PHARMACY DEPARTMENT HOSPITAL SERI MANJUNG PHARMACY BULLETIN

DRUG AND POISON INFORMATION SERVICE

2ND EDITION 2018

In This Issue:

High Alert Medication (HAM)

High Alert Medications (HAM) are medications that has higher risk of causing significant patient harm when these medications are used wrongly.

High Alert Medication Category

Category
Adrenergic agonists, IV
Adrenergic antagonists, IV
Anaesthetic agents, general, inhaled and IV
Antiarrythmias IV
Antifibrinolytics, hemostatic
Antithrombotic agents
Antivenom
Chemotherapeutic agents, parenteral and oral
Dextrose, Hypertonic, 20% or greater
Epidural and intrathecal medications
Glyceryl Trinitrate injection
Inotropic medications, IV
Insulin, subcutaneous and IV
Magnesium Sulphate Injections
Moderate sedation agents, IV
Neuromuscular blocking agents
Opiates and Narcotics
Parenteral Nutrition preparations
Potassium salt injections
Sodium Chloride Solution (greater than 0.9%)

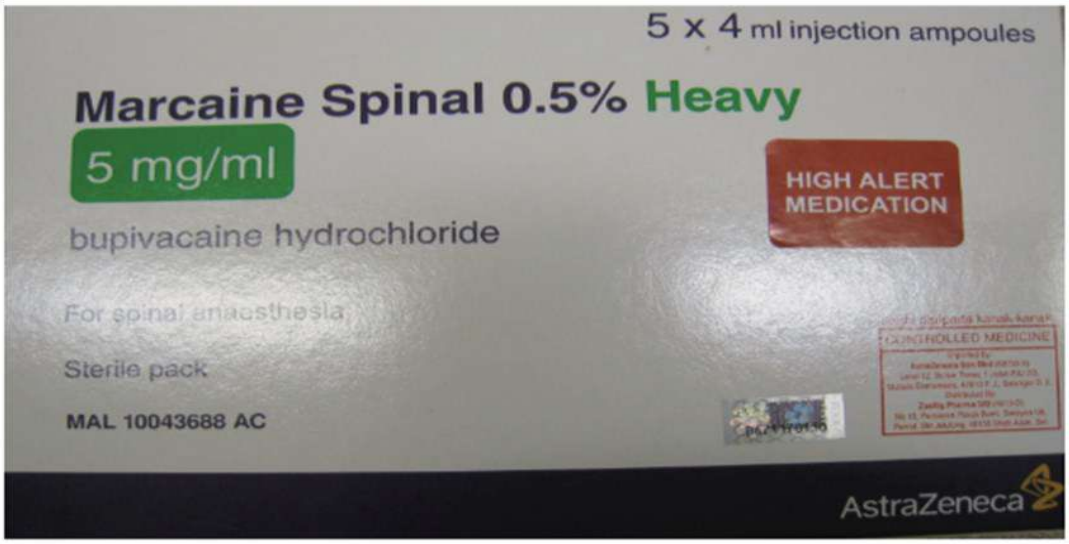
Common risk factors causing medication error with HAM

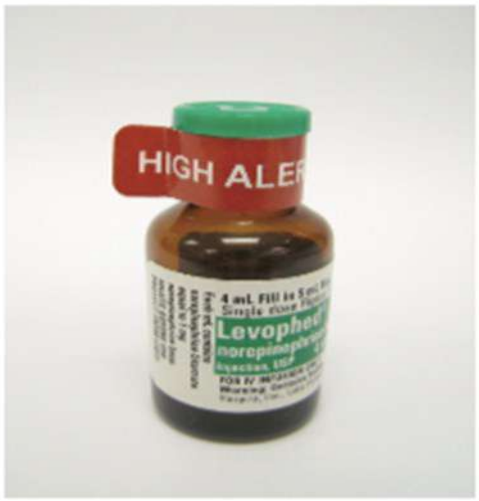
- Poorly written medication orders – incomplete direction or illegible handwriting.
- Incorrect dilution procedures.
- Confusion between IM, IV, Intrathecal, epidural preparations.
- Confusion between different strengths of the same medications.
- Ambiguous labeling on concentration and total volume of medications.
- Wrong infusion rate.
- Look alike or sound alike (LASA) product and similar packaging.

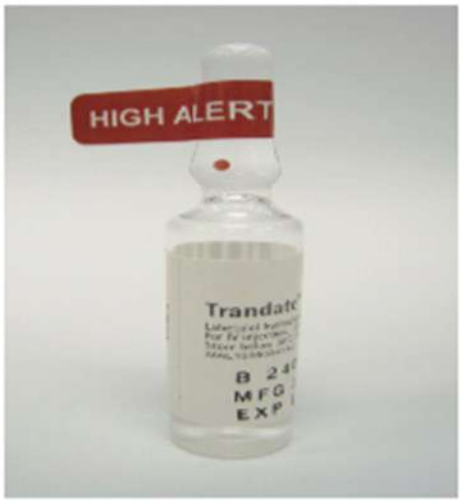
Managing High Alert Medication

- High Alert Medications should have “HIGH ALERT MEDICATION” labels on storage shelves, containers, product packages and loose vials or ampoules

Examples:







- High Alert Medications (HAM) must be double checked through established system before they are prepared, dispensed and administered to patients to ensure medication safety and accuracy.
- Equipment used in preparation and/or administration of HAM must be calibrated and maintained according to Standard Operating Procedure (SOP).
- Staff dealing with HAM should be educated with "Guidelines on Safe Use of High Alert Medication 2011" by Pharmaceutical Services Department, Ministry of Health Malaysia.

