra, pit viper antivenom
- 8 Chemotherapeutic agents, parenteral and oral**
- 9 Dextrose, Hypertonic, 20% or greater**
- 10 Epidural and intrathecal medications**
- 11 Glyceryl Trinitrate injection**
- 12 Inotropic medications, IV**
e.g. digoxin, dobutamine, dopamine
- 13 Insulin, subcutaneous and IV**
- 14 Magnesium Sulphate Injections**
- 15 Moderate sedation agents, IV**
- 16 Neuromuscular blocking agents**
e.g. pancuronium, atracurium, rocuronium, vecuronium
- 17 Opiates and Narcotics**
- 18 Parenteral Nutrition preparations**
- 19 Potassium salt injections**
- 20 Sodium Chloride Solution (greater than 0.9%)**



High Alert Medications Category

High alert stickers for containers or product packages



High alert labels for storage shelves in pharmacy

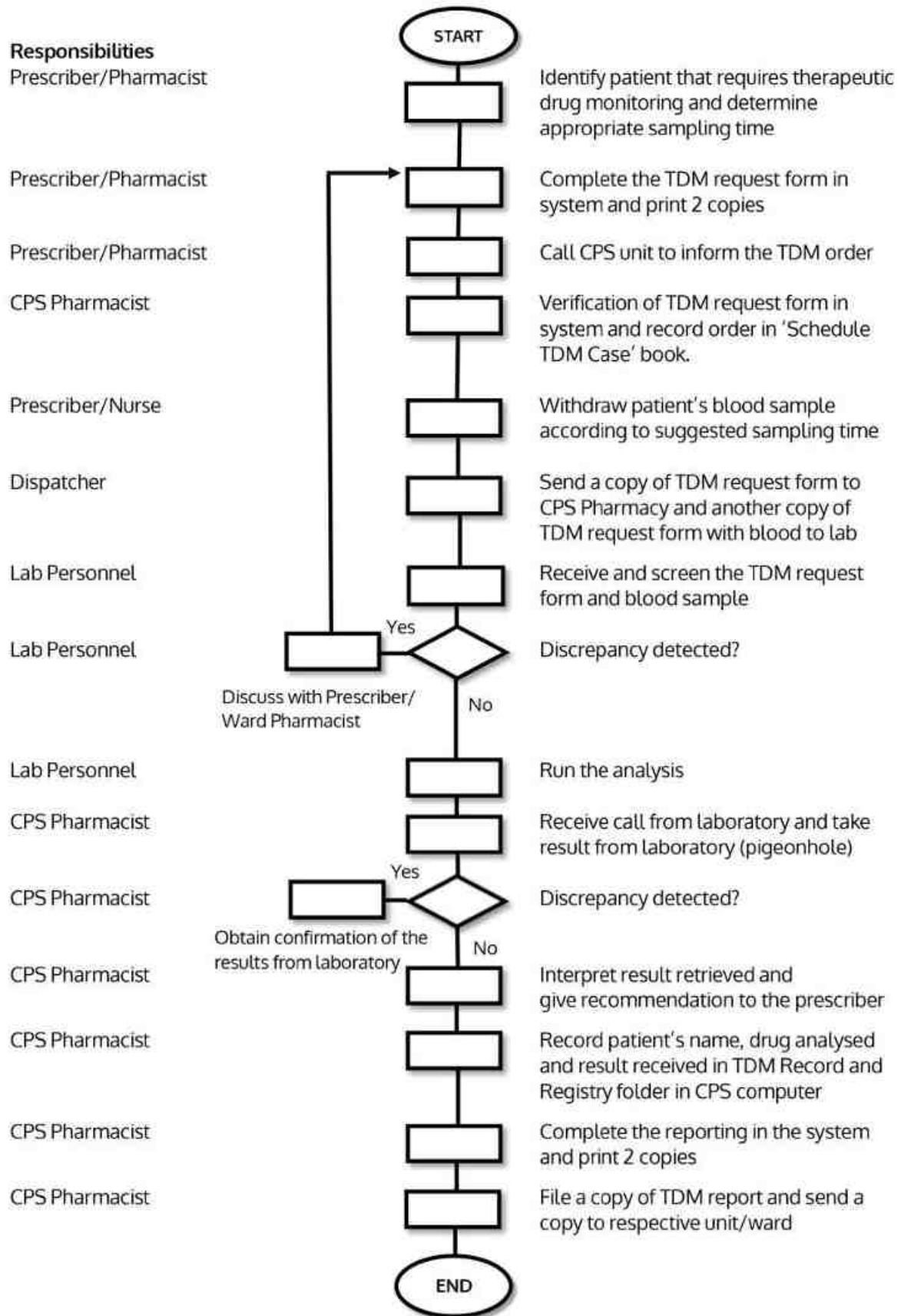
High alert stickers for ampoules or vials

- ⚠ High Alert Medications must be **double checked** before they are prepared, dispensed and administered to the patients.
- ⚠ All High Alert Medications issued from the pharmacy must be **counterchecked and verified by another pharmacy staff** prior to dispensing for the purpose of medication safety and accuracy.
- ⚠ Any changes of brand/colour/preparation of High Alert Medications must be **informed to the users** as soon as possible.
- ⚠ All equipment or devices used in the preparation and/or administration of medications shall be **calibrated and maintained** according to Standard Operating Procedure (SOP).
- ⚠ All staff involved in the handling of High Alert Medications should be educated on this guideline.

