

SPECIAL TOPIC:

PARKINSON'S DISEASE

PUBLISHED BY: JABATAN FARMASI HOSPITAL TENGKU AMPUAN AFZAN, KUANTAN, PAHANG

FEATURED ISSUES:

- Staff Updates
- Disease Management [Parkinson's Disease]
- Drug Updates [Darbepoetin Alfa & Omalizumab]
- Medication Safety [High Alert Medication: Insulin and Its Potential Harm]
- Pharmacy R&D
- Pharmacy Activities



ADVISOR

Hajah Samehah Almuna
bt Haji Ismail

EDITORS

Soh Shen-ni
Siti Sarah bt Ilias
Fareha bt Abdul Ghani
Siti Aisyah bt Mohd Yusof
Nor Akma Idayu bt Mohd
Yusoff

CONTRIBUTORS

Aisyah Shafiqah bt Roslan
Norsyazwani Qayyum bt Mohd Zubir
Nurul Fazihah bt Malek Ribuan
Nor Ameerah Izzati bt Mohd Nor
Atikah bt Ali @ Jaafar
Nurul Syahirah Asmaa bt Mohd Zain
Nurul Izzati Liyana bt Azlan

HTAA PHARMACY STAFF UPDATES 2020

TRANSFERRED IN



NAME: NAJIHAH BINTI CHE SEMAN
POSITION: PEGAWAI FARMASI UF44
FROM: KK BANDAR JENGKA
TO: FARMASI BEKALAN WAD
DATE REPORTED DUTY: 28/12/2020



NAME: ABDUL QAYYUM BIN MAT ZAID
POSITION: PEGAWAI FARMASI UF44
FROM: HOSPITAL KUALA LIPIS
TO: FARMASI SATELIT
DATE REPORTED DUTY: 28/12/2020



NAME: TAN CHUNG HAN
POSITION: PEGAWAI FARMASI UF44
FROM: HOSPITAL PEKAN
TO: FARMASI MTAC
DATE REPORTED DUTY: 28/9/2020

HTAA PHARMACY STAFF UPDATES 2020

TRANSFERRED IN



NAME: NURUL ELIFA BT MOHD ZAINI TEE
POSITION: PEGAWAI FARMASI UF41
FROM: HOSPITAL SHAH ALAM
TO: FARMASI WAD
DATE REPORTED DUTY: 14/9/2020



NAME: NOR ANIZA BT MUSA
POSITION: PEGAWAI FARMASI UF41 (K)
FROM: HOSPITAL SULTAN HAJI AHMAD
SHAH, TEMERLOH
TO: FARMASI SATELIT
DATE REPORTED DUTY: 14/9/2020



NAME: NUR UMAIRAH BT SALLEH
POSITION: PEGAWAI FARMASI UF41 (K)
FROM: HOSPITAL SULTANAH HAJJAH
KALSOM, CAMERON HIGHLANDS
TO: FARMASI KLINIK PAKAR
DATE REPORTED DUTY: 14/9/2020

HTAA PHARMACY STAFF UPDATES 2020

TRANSFERRED OUT



NAME: NURSALIHAH BINTI MUHAMMAD
POSITION: PEGAWAI FARMASI UF44
TO: PKD KUALA SELANGOR
DATE TRANSFERRED OUT: 23/11/2020



NAME: VANITHA A/P MUTHUSAMY
POSITION: PEGAWAI FARMASI UF44
TO: PKD TITIWANGSA, KUALA LUMPUR
DATE TRANSFERRED OUT: 9/11/2020



NAME: KOKIELA A/P KANTHAIYAH
POSITION: PEGAWAI FARMASI UF44
TO: HOSPITAL MIRI
DATE TRANSFERRED OUT: 16/11/2020

HTAA PHARMACY STAFF UPDATES 2020

TRANSFERRED OUT



**NAME: NURFATIHIN IZANI BINTI MOHD
HAZANI
POSITION: PEGAWAI FARMASI UF41 (K)
TO: HOSPITAL QUEEN ELIZABETH
DATE TRANSFERRED OUT: 23/11/2020**