Suggested Strategies to avoid errors involving High Alert Medications

Procurement

- Limit the drug strengths available in the facility formulary
- Avoid frequent changes of brand or colour
- Inform all relevant personnel regarding new High Alert Medications
- Purchase equipment and consumables with safety features for administration

Storage

- Read the High Alert Medication labels carefully before storing
- Keep HAM in separate container.
- All containers keeping High Alert Medications must have "HIGH ALERT MEDICATION" label.
- Do not keep look-alike sound-alike drugs or different strengths of the same drug side by side.
- Use TALL-man lettering
- Limit ward's floor stock drugs to standard requirement.

Prescribing

- Avoid abbreviations when prescribing HAM.
- Specify the dose, route and rate of infusion for High Alert Medications prescribed. (e.g: IV Dopamine 5mcg/kg over 1 minute)
- Prescribe oral liquid medications with the dose specified in milligrams.
- Use standardized order forms for cytotoxic drugs and parenteral nutrition
- Use computerized prescriber order entry as far as possible

Preparation

- Counterchecking system should be established for preparations involving High Alert Medications.
- All calculations for cytotoxic drugs and parenteral nutrition shall be independently counter checked by another pharmacist; for extemporaneous preparations, by at least another trained personnel
- Every diluted preparation must be immediately labelled with name and strength of the preparation.

Example of label:

DRUG: CONCENTRATION: _____ mg in _____ mL NS/D5/_____	
DATE:	TIME:
PATIENT'S NAME: R/N:	
PREPARED BY:	CHECKED BY:

Dispensing/Supply

- Every individual containers, product packages and loose vials or ampoules of High Alert Medications supplied to wards/units must be labelled with "HIGH ALERT MEDICATION" with the exception of parenteral nutrition preparations.
- Preparations to be dispensed to patients do not need to be labelled with "HIGH ALERT MEDICATION".
- High Alert Medications must be counter checked prior to being dispensed.
- Health care providers must check High Alert Medications upon receiving them.

Administration

- Two appropriate persons shall independently double checked the following particulars against the prescription or medication chart before administration:
  1. Patient's name and RN
  2. Name and strength of medications
  3. Dose
  4. Route and rate (pump setting and line placements when applicable)
  5. Expiry date
- The distal ends of all access lines must be labelled to distinguish IV from epidural lines.
- Special measures should be implemented to prevent distractions from happening during administration of medications to patient.
- All unused or remaining specially formulated preparations should be returned to pharmacy.
- Administration of intrathecal, cytotoxic drugs, epidural analgesics and parenteral nutrition should be performed by trained personnel only.
- Verbal ordering of High Alert Medications should be avoided. Phone orders have to be repeated and corroborated in emergency situations.

Monitoring

- Vital signs, laboratory data, patient's response before and after administration of High Alert Medications should be monitored closely.
- Antidotes and resuscitation equipment should be kept in wards/units.

Training

All personnel shall be trained prior to handling of High Alert Medications and documentation to prevent errors and enable prompt response when mistakes occur.

Information

References or dilution guide should be made available in the wards and pharmacy.

Patient Education

1. Educate patient and family members / caregivers on

- Name and purpose of medications
- How much and when to take the medications
- How to take their medications
- Common side effects

2. Encourage patient and family involvement by:

- Asking what medications are being given and why they are being given
- Ensuring positive identification before receiving medications

3. Storage of High Alert Medications.

4. Disposal of expired/ unused High Alert Medications.

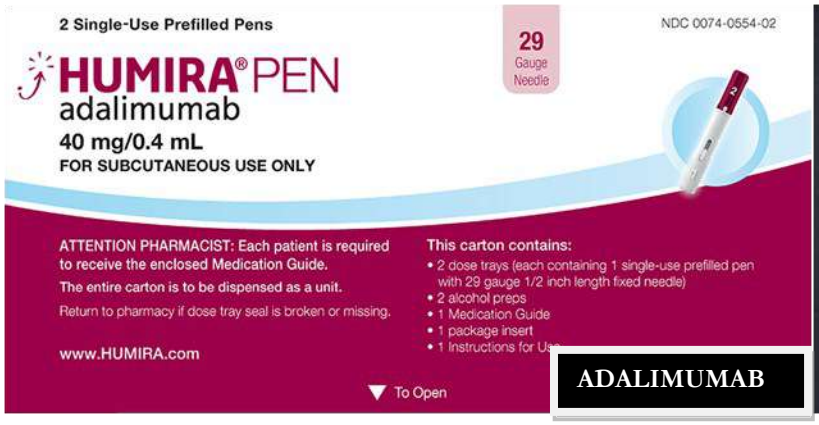
Evaluation of Action

Monitor adverse drug reactions and medication errors related to High Alert Medications.

Biologic Agents

- Biologic agents are molecules of biological origin that are being used therapeutically.
- Biologic agents are based on antibodies or receptor proteins. These agents are biologically modified in attempt to make them less immunogenic in humans.
- Biologic agents is beneficial by giving an alternative to the conventional treatment of disease-modifying anti-rheumatic drugs and other immunosuppressive medications.
- The major targets of most biologic therapies are cytokines, B cells, and co-stimulation molecules.