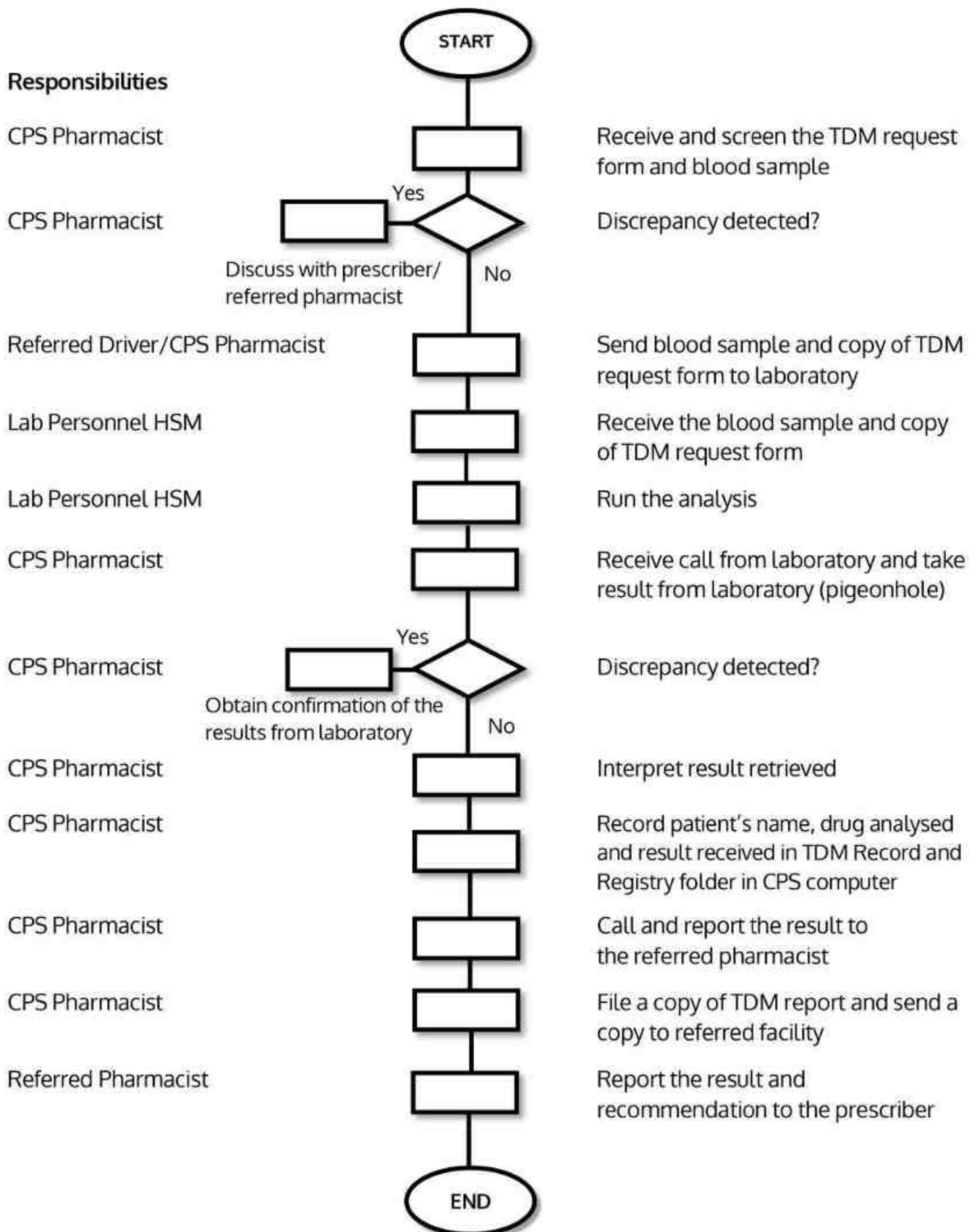
TDM WORKFLOW

by Cik Nur Farhah binti Samsuddin

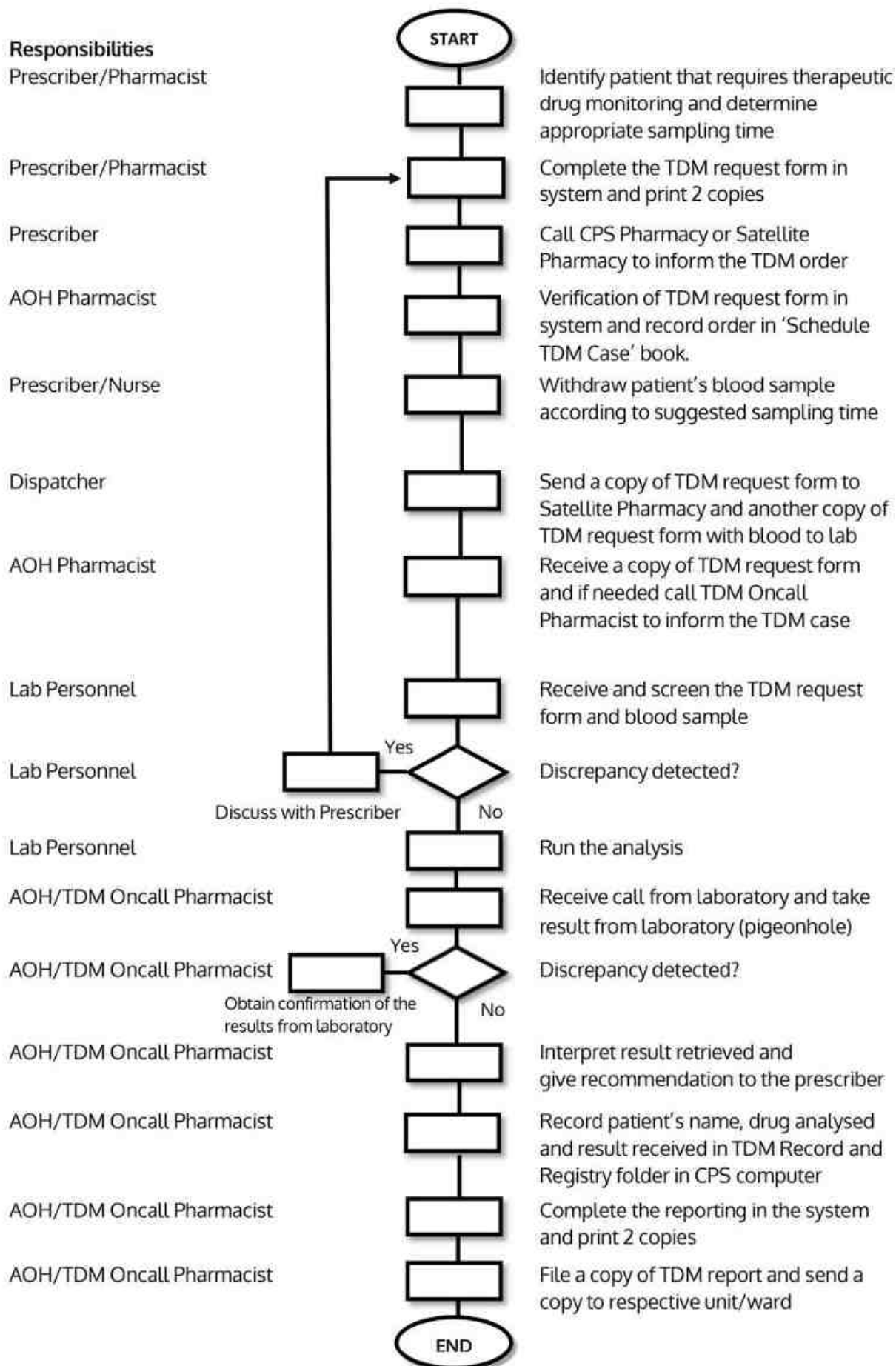
Therapeutic Drug Monitoring (Lab-based)



Outsourced Therapeutic Drug Monitoring (Lab-based)



After Office Hour Therapeutic Drug Monitoring (Lab-based)