HTAA PHARMACY STAFF UPDATES 2020

RESIGNED



NAME: CHEE ZHEN WEI
POSITION: PEGAWAI FARMASI UF41 (K)
TO: SULTAN HAJI AHMAD SHAH
MEDICAL CENTER @ IIUM, Kuantan
DATE: 2/11/2020



NAME: CHIEW YUEN KIAT
POSITION: PEGAWAI FARMASI UF41 (K)
TO: MEDIWELL PHARMACY, JOHOR
DATE: 30/11/2020



NAME: KOO BOON JIN
POSITION: PEGAWAI FARMASI UF41 (K)
TO: BIG PHARMACY, Kuantan
DATE: 24/12/2020

HTAA PHARMACY STAFF UPDATES 2020

NEWLY APPOINTED



NAME: NURUL HUDA BINTI FAKHRUDDIN
POSITION: PEGAWAI FARMASI UF41 (K)
TO: FORMER PRP IN HTAA
DATE REPORTED DUTY: 14/11/2020



PARKINSON'S DISEASE

by Ameerah Izzati & Atikah Ali

WHAT IS PARKINSON'S DISEASE?

Parkinson's disease is a long-term, progressive degenerative disorder of the central nervous system.¹ PD is characterized by both motor and non-motor features. The term 'parkinsonism' is used to describe the motor features which include bradykinesia, resting tremor and muscle rigidity. Non-motor features include sleep disorders, depression and cognitive changes.²

EPIDEMIOLOGY

Parkinson's disease affects 1-2 per 1000 of the population at any time. The prevalence of PD is reported to be approximately 1% in people 60 years of age and older and increases to 1% to 3% in the 80-plus age group.²

PATHOPHYSIOLOGY³

In Parkinson's disease, dopaminergic neurons of the substantia nigra progressively degenerate. As a result, the amount of dopamine available for neurotransmission in the corpus striatum is lowered, resulting in more excitatory neurotransmitters (acetylcholine) than inhibitory neurotransmitters (dopamine). Striatal neurons are responsible for relaying messages to the higher motor centers that control and refine motor movement, thus the imbalance affects voluntary movement of the body.

Clinical symptoms do not appear until 60% of the dopaminergic neurons are lost and the striatal dopamine level is decreased by 80%.