Drug name Suffix	Type of biologic agent	Example
-mab	Monoclonal antibody drug	Adalimumab Tocilizumab Infliximab Secukinumab
-inib	Kinase inhibitor	Tofacitinib



ADALIMUMAB

TOCILIZUMAB

INFLIXIMAB

SECUKINUMAB

TOFACITINIB

Biologic Agents

Drug	Indication	Dose
Adalimumab 40mg/0.4ml **Category :** A* **Price:** RM 2015.00 per pen **Pregnancy category:** B **Drug class:** Antirheumatic/Tumor necrosis factor (TNF) blocking agent	**i) Third line treatment of:** **- Severe rheumatoid arthritis** **- Psoriatic arthritis** **- Ankylosing spondylitis** after failure of conventional DMARDs or other biologics **ii) Treatment of moderate to severe chronic plaque psoriasis** For patient who have not responded to, have contraindication **or** are unable to tolerate phototherapy **and/or** systemic therapies including acitretin, methotrexate and cyclosporine **iii) Treatment of moderately to severely active Crohn's Disease** For adult patients who: • have inadequate response to conventional therapy • have lost response to or are intolerant to infliximab **iv) Ulcerative Colitis** For treatment of moderately to severely active ulcerative colitis in adult patients who • have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine, • who are intolerant to or have medical contraindications for conventional therapies	**i) Severe rheumatoid arthritis** **Psoriatic arthritis** **Ankylosing spondylitis :** Subcutaneous 40 mg every other week **ii) Chronic plaque psoriasis:** Initial, 80 mg SC, followed by 40 mg SC every other week starting one week after the initial dose **iii)&iv) Crohn's disease & Ulcerative colitis:** 160mg at week 0 (dose can be administered as four injections in one day or as two injections per day for two consecutive days) and 80mg at week 2. After induction treatment, the recommended maintenance dose is 40mg every other week via subcutaneous injection. **Monitoring parameters:** • Latent TB screening (prior to therapy initiation) • Complete Blood Count with differential • Signs & symptoms or worsening of heart failure • Signs & symptoms of infection (prior, during and after therapy) • HBV screening prior to initiating • Signs & symptoms of lupus-like syndrome • Signs & symptoms of malignancy

Biologic Agents

Drug	Indication	Dose
Tocilizumab 162mg/0.9ml Injection in prefilled syringe (for subcutaneous injection) **Category :** A* **Price:** RM 638.24 per prefilled syringe **Pregnancy category:** C **Drug class:** Antirheumatic/ Interleukin-6 receptor antagonist	**Treatment of moderate to severe active rheumatoid arthritis (RA)** in adult patients: i) with inadequate respond or intolerance to conventional disease- modifying antirheumatic drugs (DMARDS) ii) who has failed antitumour necrosis factors (antiTNFs) iii) where TNF is contraindicated (patients with history of pulmonary tuberculosis [PTB]) It also can be used as monotherapy or with combination with methotrexate (MTX) and/ or other DMARDS.	Adult patients: 162mg given once every week as a subcutaneous injection. **Monitoring parameters:** • Latent TB screening (prior to therapy initiation) • Neutrophils • Platelet • ALT/AST (piror to therapy, 4 to 8 weeks after start of therapy, and every 3 months) • Lipid Profile (prior to, at 4 to 8 weeks following initiation, and approximately every 6 months) • Sign and symptoms of infection (prior to, during and after therapy) • Sign and symptoms of CNS demyelinating disorders
Infliximab 100mg Injection **Category :** A* **Price:** RM 1750.00 per vial **Pregnancy category:** B **Drug Class:** Antirheumatic/Tumor necrosis factor (TNF) blocking agent	**i) Rheumatoid arthritis** (moderate to severe), in combination with methotrexate **ii) Ankylosing spondylitis** in patients with active disease despite treatment with methotrexate **iii) Crohn's Disease** in patients who have an inadequate response to conventional therapies. **iv) Fistulizing Crohn's Disease** in patients who have an inadequate response to conventional therapies **v) Ulcerative Colitis** in patients who have an inadequate response to conventional therapies	**i) Rheumatoid arthritis:** ADULT over 18 years old: 3 mg/kg at 0, 2, 6 weeks, then every 8 weeks; May increase to 10 mg/kg or increase dosing frequency to 4 weekly for patients with incomplete response. Discontinue if no response by 12 weeks of initial infusion or after dose adjustment **ii) Ankylosing spondylitis:** ADULT over 18 years: 5 mg/kg IV over 2 hour given at week 0, 2, and 6 then every 6-8 weeks. Discontinue if no response by 6 weeks of initial infusion. **iii), iv) & v)** 5 mg/kg given as an IV infusion over a 2-hour period followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter

Biologic Agents

Drug	Indication	Dose
		Monitoring parameters: • Latent TB screening (prior to therapy initiation) • Complete blood count • Signs & symptoms of infection (prior, during and after therapy) • HBV screening prior to initiating • Liver function test • Signs & symptoms of lupus-like syndrome
Secukinumab 150mg/ml Injection **Category :** A* **Price:** RM 1428.00 per vial **Pregnancy category:** B **Drug Class:** Anti-interleukin 17A monoclonal antibody/ Antipsoriatic agent	**i) Psoriatic Arthritis:** Secukinumab, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. **ii) Ankylosing Spondylitis:** Secukinumab is indicated for the treatment of active ankylosing spondylitis (AS) in adults who have responded inadequately to conventional therapy. • **Prescribing Restriction:** 2nd or 3rd line, after failure of conventional DMARDs or TNF-inhibitors	**i) Psoriatic Arthritis (PsA):** 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2 and 3, followed by monthly maintenance dosing starting at Week 4 For patients who are anti-TNF**α** inadequate responders (IR) or patients **with concomitant moderate to severe plaque psoriasis**: 300 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2 and 3, followed by monthly maintenance dosing starting at Week 4. Each 300 mg dose is given as two subcutaneous injections of 150 mg. **ii) Ankylosing Spondylitis (AS):** Recommended dose: 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2 and 3, followed by monthly maintenance dosing starting at week 4. **Monitoring parameters:** • Signs & symptoms of infection • Active TB (during and after treatment) • Sign and symptoms of inflammatory bowel disease