Task List Therapeutic Drug Monitoring

No.	Task	Responsibilities	
		Office Hour	After Office Hour
1.	Order TDM in PhIS	Prescriber	Prescriber
2.	Print 2 copies TDM Request Form	Prescriber	Prescriber
3.	Call CPS Pharmacy or Satellite Pharmacy to inform order TDM	Prescriber	Prescriber
4.	Verify TDM Request Form in PhIS	CPS Pharmacist	AOH Pharmacist
5.	Withdraw Blood	Prescriber/Nurse	Prescriber/Nurse
6.	Send a copy of TDM Request Form to Satellite Pharmacy	Dispatcher	Dispatcher
7.	Reconfirm the sampling details with prescriber	CPS Pharmacist	AOH Pharmacist
8.	Send blood sample with TDM Request Form to laboratory	Dispatcher	Dispatcher
9.	Call laboratory to allow sample analyse	CPS Pharmacist	AOH Pharmacist
10.	Run the analysis	Lab Personnel	Lab Personnel
11.	Call TDM Oncall PRP (if needed)	-	AOH Pharmacist
12.	Call CPS Pharmacy or Satellite Pharmacy to inform readiness of result (Ext: 6696/6695)	Lab Personnel	Lab Personnel
13.	Receive result from laboratory (pigeonhole)	CPS Pharmacist	AOH/TDM Oncall Pharmacist
14.	Interpret and give recommendation	CPS Pharmacist	AOH/TDM Oncall Pharmacist
15.	Inform result and recommendation to prescriber	CPS Pharmacist	AOH/TDM Oncall Pharmacist
16.	Record patient's data in TDM Record and Registry folder in CPS computer	CPS Pharmacist	AOH/TDM Oncall Pharmacist
17.	Complete reporting in PhIS	CPS Pharmacist	AOH/TDM Oncall Pharmacist
18.	Print 2 copies the TDM Report	CPS Pharmacist	AOH/TDM Oncall Pharmacist
19.	File a copy of TDM Report	CPS Pharmacist	AOH/TDM Oncall Pharmacist
20.	Send to ward a copy of TDM Report	CPS Pharmacist	AOH/TDM Oncall Pharmacist

Reference: Hospital Seri Manjung TDM Workflow, 2018

PHIS TPN ORDER

by Cik Nur Farhah binti Samsuddin

PHIS TPN Order Management

- 1 **Order Management** → **Medication Order** → **Select Patient** (Name, MRN, Location)
- 2 **Parenteral Nutrition Order** → **Nutritional Assessment (SGA)** → **Calorie Calculator**
- 3 Decide Medication Order for **Standard Neonate** or **Standard Adult** (Refer below)
- 4 **Manage Order**
 - Modify Order
 - Hold/Resume Order
 - Cancel/Stop Order

Medication Order for Standard Neonate

Commercial/MOH Pre-Mix Std. Solution

- 1 Click **Search button** and **select** accordingly:
 - PN Solution 100ml **Starter** Dextrose 10%
 - PN Solution 3,400ml **Preterm** Dextrose 10% **Normal Sodium**
 - PN Solution 4,300ml **Preterm** Dextrose 10% **Na⁺ 6mmol**
 - PN Solution 500ml 282.5kcal **Term Standard** Dextrose 12%
 - Lipid Solution 36ml Lipid + Water-Soluble Vitamin (6.4g/36ml)

2 Key in both **Birth Weight** and **Current Weight**

3 **Administration Info**


Key in required:

- **PN Bag volume over 24 hours**
- **Lipid volume over 24 hours (new prescription)**

PN Indication

PN Duration

Select infusion line: **Peripheral/Central**

4 - 6 Click  to **add prescription**

Click  to **save prescription**

Click **Confirm Order** to confirm prescription

Note (Optional):

- Click on **Print Prescription button** to view/print PN Prescription
- Click **New Prescription** to order a new prescription

Medication Order for Standard Adult

Commercial/MOH Pre-Mix Std. Solution Add Additive

1 Click **Search button** and **select** accordingly:

- SMOF Kabiven Peripheral 1,000kcal (1.5L)
- SMOF Kabiven Central 1,600kcal (1.5L)

2 - 3 Click **Add Additive**

Click **Body Weight**

BMI	Click Body Weight
<18.5	Ideal Body Weight
18.5 - 24.9	Actual/Ideal Body Weight
25.0 - 29.9	Ideal Body Weight
30.0	Adjusted Body Weight



4

Administration Info

Key in required **PN Bag volume over 24 hours**

PN Indication

PN Duration

Select infusion line: **Peripheral/Central**

Add remark: **Infusion rate ____ mL/hr**

5

Enter value of:

- Trace element (**Addamel**): 10ml/vial
- L-glutamine (**Dipeptiven**): 100ml/vial
- Click for Single Vitamin:
 - Water soluble (**Soluvit**): 10ml/vial
 - Lipid soluble (**Vitalipid**): 10ml/vial

6 - 8

Click  to **add prescription**

Click  to **save prescription**

Click **Confirm Order** to confirm prescription

Note (Optional):

- Click on **Print Prescription button** to view/print PN Prescription
- Click **New Prescription** to order a new prescription

- 6-8** Enter **Dispensed To** → Select **Dispensed At** → Select **Remarks** → Select **Dispensed Date and Time** → Enter **Collected by** → Click on the button and alert message will be displayed → Click on the button **YES** to dispense order

COLLECTOR DETAILS

Dispensed To: PUSKESMAS MANJUNG

Dispensed At: Pharmacy Counter

Dispensed Date and Time: 17/04/2014 04:11:22 PM

Collected By:

Remarks:

Reference:

- Hospital Seri Manjung TPN Workflow, 2019

DOSSIER D4

by Cik Liew Ka Kei

What is Dossier D4?