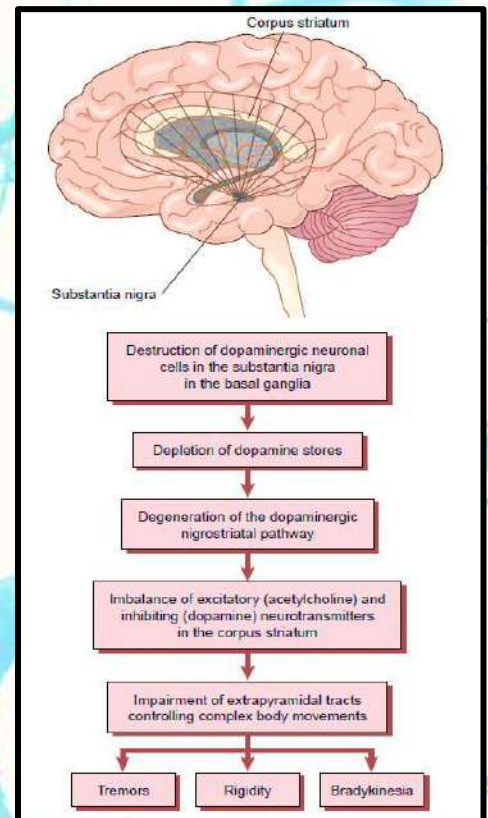


Figure 1: Pathophysiology of Parkinson's disease

SIGNS & SYMPTOMS

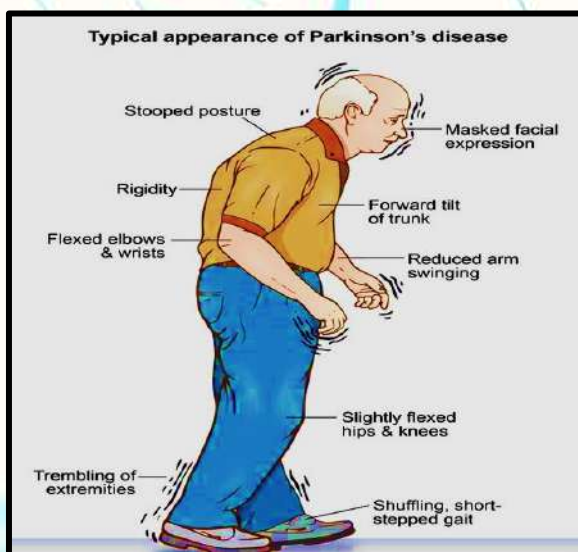


Figure 2: Motor symptoms of Parkinson's disease⁴

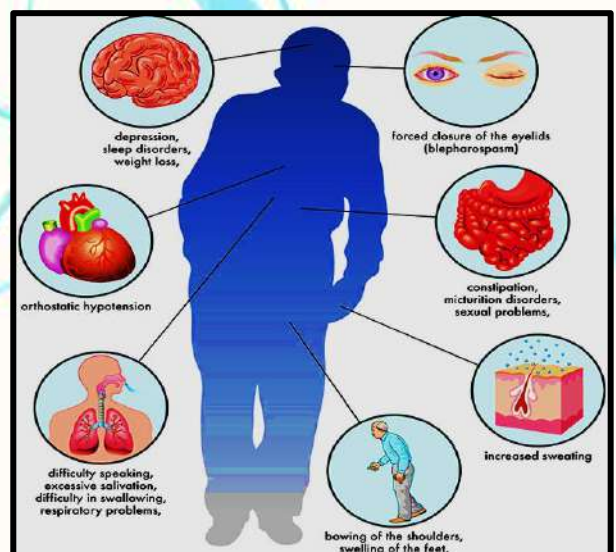
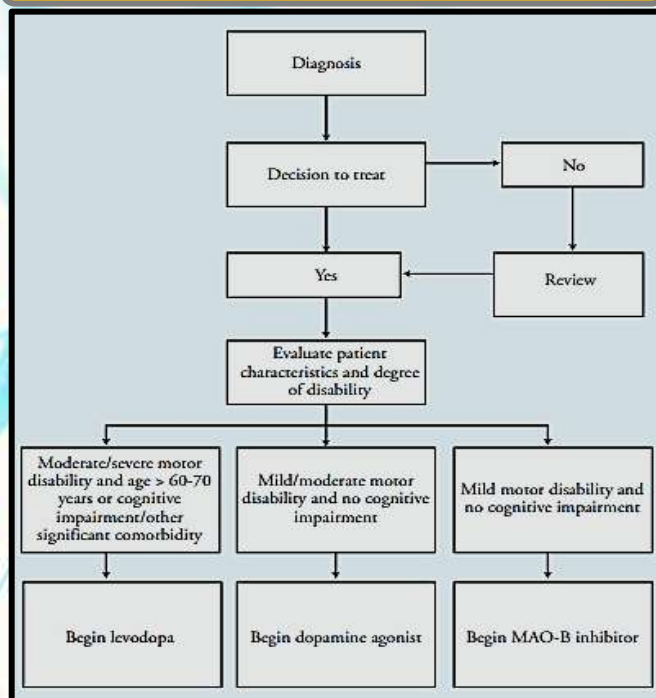
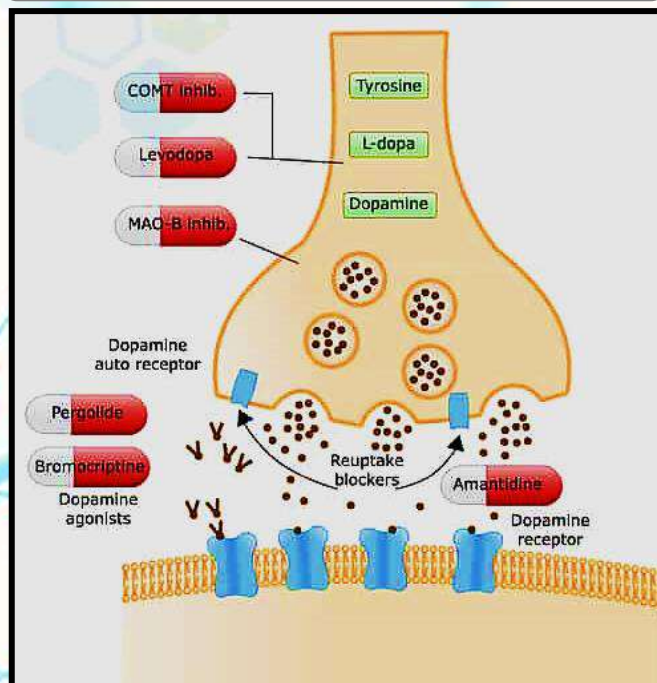