Biologic Agents

Drug	Indication	Dose
Tofacitinib Citrate 5mg Film Coated Tablet **Category :** A* **Price:** RM 53.52 per tablet **Pregnancy category:** C **Drug Class:** Antirheumatic / Janus Kinase Inhibitor	Indicated for the treatment of adult patients with **moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate.** It may be used as monotherapy or in combination with methotrexate or other non-biologic disease-modifying antirheumatic drugs (DMARDs).	One tablet twice daily **Monitoring parameters:** • Signs & symptoms of infection (during and after treatment) • Liver Function Test • Lymphocytes count (baseline and every 3 months) • Neutrophil / platelet count, haemoglobin (baseline, after 4-8 weeks and every 3 months thereafter) • Lipids (4-8 weeks after initiation and periodically)

Comparison between DPP-4 inhibitors (gliptins) & SGLT2 inhibitor

Background

Both dipeptidyl peptidase-4 (DPP-4) inhibitors and sodium glucose cotransporter 2 (SGLT2) inhibitors are used for the treatment of type 2 diabetes mellitus (T2DM) that is inadequately controlled with insulin therapy.

DPP-4 Inhibitors

MOA: Increases insulin secretion by reducing degradation of endogenous GLP-1, decreases glucagon secretion

- Metabolised by renal excretion (require renal dose adjustment) except for linagliptin as it is mainly metabolised through biliary route.

Ex: Saxagliptin (Onglyza), Linagliptin (Trajenta) & Vildagliptin (Galvus)

SGLT2 Inhibitors

MOA: Inhibits glucose reabsorption in the proximal renal tubule, resulting in increased renal glucose excretion

- Contraindicated in patients with CrCl < 45ml/min as its efficacy is dependant on renal function.

Ex: Empagliflozin (Jardiance) , Canagliflozin (Invokana)

Abbreviation:

MOA = Mechanism of action

GLP-1 = Glucagon-like peptide 1

CrCl = creatinine clearance

Comparison between DPP-4 inhibitors (gliptins) & SGLT2 inhibitor

- **SGLT2 inhibitors achieved better glycaemic control and greater weight reduction than DPP-4 inhibitors without increasing the risk of hypoglycaemia.**
- **DPP-4 inhibitors are better tolerated by the elderly.** (Empagliflozin is not recommended in patients > 85 years old)
- **DPP-4 inhibitors are safe to use in patients with renal impairment compared to SGLT2 inhibitors.** (Linagliptin does not require renal dose adjustment while Saxagliptin and Vildagliptin require renal dose adjustment for patients with CrCl < 50ml/min. However, Empagliflozin is contraindicated for patients with CrCl < 45ml/min)

SGLT2 inhibitors

Advantages of SGLT2 inhibitors :

1. Weight loss
2. Reduce cardiovascular risk
3. Low risk of hypoglycaemia
4. Blood pressure reduction

Side effects of SGLT2 inhibitors:

1. Urinary tract infection (UTI)
2. Increased urination
3. Potential for postural hypotension (due to sodium depletion)

DPP-4 inhibitors

Advantages of DPP-4 inhibitors :

1. Weight neutral (Prevent further weight gain)
2. Low risk of hypoglycaemia
3. Can be used in patient with renal impairment and those on haemodialysis

Side effects of DPP-4 inhibitors :

1. Upper respiratory tract infection
2. Nasopharyngitis
3. Joint pain

References :

1. Saxagliptin Product Leaflet
2. Linagliptin Product Leaflet
3. Vildagliptin Product Leaflet
4. Empagliflozin Product Leaflet
5. Xourgla, E., Papazafiropoulou, A., Karampousli, E., & Melidonis, A. (2017). DPP-4 Inhibitors vs. SGLT-2

Comparison between Saxagliptin, Linagliptin, Vildagliptin & Empagliflozin

Name	Dose	Renal Dose Adjustment	Contraindi-cation	Price	Quota
Saxagliptin 5mg Tablet	2.5 – 5mg OD	CrCl ≤ 50ml/min : 2.5mg OD For HD, adminis-ter after HD	-	RM27.20 / 28's	50 pts / year
***Linagliptin 5mg Tablet**	5mg OD	No renal dose ad-justment	-	RM54.00 / 30's	50 pts / year
Vildagliptin 50mg Tab-let	- 50mg BD - 50mg OD when combine with sulphonylure-as	CrCl < 50ml/min : 50mg OD	- Hepatic impairment	RM25.00 / 56's	Not yet available in HSM
Empagli-flozin 25mg Tablet	10 – 25mg OD Start : 10mg Max : 25mg	No renal dose ad-justment in CrCl > 45ml/min *not recommend-ed for pt ≥ 85 years old	- CrCl < 45ml/min - Severe renal impairment - ESRD - Dialysis	RM50.15 / 30's	100 pts / year

*Linagliptin was removed from FUKKM Bil. 1/2018 & HSM Formulary

Comparison between Anoro Ellipta & Ultibro Breezhaler

Background

Contents : Anoro Ellipta (Umeclidinium 62.5mcg/ Vilanterol 25mcg)
Ultibro Breezhaler (Glycopyrronium 50mcg/ Indacaterol 110mcg)

Indication : Maintenance bronchodilator treatment in adult patients with chronic obstructive pulmonary disease (COPD)

Both Anoro & Ultibro are a combination of long-acting muscarinic antagonists (LAMA) and long-acting β2 agonists (LABA), indicated for long term, once-daily maintenance treatment of COPD.

Anoro Ellipta (RM 89.45 / 30 doses)

- Dose: 1 inhalation OD
- Total dose: 30 doses
- Has a dose counter
- No dose adjustment required in renal-impaired patients
- No dose adjustment is required in patients with mild or moderate hepatic impairment, used with caution for patients with severe hepatic impairment.
- Ready to be used as it is.
- Discard 6 weeks after opening.