- Dossier D4 is to be used by the applicant (consultant/ specialist/ medical officer/ pharmacist) for the purpose of listing medicines into their institution's Medicines Formulary.
- A medicine/ indication is eligible for consideration to be added into the institution's Medicines Formulary only when it is listed/ approved in the Ministry of Health Medicines Formulary (MOHMF).
- The form should be submitted to the Secretariat of the institution's Drug and Therapeutic Committee (DTC). The Secretariat will present a brief review of the application in the DTC meeting for approval.



What Secretariat should do?

The Secretariat should take into consideration the following matters:

- Current available alternatives in the institution's Medicines Formulary
- Available budget for each discipline/ activity
- Impact of adding the new medicine(s) to the overall medicine budget
- Estimated number of patients to be treated with the new medicine
- Training required in handling new medicine (if any)

What Pharmacist should do?

Pharmacist should monitor the utilization, costs and adverse effects of the newly approved medicine.

Approval for the said medicine for the Institution Medicines Formulary should be of the same prescriber category as the MOHMF or higher.



DOSSIER D4 New Drug Application Form

To be filled by applicant (consultant/ specialist/ medical officer/ pharmacist)

DOSSIER D4
To Add Medicines/ Indication Listed in the MOH Medicines Formulary into Institution's Medicines Formulary

1. MEDICINE PARTICULARS (to be filled by applicant)

1. Generic name (specify dosage form(s) & strength(s)/ concentration(s))	
2. Indication(s) approved for MOH Medicines Formulary	
3. Approved category of prescriber	
4. Proprietary name	
5. Dosing, frequency and duration of treatment	
6. Existing medicine(s) with the same/ similar indication & annual procurement	Generic name 1: _____ Year: _____ RM: _____ Generic name 2: _____ Year: _____ RM: _____
7. The main reason(s) to list the product. Please tick the main reason of the proposal.	<input type="checkbox"/> Has therapeutic advantage over an existing drug <input type="checkbox"/> A cheaper alternative to an existing drug <input type="checkbox"/> Improve compliance <input type="checkbox"/> Others (please specify below): _____
8. Is this a replacement for existing medication?	No: _____ Yes: _____
9. Other details on rationale of application.	

3. COSTS AND BUDGET IMPLICATION TO THE INSTITUTION

1. Estimated number of patients per year (a)	
2. Price per pack size (RM)	
3. Dosing, frequency and duration of treatment	
4. Total medicine cost per patient per year (b)	
5. Estimated total cost of medicine incurred per year (a x b)	
6. Available budget for the relevant discipline/activity	

2. APPLICANT'S STATEMENT OF DECLARATION

STATEMENT OF DECLARATION

I, the undersigned, declare herewith that to my best knowledge and professional responsibility all information submitted within this dossier is complete and correct.

Signature: _____ Date: _____
 Name of Officer: _____ Contact Number: _____
 Designation: _____ Email Address: _____
 Official Stamp: _____

4. HEAD OF DEPARTMENT

SUPPORT NOT SUPPORT

Comment: _____

Signature: _____
 Date: _____
 Name & Stamp: _____

5. HEAD OF PHARMACY DEPARTMENT

SUPPORT NOT SUPPORT

Comment: _____

Signature: _____
 Date: _____
 Name & Stamp: _____


6. APPROVAL BY DRUGS & THERAPEUTICS COMMITTEE

SUPPORT NOT SUPPORT

Comment: _____

Signature (Chairperson): _____
 Meeting Date: _____
 Name & Stamp: _____

Application Form to Increase Number of Quota Drugs in HSM

 **JABATAN FARMAK**
HOSPITAL SERI MANJUNG
DUAH SERI MANJUNG
PERAK DARUL KEJAYAAN
KEMENTERIAN KESEHATAN MALAYSIA

HSM - FAR - Brg. 11
No. Tel : 05-6996600
No. Fax : 05-6884013

**PERMOHONAN TAMBAHAN KUOTA YANG DIPERLUKAN BAGI RAWATAN PESAKIT
DI HOSPITAL SERI MANJUNG**

Bil.	Nama Ubat & Kekuatan (Generik / Trade Name)	UNTUK DIMULAI PERMOHONAN			UNTUK KEPUTUSAN		
		Kuota Asal (Sebelum / Setelah)	Kuota Tambahan (Sebelum / Setelah)	Sebab Diperlukan / Justifikasi Menambah Kuota	Implikasi Kes	Setuju / Tidak Setuju	Ulasan

PAKAR YANG MEMOHON:
 Nama: _____
 Tandatangan & Cop: _____
 Tarikh: _____

Diluluskan Oleh:
 (_____)
 Pengerusi Jawatankuasa
 Perolehan Ubat-ubatan
 Hospital Seri Manjung

Dibincangkan dalam Mesyuarat Bil. _____ pada tarikh _____

Reference:

Guidelines on Submission of Dossier for Listing into the Ministry of Health Medicines 2nd Edition) (2019). Pharmaceutical Services Division, Ministry of Health Malaysia.