Figure 3: Non-motor symptoms of Parkinson's disease⁵

INITIATION OF ANTI-PARKINSONIAN DRUGS

Figure 4: Decision pathway for the initiation of medication treatment for Parkinson's disease¹

PHARMACOLOGICAL PATHWAY OF ANTI-PARKINSONIAN DRUGS

Figure 5: Pharmacological therapy for Parkinson's disease and their target of action⁶

PHARMACOLOGICAL TREATMENT

CLASS / DRUG	MECHANISM OF ACTION	REGIMEN	POSSIBLE SIDE EFFECTS ^{1,8}
Dopamine precursor+ decarboxylase inhibitor Levodopa+ Carbidopa, Levodopa+ Benserazide	Levodopa is the immediate metabolic precursor of dopamine. It is converted into dopamine in the brain. Levodopa is usually combined with decarboxylase inhibitor to prevent levodopa from being broken down before it reaches the brain. ⁷	Starting at a dose of 50 mg daily, increase every 3-7 days by 50 mg to an initial maintenance dose of 50-100 mg 3x daily, or until satisfactory clinical response is obtained. ¹	<ul style="list-style-type: none"> Nausea Postural hypotension Daytime sleepiness
Monoamine Oxidase-B (MAO-B) Inhibitor Selegiline	Binds to MAO-B within the nigrostriatal pathways in the CNS thus blocking microsomal metabolism of dopamine and enhancing the dopaminergic activity in the substantia nigra. ⁸	The usual dose is 10 mg in the morning in 1 or 2 divided doses (taken at breakfast and lunch) ¹	<ul style="list-style-type: none"> Dyskinesia Nausea Abdominal pain Dry mouth
Catechol-o-methyl-transferase (COMT) Inhibitor Entacapone	Inhibits peripheral metabolism of levodopa by COMT, allowing a higher concentration of levodopa to cross the blood-brain barrier. ⁸	200mg with each daily dose of levodopa / dopa-decarboxylase inhibitors. Maximum dose is 2000mg/day. ¹	<ul style="list-style-type: none"> Dyskinesia Nausea Hyperkinesia Urine discolouration
Dopamine Receptor Agonists Piribedil, Ropinirole, Pramipexole, Bromocriptine, Pergolide	Directly stimulates postsynaptic dopamine receptors to provide antiparkinsonian benefits. ⁹	<ul style="list-style-type: none"> Piribedil starting dose: 25-50mg. Max: 300mg/ day. Ropinirole starting dose: 0.25mg (IR) & 2mg (SR). Max: 24mg/day. Pramipexole starting dose: 0.125mg (IR) & 0.375mg (SR). Max: 4.5mg/day.¹ 	<ul style="list-style-type: none"> Confusion Hallucinations Impulse control disorders
Others NMDA Antagonist Amantadine	It increases the release of dopamine, blocks cholinergic receptors and inhibits NMDA type of glutamate receptors. ⁹	Initial dose is 100mg once daily or twice daily. Maximum dose is 300mg/day. Some patients with dyskinesias may require up to 400mg/day in 2-4 divided doses. ¹	<ul style="list-style-type: none"> Confusion Hallucinations Leg swelling

MOTOR RESPONSE COMPLICATION¹

Patients who have been taking dopaminergic medications for some time (usually years) may develop motor fluctuations and dyskinesia.