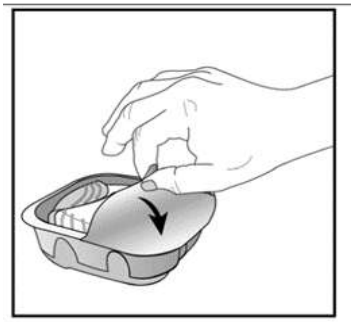
Anoro (Umeclidinium 62.5mcg/ Vilanterol 25mcg)

Ultibro Breezhaler (RM 126.70/ 30 capsules)

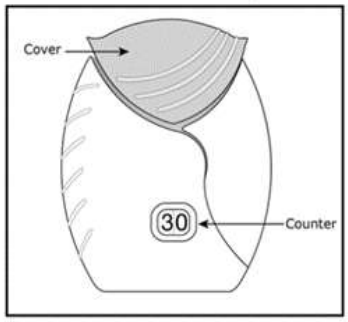
- Dose: 1 capsule inhalation OD
- Total dose: 30 capsules
- Does not have dose counter
- No dose adjustment for mild to moderate renal impairment. In patients with severe (GFR<30ml/min) or end-stage renal disease only use if the expected benefit outweighs the risk.
- No dose adjustment is required in patients with mild or moderate hepatic impairment, used with caution for patients with severe hepatic impairment.
- Capsule need to be pierced immediately before use.
- Dispose each inhaler after 30 days of use.

Ultibro (Glycopyrronium 50mcg/ Indacaterol 110mcg)

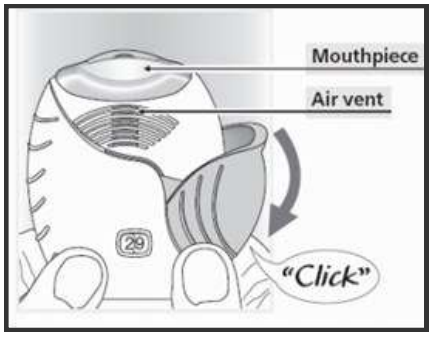
Counselling Steps for Anoro Ellipta



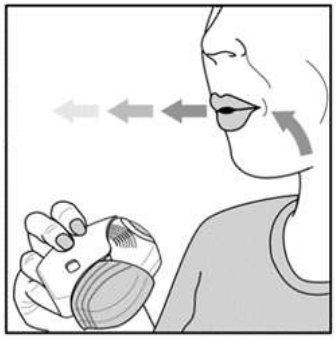
1. Peel back the lid to open the tray. Do not open the cover of the inhaler until you are ready to use it.



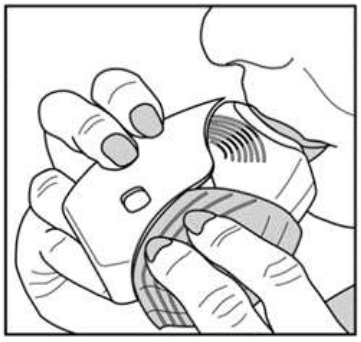
2. Before the inhaler is used for the 1st time, the counter should show the number 30. Each time you open the cover, 1 dose of medicine is prepared and the counter goes down by 1.



3. Slide the cover down until a “click” sound is heard to expose the mouth-piece. The counter will go down by 1 number.

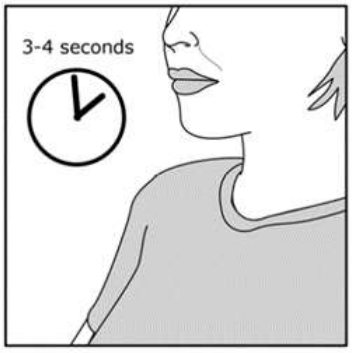


4. Breathe out away from the mouthpiece.

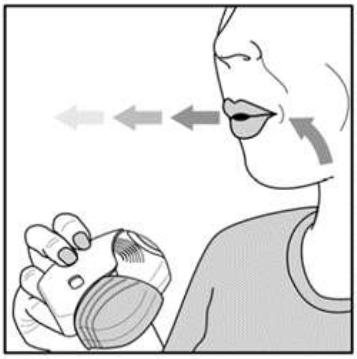


5. Put the mouthpiece between the lips, and close the lips firmly around it. Take 1 long and deep breath in through the mouth.

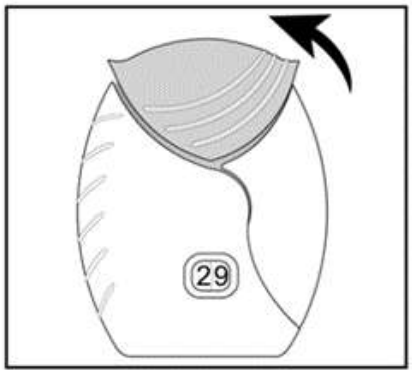
6. Do not block the air vent with your fingers.



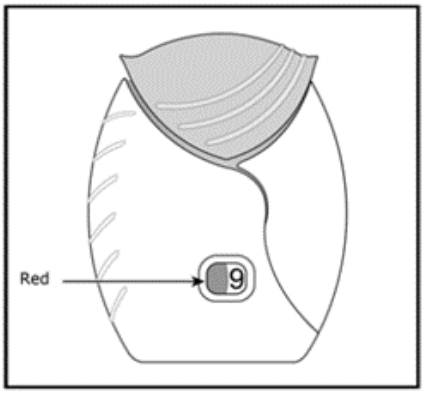
7. Remove the inhaler from the mouth and hold breath for about 3 to 4 seconds or as long as comfortable.