OCTAPLEX

by Cik Nur Dayana Syazlina binti Rusli

Octaplex (Human Prothrombin Complex) contains:

1. Medicinal ingredients

Coagulation factor II, VII, IX, X and Protein C and S

2. Non-medicinal ingredients

Heparin, sodium citrate, solvent (Water for Injection)



One package of Octaplex contains:

- 1 powder vial containing active ingredients and excipients
- 1 vial containing 20/40ml of diluent and a Mix2Vial transfer set with integrated filter

Indication

To treat and prevent bleeding:

- Caused by Vitamin K antagonists (i.e. warfarin) that block the effect of Vit. K and cause a shortage of Vit. K dependent clotting factors in the body. Octaplex is used when rapid correction of the shortage is required.
- In people born with shortage of Vit. K dependent clotting factors II and X. Octaplex is used when purified specific clotting factor product is not available

Contraindication

- Patients who are hypersensitive to this active ingredients or its excipients
- Patients with Type II heparin-induced thrombocytopenia or with known allergies to heparin
- Patients who have immunoglobulin A (IgA) deficiency with known antibodies against IgA.
- Patients who have recent myocardial infarction with a high risk of thrombosis or with angina pectoris except:
 - Life-threatening bleeds due to overdose of oral anticoagulants
 - Emergency surgical procedure indicated in patients on Vit. K antagonists and an INR > 3
- Patients treated for coagulation disorders due to chronic liver disease or liver transplantation

Dose

1. Bleeding and prevention of bleeding during Vitamin K antagonist treatment:

Dose depends on the INR before treatment and the targeted INR. Following table shows approximate doses required for normalisation of INR (≤ 1.2 within 1 hour) at different initial INR levels.

Initial INR	2 - 2.5	2.5 - 3	3 - 3.5	>3.5
Approximate dose* (mL Octaplex/kg body weight)	0.9 - 1.3	1.3 - 1.6	1.6 - 1.9	>1.9

* Single dose should not exceed 3,000 IU (= 120 mL Octaplex). As these recommendations are empirical and recovery and the duration of effect may vary, monitoring of INR during treatment is mandatory.

2. Bleeding and perioperative prophylaxis in congenital deficiency of factors II and X when specific coagulation factor product is not available:

The calculated required dosage for treatment is based on the empirical finding that approximately 1 IU of factor II or X per kg body weight raises the plasma factor II or X activity by 0.02 and 0.017 IU/mL, respectively.

Required dosage for factor X:

Required units =

body weight (kg) x desired factor X rise (IU/mL) x 60

*where 60 (mL/kg) is the reciprocal of the estimated recovery

Required dosage for factor II:

Required units =

body weight (kg) x desired factor II rise (IU/mL) x 50

*where 50 (mL/kg) is the reciprocal of the estimated recovery.

If the individual recovery is known, that value should be used for calculation

Administration

Administered intravenously.

The infusion should start at a speed of 1ml per minute, followed by 2-3 ml per minute using an aseptic technique.

The single dose should not exceed 3000 units for Factor IX (120mls of Octaplex)

Instructions for Reconstitution

Reconstitute product at room temperature and on a stable surface. Remove the flip caps from the Octaplex[®] vial and the WFI vial and disinfect the rubber stoppers with alcohol swabs



- 01** Peel away the lid of the outer package of the Mix2Vial™ package.



- 02** Firmly push the blue end of the Mix2Vial™ through the rubber stopper of the WFI vial in one swift motion



- 03** While holding onto the WFI vial, carefully remove the outer package from the Mix2Vial™



- 04** Quickly invert the WFI vial (with the Mix2Vial™ attached) and push the transparent plastic end of the Mix2Vial™ through the stopper of the Octaplex[®] vial. Maintain pressure until there is complete transfer of water into the powder vial



- 05** With both vials still attached, slowly rotate the Octaplex[®] vial to ensure the product is fully dissolved to a clear or slightly opalescent solution



- 06** Unscrew the Mix2Vial™ into two separate pieces with the vials still attached. Discard the empty WFI vial and the blue part of the Mix2Vial™. The transparent part must stay on the Octaplex[®] vial as it contains filter



- 07** After Octaplex[®] has been reconstituted, attach a plastic sterile disposable syringe to the transparent part of Mix2Vial™. Invert the system and draw the reconstituted Octaplex[®] into the syringe

Interactions

- Octaplex must not be mixed with other medicinal products.
- Octaplex stops the effect of vitamin K antagonist medicines (e.g. warfarin), but no interactions with other medicines are known.
- Octaplex may affect the results of clotting tests which are sensitive to heparin.