"Wearing off"	"Wearing off" is a condition where patients with Parkinson's disease (PD) begin to feel the benefits gained from a dose of dopaminergic medication gradually fading off before the next dose. Patients usually experience improvements within ½ to 1 hour after taking a dose of PD medication ("ON"-medication state) but start to experience a recurrence or worsening of their PD symptoms (wearing-off) before it is time to take the next dose of medication ("OFF"-medication state). Some patients may also experience non-motor fluctuations (e.g., pain, mood or panic symptoms, or slowness of thinking that occur or worsen during "OFF" periods).
Dyskinesia	Dyskinesia, often referred to as levodopa-induced dyskinesia is involuntary, erratic, writhing movements of the face, arms, legs or trunk which usually happen when patients are "ON"-medication state ("peak-dose" dyskinesia). It occurs in about 50% of patients after 5 years of treatment with L-dopa. Dyskinesia can also occur before a dose of medication takes full effect and/or during the "wearing-off" phase ("biphasic" dyskinesia).

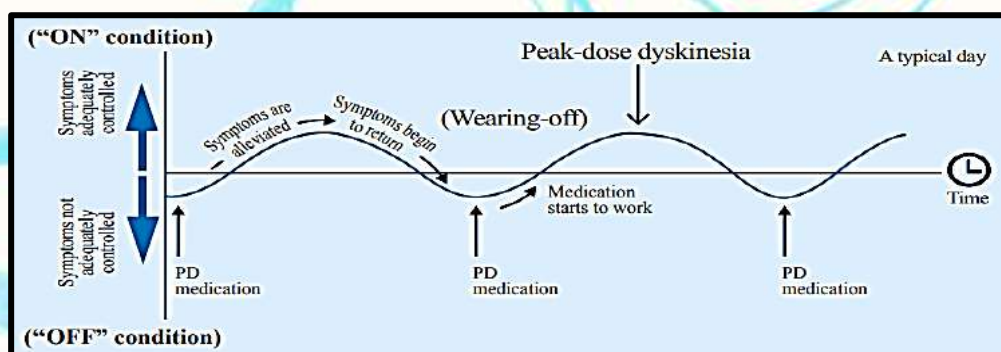


Figure 6: Fluctuations and dyskinesia in relation to the timing of PD medication intake¹

Treatment of motor fluctuation¹

Wearing off

- Increase dose and/or frequency of PD medications
- Addition of dopamine agonist, COMT inhibitor or MAO-B inhibitor. Addition of dopamine agonist is typically more effective which have comparable efficacy. In patients with overnight wearing-off, dopamine agonist therapy has also been shown to have beneficial effects on night-time sleep.
- Controlled-release L-dopa can be used for overnight wearing off. However, it is not the first line treatment, as this agent may be erratically absorbed; resulting in delayed "ON" or no "ON" responses.

Dyskinesia

- Since dyskinesia tends to occur at peak concentrations of levodopa, one management strategy is to reduce dopamine levels. This can be done with small decreases in levodopa dosage or by removing other dopaminergic medications (e.g., dopamine agonists, COMT inhibitors or MAO-B inhibitors).
- Amantadine may be added to the medication regimen to reduce dyskinesias without worsening "off" periods.