8. Breathe out slowly and gently.



9. Close the inhaler by sliding the cover up and over the mouthpiece as far as it will go.



10. When the inhaler has fewer than 10 doses remaining, the left half of the counter shows red as a reminder to get a refill.

    The counter will show “0” when you inhaled the last dose and now the inhaler is empty.

    Throw the empty inhaler away in household trash out of reach of children.

    * If the inhaler cover is opened and closed without inhaling, the dose will be lost. The lost dose will no longer be available to be inhaled. It is not possible to take double dose.

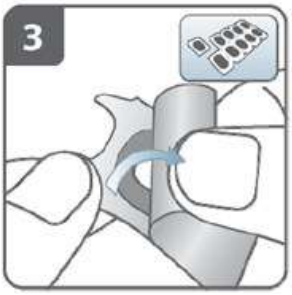
Cleaning : Clean the mouthpiece with a dry tissue after each inhalation before closing the cover.

3 easy steps to use Anoro Ellipta

Counselling Steps for Ultibro Breezhaler

1. Pull off the cap of the inhaler.

2. Open the inhaler by tilting the mouthpiece.

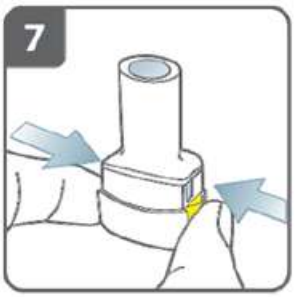


3. Separate 1 of the blisters from the blister card by tearing along the perforation. Take 1 blister and peel away the protective backing to expose the capsule. Do not push capsule through the foil.

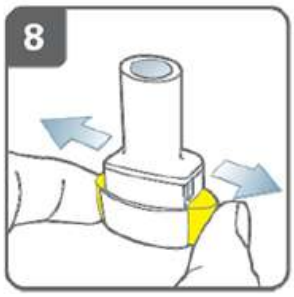
4. Capsules should always be stored in the blister and only removed immediately before use. **Do not swallow the capsule.**

5. Place the capsule into the capsule chamber, NOT into the mouthpiece.

6. Close the inhaler until a “click” sound is heard.



7. Hold the inhaler upright with the mouthpiece pointing up. Pierce the capsule firmly by pressing together both side buttons at the same time. **Do this only once.** A “click” sound is heard as the capsule is being pierced.

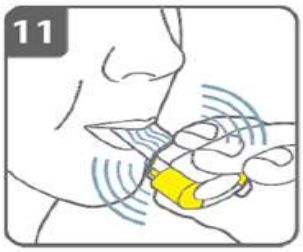


8. Release the side buttons fully.

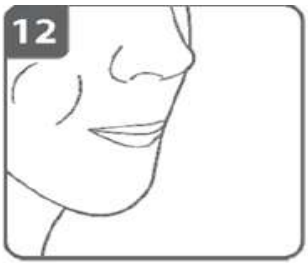
9. Breathe out fully away from the mouthpiece.

10. To breathe the medicine deeply:
    - Hold the inhaler as shown.
    - Place the mouthpiece in your mouth & close your lips firmly around it.
    - Breathe in rapidly and as deeply as possible.

      Do not press the side buttons.

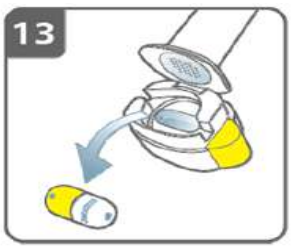


11. A whirring noise should be heard as it is breathed in. If a whirring noise is not heard, the capsule may be stuck in the capsule chamber. If this happens:
    - Open the inhaler and carefully loosen the capsule by tapping the base of the inhaler. **Do not press the side buttons.**
    - Inhale the medication again by repeating steps 9 and 10.



12. Hold breath for at least 5-10 seconds or as long as possible while taking the inhaler out of the mouth. Then breath out. Open the inhaler to see if any powder is left in the capsule.

    If there is powder left in the capsule:
    - Close the inhaler.
    - Repeat steps 9 to 12.



13. After finishing, open the mouthpiece and remove the empty capsule by tipping it out. Throw the empty capsule into household waste.

    Close the inhaler and replace the cap.

Cleaning : Never wash the inhaler with water. Wipe the mouthpiece inside and outside with a clean, dry cloth to remove any powder residue.

References

1. Ultibro Breezhaler product leaflet
2. Anoro Ellipta product leaflet

Updates on MOH Formulary (FUKKM) 1/2018

Drugs Newly Approved for Inclusion in MOH Formulary

Generic Name	Prescriber Category	Approved Indication
Dexlansoprazole 30 mg delayed release capsules Dexlansoprazole 60 mg delayed release capsules	A*	**Approved Indication(s):** Treatment of erosive esophagitis (EE) Maintenance of healed erosive esophagitis (EE) Symptomatic treatment of non-erosive gastroesophageal reflux disease. **Prescribing Restriction(s):** As a second-line therapy for: i) Patients with refractory EE; ii) Geriatrics; iii) Patients with polypharmacy. **Dose:** Treatment of EE – 60 mg once daily for 8 weeks Maintenance of healed EE – 30 mg once daily for 6 months Symptomatic non-erosive gastroesophageal reflux disease – 30 mg once daily for 4 weeks.
Teriflunomide 14 mg tablet	A*	**Approved Indication(s):** Treatment of adult patients with relapsing remitting multiple sclerosis (MS) **Dose:** 14mg once daily.