Pregnancy and breast feeding

Octaplex should only be used during pregnancy and breast-feeding if clearly needed.

Storage and stability

3 years shelf-life.

After reconstitution the solution is to be used immediately. Octaplex must be stored in the fridge at 2 - 8°C, provided sterility of the stored product is maintained.

Do not freeze. Protect from exposure to light.

Reference:

Package Leaflet Octaplex 500IU and 1000IU powder and solvent for solution for infusion

PRAXBIND

by Ng Qiao Wei

What is PRAXBIND?

Idarucizumab (Praxbind) is a specific reversal agent for dabigatran. It is a humanized monoclonal antibody fragment (Fab) that binds to dabigatran with very high affinity.

The idarucizumab-dabigatran complex is characterised by a rapid on-rate and extremely slow off-rate resulting in a very stable complex. Due to high affinity of idarucizumab towards dabigatran than dabigatran to thrombin, the anticoagulant effect of dabigatran is reversed.



Idarucizumab (Praxbind)
2.5g/50mL solution for
injection/infusion

Indication

Adult patients treated with Pradaxa (dabigatran etexilate) when rapid reversal of its anticoagulant effects is required in:

- Emergency surgery/urgent procedures
- Life-threatening or uncontrolled bleeding

Contraindication

None

Dose



5g
(2 separate vials, each containing 2.5g/50mL)

No dose adjustment is needed for patient with renal impairment or elderly. There is no study about dose adjustment in hepatic impairment patient.

Administration of a second 5g dose of Praxbind may be considered in the following situations:

- Recurrence of clinically relevant bleeding together with prolonged clotting times
- Patients require a second emergency surgery/urgent procedure and have prolonged clotting times.

Administration

Praxbind (2x2.5 g/50 mL) is administered intravenously as:



**2 consecutive infusions
over 5 to 10 minutes each**



**Bolus injection
(consecutively one after
another via syringe)**

IV line must be flushed with sodium chloride 9 mg/ml (0.9 %) solution for injection prior to and at the end of infusion.

This medicinal product must not be mixed with other medicinal products. No other infusion should be administered in parallel via the same intravenous access.

Precautions

1. Thromboembolic events

Reversing dabigatran therapy exposes patients to the thrombotic risk of their underlying disease. To reduce this risk, resumption of anticoagulant therapy should be considered as soon as medically appropriate.

2. Hypersensitivity

If anaphylactic reaction or other serious allergic reaction occurs, administration of Praxbind should be discontinued immediately and appropriate therapy should be initiated.

3. Hereditary fructose intolerance

The recommended dose of Praxbind contains 4g sorbitol as an excipient. In patients with hereditary fructose intolerance, parenteral administration of sorbitol has been associated with hypoglycemia, hypophosphatemia, metabolic acidosis, increase in uric acid, acute liver failure with breakdown of excretory and synthetic function, and death.

If Praxbind is administered in these patients, intensified medical care during Praxbind exposure and within 24 hours of exposure is required.

Restarting Antithrombotic Therapy

Pradaxa (Dabigatran etexilate) treatment can be re-initiated 24 hours after administration of Praxbind if the patient is clinically stable and adequate haemostasis has been achieved.

Other antithrombotic therapy (e.g. low-molecular weight heparin) can be started at any time, if the patient is clinically stable and adequate haemostasis has been achieved.

Pregnancy and breastfeeding

There are no data for the use of Praxbind in pregnant women. Preclinical results do not suggest a risk to fertility or embryo-fetal development. It is also unknown whether Praxbind is excreted in human milk. Praxbind may be used during pregnancy and breastfeeding, if the expected clinical benefit outweighs the potential risks.

Storage and stability

Store in a refrigerator (2 - 8 °C). Do not freeze.

Store in the original package to protect from light. The solution should not be exposed to light for more than 6 hours (in unopened vial and/or in-use).

Prior to use, the unopened vial may be kept at room temperature (up to 30 °C) for up to 48 hours.

References:

- Product leaflet PRAXBIND (Idarucizumab 2.5g/50mL solution for injection/infusion), 2018. Boehringer Ingelheim Limited.
- Medscape. (2019). Praxbind (idarucizumab) dosing, indications, interactions, adverse effects, and more. [online] Available at: <https://reference.medscape.com/drug/praxbind-idarucizumab-1000042#5> [Accessed 10 Apr. 2019].