REFERENCES

1. MDC Consensus Guideline for the Treatment of Parkinson's Disease 2012
2. DeMaagd, G., & Philip, A. (2015). Parkinson's Disease and Its Management: Part 1: Disease Entity, Risk Factors, Pathophysiology, Clinical Presentation, and Diagnosis. P & T : a peer-reviewed journal for formulary management, 40(8), 504–532.
3. Parkinson's disease. (n.d.). BrainKart. https://www.brainkart.com/article/Parkinson---s-Disease_32540/
4. What is Parkinson's disease. (2020, November 8). Parkinson's Nebraska. <https://parkinsonsnebraska.org/understanding-parkinsons-disease/>
5. Brown, G. (2018, December 18). Main symptoms of Parkinson's disease - Our best Homecare tips. Best Homecare Tips. <https://besthomecaretips.com/main-symptoms-parkinsons-disease/>
6. Neural stem cell therapy for Parkinson's disease [PD]. (n.d.). Regeneration Center. <https://stemcellthailand.org/therapies/parkinsons-disease/>
7. Haddad, F., Sawalha, M., Khawaja, Y., Najjar, A., & Karaman, R. (2017). Dopamine and Levodopa Prodrugs for the treatment of Parkinson's disease. Molecules, 23(1), 40. <https://doi.org/10.3390/molecules23010040>
8. Hauser, R. A. (2020, June 4). Parkinson disease medication: Dopamine agonists, anticholinergic, MAO-B inhibitors, Acetylcholinesterase inhibitors, central, NMDA antagonists, COMT inhibitors, selective serotonin inverse agonists (SSIA), adenosine antagonists. Diseases & Conditions - Medscape Reference. <https://emedicine.medscape.com/article/1831191-medication#4>
9. Lippincott's Pharmacology Illustrated Reviews 6th Edition



High Alert Medication: Insulin and its potential harm

by Nurul Fazifah MR

Diabetes is a major public health concern in Malaysia. As of 2016, Type 2 diabetes (T2D) prevalence has escalated to 20.8% in adults above the age of 30, affecting 2.8 million individuals.¹ This in turn has resulted in insulin becoming one of the most well-known medications available on the market. Insulin lowers blood glucose levels. It regulates carbohydrate, protein and fat metabolism by inhibiting hepatic glucose production, lipolysis and enhancing peripheral glucose disposal.² Insulin is recognized as a High Alert Medication (HAM) because of its potential to cause detrimental patient harm when used in error.³ In the case of insulin overdose, it may cause serious complications which include intermittent cerebral impairment (73%), hypokalaemia (49%), electrolyte imbalance (42%), hepatic disturbances (7%) and cardiac toxicity (e.g. cardiac arrhythmia) (9%).⁴

Risk of Cutaneous Amyloidosis

Apart from the above list of serious complications, insulin may also cause cutaneous amyloidosis. Cutaneous Amyloidosis is a clump of abnormal amyloid proteins built up in wave-like projections (dermal papillae) between the dermis and the epidermis.⁵ It may be associated with the use of insulin injections and could be a class effect for all insulins.⁶ Because of this risk, the National Pharmaceutical Regulatory Agency (NPRA) has asked to revise the safety information on the medication packaging, as well as its information leaflet on the risk of **cutaneous amyloidosis following insulin administration**. In line with NPRA, the Japanese Pharmaceutical & Medical Devices Agency (PMDA) urged pharmaceutical companies to add on the importance of precaution regarding insulin injection as **cutaneous amyloidosis** or lipodystrophy may occur at the injection site if subjected to repeated injection into the same area.⁷ The European Medicine Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) concluded that the cumulative evidence supports a causal relationship between **insulin-containing medicines and cutaneous amyloidosis**, with the potential for associated changes in glycaemic control.⁸

INSULIN RELATED ADVERSE DRUG REACTIONS (ADRS) n=13,122 (1969-2020) ⁸

CATEGORY	ADRs
Metabolism and nutrition disorders (n=5702, 43%)	Hypoglycaemia, Hyperglycaemia, Diabetes mellitus, Hypokalaemia
General disorders and administration site conditions (n=3923, 29.9%)	Therapeutic response decreased, Injection site reaction, Drug ineffective, Injection site pain
Nervous system disorders (n=2441, 18.6 %)	Dizziness, Seizure, Loss of consciousness, Coma, Syncope
Skin and subcutaneous tissue disorders (n=2088, 15.9 %)	Pruritus, Rash, Urticaria, Hyperhidrosis, Lipodystrophy acquired