Generic Name	Prescriber Category	Approved Indication
Pimecrolimus 1% cream	A*	**Approved Indication(s):** Short-term and intermittent long-term therapy of mild to moderate atopic dermatitis in non-immunocompromised patients aged 2 years and older, in whom the use of alternative, conventional therapies are deemed inadvisable because of potential risks, or in the treatment of patients who are not adequately responsive to or intolerant of alternative, conventional therapies. **Prescribing Restriction(s):** • First line for periorbital eczema; • Second line for facial eczema. **Dose:** Apply a thin layer of the cream to the affected skin twice daily.
Febuxostat 80 mg tablet	A*	**Approved indication(s):** 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 restriction(s):** As second line for patients who are allergic or intolerant to allopurinol. **Dose:** The recommended oral dose is 40 mg or 80 mg once daily without regard to food. The recommended starting dose is 40 mg once daily. If serum uric acid is > 6.0 mg/dL (357 µmol/L) after 2-4 weeks, 80 mg once daily may be considered. The 80 mg tablet can be divided into equal halves. In order to provide a 40 mg dose, the tablet should be split just before use. Prescribers should advise patients on how to break the tablets in half and to keep the other half for the next dose.

Generic Name	Prescriber Category	Approved Indication
Sacubitril/ Valsartan 50 mg tablet; Sacubitril/ Valsartan 100 mg tablet; Sacubitril/ Valsartan 200 mg tablet.	A*	**Approved Indication(s):** Treatment of symptomatic chronic heart failure in adult patients with reduced ejection fraction. **Prescribing Restriction(s):** • NYHA class II-IV; • Patients who are symptomatic despite being on optimized treatment with an ACEi / ARB, a beta blocker, a diuretics and an mineralocorticoid receptor agonist (MRA). **Dose:** 1a. Adult dosing: • The recommended starting dose of sacubitril/valsartan is one tablet of 100 mg twice daily. The dose should be doubled at 2-4 weeks to the target dose of one tablet of 200 mg twice daily, as tolerated by the patient • For the following patients, initiate with sacubitril/valsartan 50 mg twice daily, double the dose at every 3-4 weeks to achieve the target dose of 200 mg twice daily as tolerated by the patient: - Not currently on ACEI/ ARB; - Switching from low dose of ACEI/ ARB; - In patients with systolic BP ≥100 to 110 mmHg; - In patients with moderate renal impairment (eGFR 30-60 ml/min/1.73 m2); In patients with moderate hepatic impairment (Child-Pugh B classification). 1b. Dose in renal impairment • Mild Renal Impairment: No dose adjustment is required in patients with mild (Estimated Glomerular Filtration Rate [eGFR] 60-90 ml/min/1.73 m2) renal impairment. • Moderate (eGFR 30-60 ml/min/1.73 m2) & severe (eGFR<30 ml/min/1.73 m2) renal impairment: A starting dose of 50 mg twice daily. • End-stage renal disease: There is no experience in patients with end-stage renal disease and use of sacubitril/ valsartan is not recommended.

Generic Name	Prescriber Category	Approved Indication
		1c. Dose in liver failure • Mild hepatic impairment: No dose adjustment is required (Child-Pugh A classification). • Moderate hepatic impairment: In patients with moderate hepatic impairment (Child-Pugh B classification) or with AST/ALT values more than twice the upper limit of the normal range, the recommended starting dose is 50 mg twice daily. • Severe hepatic impairment: Sacubitril/valsartan is contraindicated in patients with severe hepatic impairment, biliary cirrhosis or cholestasis (Child-Pugh C classification)

Amendments of Indication Approved for Inclusion in MOH Formulary

Generic Name	Amendment	Details
Micafungin sodium 50mg injection	**Approved to add indication(s):** Treatment of invasive candidiasis in children.	**Category of Prescriber:** A* **Dose:** i. Body weight ≤ 40kg: 2mg/kg/day ii. Body weight > 40kg: 100mg/day

Addition of Strength Approved for Inclusion in MOH Formulary

Added/ Amended Strength	Existing Strength	Existing Strength Availability in HSM
Approved to add new strength: Insulin glargine 300 units/ml injection (pre-filled pen).	Insulin glargine 100 units/ml injection (pre-filled pen).	Yes
Approved to amend the strength to: Potassium Chloride 1 g/10 ml mixture	Potassium Chloride 1 g/15 ml mixture	Yes

Amendments of Prescriber Category Approved in MOH Formulary

Generic Name	Previous Category	Amended Category
Bromhexine 8mg tablet **Approved Indication(s):** Secretolytic therapy in acute and chronic bronchopulmonary diseases associated with abnormal mucous secretion and impaired mucous transport	B	C
Hyoscine N-Butylbromide 10 mg Tablet **Approved Indication(s):** Gastrointestinal tract and genito-urinary tract spasm, dyskinesia of the biliary system	B	C
Mefenamic acid 250mg capsule **Approved Indication(s):** Mild to moderate pain	B	C
Miconazole 2% cream **Approved Indication(s):** Fungal infections: Tinea pedis, Tinea corporis, Tinea capitis and other dermatophyte infections caused by Trichophyton and Epidermophyton species. Antifungal agent that has been in various candida infections including vaginal candidiasis.	B	C

Generic Name	Previous Category	Amended Category
Vildagliptin 50mg tablet **<u>Approved Indication(s):</u>** i) As second line therapy in type 2 diabetes patients inadequately controlled on maximal tolerated dose of metformin monotherapy and high risk of hypoglycaemia. ii) As second line therapy in type 2 diabetes patients inadequately controlled on maximal tolerated dose of sulphonylurea and intolerant/contraindicated for metformin therapy. iii) As third line therapy in type 2 diabetes patients inadequately controlled with dual OAD combination therapy with sulphonylurea and metformin. iv) As a monotherapy in type 2 diabetes mellitus patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance. v) An adjunct to diet and exercise to improve glycaemic control in patients with type 2 diabetes mellitus: As a dual therapy in combination with insulin in patients with insufficient glycaemic control. Insulin dose and regimen should be optimized before addition of vildagliptin. FUKKM restriction: As add-on therapy for patient who failed therapy and/or contraindicated/unable to tolerate metformin and/or sulphonylurea.	A*	A/KK