NEW INHALER AVAILABLE IN HSM

by Cik Loh Li Vien

SPIOLTO RESPIMAT



SEEBRI



FLUTIFORM



Active Ingredients	2.5mcg tiotropium bromide/ 2.5mcg olodaterol hydrochloride per puff	50mcg glycopyrronium	Flutiform 250mcg fluticasone propionate/ 10mcg formoterol
Pharmaceutic Form	Pressurised inhalation, suspension	Inhalation powder, hard capsule	Clear, colourless, inhalation solution
Indication	Chronic obstructive pulmonary disease (COPD)	Chronic obstructive pulmonary disease (COPD)	Treatment of asthma for: <ul style="list-style-type: none"> • Patients not adequately controlled with inhaled corticosteroids and 'as-required' inhaled short-acting β_2 agonist • Patients already adequately controlled on both inhaled corticosteroid and long-acting β_2 agonist

SPIOLTO RESPIMAT

SEEBRI

FLUTIFORM

Mechanism of Action

- Tiotropium bromide is a long-acting specific antagonist at muscarinic receptors. It competitively and reversibly binds to the M₃ receptors in the bronchial smooth musculature, resulting in bronchial smooth muscle relaxation.
- Olodaterol hydrochloride has the pre-clinical profile of a long-acting selective β_2 -adrenoceptor agonist (LABA) with a fast onset of action and a duration of action of at least 24 hours. It binds and activates β_2 -adrenoceptors, caused relaxation of airway smooth muscle cells.

Glycopyrronium is an inhaled long acting muscarinic receptor antagonist. It works by blocking the cholinergic action of acetylcholine on airway smooth muscle cells (bronchoconstriction), thereby dilating the airways.

- Fluticasone propionate is a synthetic glucocorticoid with potent anti-inflammatory in lungs when given by inhalation. It reduces symptoms and exacerbations of asthma with less adverse effects than when corticosteroids are administered systemically.
- Formoterol fumarate is a long-acting selective β_2 -adrenergic receptor agonist (LABA). Inhaled formoterol fumarate acts locally in the lung as a bronchodilator. The onset is rapid, (1-3 minutes) and the duration of effect is at least 12 hours after a single dose.

	SPIOLTO RESPIMAT	SEEBRI	FLUTIFORM
Dose and Administration	2 puffs OD (No relevant use for patient under 18 years)	1 capsule OD (No relevant use for patient under 18 years)	Flutiform 250mcg/ 10mcg inhaler 2 puffs BD (adults only, ≥18 years)
Pregnancy and Lactation	Avoid during pregnancy due to a relaxant effect on uterine smooth muscle (olodaterol component)	Only use during pregnancy if the expected benefit to the patient justifies the potential	Potential for β-agonist interference with uterine contractility, use for asthma during labour should be restricted to those patients in whom the benefit outweighs the risks
Special Warnings and Precautions	<ul style="list-style-type: none"> • Should not be used in asthma without use of long term asthma control medication • Should not be used to treat acute asthma symptoms 	<ul style="list-style-type: none"> • Should not be used in asthma or asthma-COPD overlap without an inhaled corticosteroid • Should not be used to treat acute asthma symptoms 	<ul style="list-style-type: none"> • Should not be used in patients with COPD • Should not be used to treat acute asthma symptoms
Shelf Life	3 months after first use	30 days after first use	3 months after opening the foil pouch

SPIOLTO RESPIMAT

SEEBRI

FLUTIFORM

Adverse Reactions

- **Anticholinergic adverse reaction**
Dry mouth, glaucoma, constipation, intestinal obstruction including ileus paralytic, and urinary retention.
- **β-adrenergic adverse reaction**
Arrhythmia, myocardial ischaemia, angina pectoris, hypotension, tremor, nervousness, muscle spasms, fatigue, malaise, hypokalemia, hyperglycemia, and metabolic acidosis.

Nasopharyngitis, headache, dry mouth, diarrhoea, sneezing, sore throat gastroenteritis, musculoskeletal pain, urinary tract infection

- Paradoxical bronchospasm
- **Fluticasone propionate**
Hypersensitivity reactions, anaphylaxis reaction, systemic effects may occur at high doses for prolonged periods which include Cushing's Syndrome, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract and glaucoma, contusion, skin atrophy, and susceptibility to infections.
- **Formoterol fumarate**
Hypersensitivity reactions, QTc interval prolongation, hypokalaemia, nausea, myalgia, increased blood lactate levels, increase in blood levels of insulin, free fatty acids, glycerol and ketone bodies.

References:

- <https://www.spiolto.com/product-information/summary-product-characteristics>
- Product leaflet Flutiform
- <https://www.medicines.org.uk/emc/product/2840>
- <https://www.medicines.org.uk/emc/product/6902>

- [https://www.medicines.org.uk/EMC/medicine/26954/SPC/fluti form+50+microgram+5+microgram,+125+microgram+5+microgram+and +250+microgram+10+microgram+per+actuation+pressurised+inhalation, +suspension/](https://www.medicines.org.uk/EMC/medicine/26954/SPC/fluti+form+50+microgram+5+microgram,+125+microgram+5+microgram+and+250+microgram+10+microgram+per+actuation+pressurised+inhalation,+suspension/)