Pic 1:
Cutaneous
Amyloidosis

Until August 2020, the NPRA has received 3,053 adverse events that were suspected to be related to insulin. Amongst these, 37 cases were injection site swelling. However, **no events involving cutaneous amyloidosis or skin hypertrophy/lipohypertrophy has been reported.** ⁹

Did you know that most Insulins are categorised under **Look Alike and Sound Alike (LASA) Medications**? ¹⁰

Look Alike



Insulin Glargine
300IU/ml
Injection (Prefilled Pen)
(TOUJEO)



Insulin Glargine
300IU/3ml Injection
(Prefilled Pen)
(LANTUS)



Insulin Aspart
100IU/ml Injection
(NOVORAPID)



Insulin Aspart 30%
and Protaminated
Insulin Aspart 70%
100IU/ml Injection
(NOVOMIX)

Sound Alike



Insulin Regular
100IU/ml Injection in
10ml vial (ACTRAPID)



Insulin Regular
100IU/ml Penfill and
Refill (ACTRAPID)



Insulin Isophane
100IU/ml in Vial for
Injection (INSULATARD)



Insulin Isophane
100IU/ml Penfill and
Refill (INSULATARD)

REFERENCES:

- Hussein, Z., Wahyu Taher, S., Gilcharan Singh, H.K. and Siew Swee, W.C., 2016. Diabetes Care in Malaysia: Problems, New Models, and Solutions. *Annals of Global Health*, 81(6), pp.851–862. DOI: <http://doi.org/10.1016/j.aogh.2015.12.016>
- 'Insulin'. MIMSGateway
- Pharmaceutical Services Division, Ministry of Health Malaysia. Guideline on Safe Use of High Alert Medications. (2011).
- Nicklas Järvelä Johansen, Mikkel Bring Christensen. A Systematic Review on Insulin Overdose Cases: Clinical Course, Complications and Treatment Options. *Basic & Clinical Pharmacology & Toxicology*, 2018, 122, 650–659. DOI: 10.1111/bcpt.12957
- U.S. National Library of Medicine. Primary localized cutaneous amyloidosis [Internet]. Bethesda, USA: National Institutes of Health, U.S Department of Health and Human Services. 2020 July 7 [Cited on 2020 June 30].
- Sullivan CA, Gedik R and Haddady S. An atypical presentation of insulin amyloidosis: An uncommon but important complication of insulin therapy. *AACE Clinical Case Reports Volume 4 No. 1 January/February 2018* [Internet]. 2018 Feb [Cited on 2020 June 30] 4(1):80-3
- Pharmaceuticals and Medical Devices Safety Information. (n.d.). Retrieved November 14, 2020, from <https://www.pmda.go.jp/files/000153570.pdf>
- "Insulin". WHO Collaborating Centre for International Drug Monitoring. www.vigiaccess.org
- National Pharmaceutical Regulatory Agency (NPRA). Safety Alert, Insulin: Risk of Cutaneous Amyloidosis. 6 August 2020.
- Album Look Alike and Sound Alike Medications, Jabatan farmasi HTAA 2019

INJECTION DARBEPOETIN ALFA 20mcg/0.5ml & 40mcg/0.5ml

A. DRUG DESCRIPTION

- Darbepoetin Alfa 20mcg/0.5ml & 40mcg/0.5ml solution contains Darbepoetin Alfa 20mcg and 40mcg respectively.
- Darbepoetin Alfa injection comes in a prefilled syringe as a colourless and clear solution either for injecting subcutaneously or intravenously.
- Darbepoetin Alfa is a biosynthetic form of erythropoietin and a long acting erythropoiesis stimulating agent.
- It is used for the treatment of anaemia in chronic renal failure patients.

B. REGISTRATION NUMBER

20mcg/0.5ml : MAL14115030ACZ
40mcg/0.5ml : MAL14115035ACZ

C. PRICE

20mcg/0.5ml : RM57.90
40mcg/0.5ml : RM116.35

D. DEPARTMENT

NEPHROLOGY

E. PRESCRIBER CATEGORY

A*
(Consultant/Specialists for specific indication only)

F. PREGNANCY CATEGORY

Category C



G. MECHANISM OF ACTION

- Darbepoetin Alfa induces erythropoiesis by stimulating the division and differentiation of committed erythroid progenitor cells.
- It also induces the release of reticulocytes from the bone marrow into the bloodstream where they mature to erythrocytes.
- This results in an increase in reticulocyte counts followed by a rise in hematocrit and hemoglobin levels.