Generic Name	Previous Category	Amended Category
Vildagliptin/Metformin HCl (50mg/500mg) Tablet ; Vildagliptin/Metformin HCl (50mg/850mg) Tablet ; Vildagliptin/Metformin HCl (50mg/1000mg) Tablet **Approved Indication(s):** i) As second line therapy in type 2 diabetes patients inadequately controlled on maximal tolerated dose of metformin monotherapy and high risk of hypoglycaemia. ii) As second line therapy in type 2 diabetes patients inadequately controlled on maximal tolerated dose of sulphonylurea and intolerant/contraindicated for metformin therapy. iii) As third line therapy in type 2 diabetes patients inadequately controlled with dual OAD combination therapy with sulphonylurea and metformin. iv) As a monotherapy in type 2 diabetes mellitus patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance. v) An adjunct to diet and exercise to improve glycaemic control in patients with type 2 diabetes mellitus: As a dual therapy in combination with insulin in patients with insufficient glycaemic control. Insulin dose and regimen should be optimized before addition of vildagliptin. FUKKM restriction: As add-on therapy for patient who failed therapy and/or contraindicated/unable to tolerate metformin and/or sulphonylurea.	A*	A/KK

Removal of Preparation Approved from Inclusion in MOH Formulary

Generic Name	Reason for removal
Linagliptin 5 mg tablet	Sufficient alternatives are available in FUKKM.
Glibenclamide 5 mg tablet	i) Risk of hypoglycaemia particularly in elderly. ii) Sufficient alternatives are available in FUKKM.
Rabeprazole sodium 20 mg tablet	Low volume of acquisition/utilization in MOH facilities
Chloramphenicol 125 mg/5 ml suspension	No usage and there are alternatives available in FUKKM.
Diphenhydramine hydrochloride 10 mg/5 ml oral solution	
Ethosuximide 250 mg/5 ml syrup	

Update of Information on Drug in MOH Formulary

Generic Name	Amendment	Details
Pneumococcal polysaccharide conjugate vaccine (adsorbed) 13-valent injection.	Prescribing restriction (addition of prescribing restriction for children)	Active immunization for the prevention of pneumococcal disease caused by Streptococcus pneumoniae serotypes 1,3,4,5,6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in these population with associated risk in Invasive Pneumococcal Disease (IPD): a) Infants/children from 2 months of age and adult with one of the following conditions: • Functional or anatomical asplenia; • Cochlear implant; • Congenital immunedeficiency; • Haematopoietic and solid organ transplant. b) High risk infants/children (from 2 months old) with one of the following conditions: • Immunosuppression (including asymptomatic HIV) • Nephrotic syndrome • Chronic lung or heart disease (Adapted from Paediatric Protocols for Malaysia Hospital, 3rd Edition).

Generic Name	Amendment	Details
		c) Adults aged 60 years and above with one of the following conditions: • Chronic lung diseases, including chronic obstructive pulmonary disease (COPD), emphysema & asthma (requiring frequent hospital visit & use of multiple medications); • Chronic liver disease including cirrhosis, biliary atresia, chronic hepatitis; • Chronic cardiac disease, including congestive heart failure, congenital heart disease, and cardiomyopathies.
Empagliflozin 10mg tablet; Empagliflozin 25mg tablet	Prescribing restriction [removal of criteria - secondary prevention of cardiovascular disease (patient that has previous cardiovascular event)]	Updated indication and prescribing restriction for Empagliflozin: Indicated in the treatment of type 2 diabetes mellitus to improve glycaemic control in adults as: Add-on combination therapy: In combination with other glucose–lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control; **Prescribing restriction** (patient must fulfil all criteria): • HbA1c not more than 8.5% on dual combination anti-diabetic therapy; • Creatinine clearance 60ml/min or eGFR 60ml/min/1.73m2 and above; • BMI: 30kg/m2 and above.

Staff Information

New Staff

1.Miss Liew Ka Kei	Pegawai Farmasi Provisional UF 41
2.Miss Loh Li Vien	Pegawai Farmasi Provisional UF 41
3.Miss Nur Dayana Syazlina Binti Rusli	Pegawai Farmasi Provisional UF 41
4.Miss Nur Farhah Binti Samsuddin	Pegawai Farmasi Provisional UF 41

Transferred In

1.Madam Kwong Chea Ing	Pegawai Farmasi UF 44
2.Miss Wong Ee Lynn	Pegawai Farmasi UF 44
3.Madam Normaizatul Shafiqah Binti Zairosli	Pegawai Farmasi UF 41
4.Mr Muhamad Amir Sabirin Bin Che Daud	Penolong Pegawai Farmasi U 29
5.Miss Siti Nur Shafiqah Binti Zainudin	Penolong Pegawai Farmasi U 29

Transferred Out

1.Madam Ngai Wen Jing	Pegawai Farmasi UF 48
2.Madam Nurul Izzati Binti Fazeli	Pegawai Farmasi UF 41
3.Miss Deepashini A/P Rajindran	Pegawai Farmasi UF 41
4.Miss Thenmoli Hanbrasi A/P Jothy	Pegawai Farmasi UF 41
5.Mr Deenesh A/L Prabakaran	Pegawai Farmasi UF 41
6.Mr Bakeri Bin Songep	Penolong Pegawai Farmasi U 32(KUP)