H. INDICATION IN FUKKM

Treatment of anaemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis.

I. DOSE AND ADMINISTRATION

Haemodialysis patients:

- **Initial dose:** 20mcg IV once weekly
- **Initial dose at switching from erythropoietin preparation :** 15-60mcg IV once weekly
- **Maintenance dose:** 15-60mcg IV once weekly, then 30-120mcg IV biweekly

Peritoneal dialysis and patients with chronic kidney disease not on dialysis:

- **Initial dose:** 30mcg IV or SC biweekly
- **Initial dose at switching from erythropoietin preparation :** 30-120 mcg IV or SC biweekly
- **Maintenance dose:** 30-120 mcg IV or SC biweekly, then 60-180 mcg IV or SC once every four week (if alleviation of anaemia is maintain by biweekly)

J. ADVERSE DRUG REACTION

General

- Severe cutaneous reactions including blistering, skin exfoliation, Erythema multiforme and SJS/TEN.

Specific condition

- **Renal anemia**
 - Increases blood pressure (17.0%)
 - Shunt thrombosis/occlusion (3.0%)
 - Headache (2.0%)
 - Malaise (1.4%)
- **Anemia with myelodysplastic syndrome**
 - Diarrhea (3.8%)
 - Increases blood alkaline phosphatase (3.8%)
 - Hyperuricaemia (3.8%)
 - Folate deficiency (3.8%)
 - Headache (3.8%)
 - Hypertension (3.8%)

Clinically significant

- Cerebral infarction (0.8%)
- Cerebral hemorrhage (0.1%)
- Hepatic function disorder, jaundice (0.1%)
- Hypertensive encephalopathy
- Shock and anaphylaxis
- Pure red cell aplasia
- Myocardial infarction , pulmonary infarction

K. WARNING AND PRECAUTIONS

- Increase in the viscosity of the blood and may potentially aggravate or induce thromboembolism.
- Development of severe cutaneous adverse reaction (SCARs) which can be life threatening or fatal.
- Increase in blood pressure and the induction of hypertensive encephalopathy.
- Occurrence of pure red cell aplasia associated with the production of anti-erythropoietin antibodies.
- Careful administration of Darbepoetin Alfa to patients with a history of hypersensitivity to any drug or an allergic predisposition.

PREPARED BY : NURUL 'IZZATI LIYANA AZLAN

L. CONTRAINDICATIONS

- Pure red cell aplasia that begins following treatment with Darbepoetin Alfa or other erythropoietin drugs.
- Serious allergic reactions to Darbepoetin Alfa.
- Uncontrolled hypertension.

M. USE IN SPECIAL POPULATION

Elderly

Blood pressure, haemoglobin concentration and hematocrit levels should be frequently measured.

Dosage and frequency of administration can be adjusted accordingly.

Pregnancy, Delivery, Lactation

Use of Darbepoetin Alfa is not recommended in pregnant and lactating women unless expected therapeutic benefits outweigh possible risks.

Patient should avoid breastfeeding during treatment.

Pediatric

The safety of Darbepoetin Alfa in pediatric patients have not been established.

N. MONITORING PARAMETER

- Hemoglobin levels at least once weekly until maintenance dose established and after dosage changes.
- Chronic kidney disease patients should be monitored at least monthly following hemoglobin stability.
- Iron stores (transferrin saturation and ferritin) prior to and during therapy.
- Others: Serum chemistry, blood pressure, fluid balance, signs of seizure.

O. STORAGE

Store in a lightproof container at 2-8°C

P. REFERENCES

Product leaflet, FUKKM, Micromedex, MIMS Gateway, UpToDate

INJECTION

OMALIZUMAB 150MG



A. DRUG DESCRIPTION

- ❖ Omalizumab (Xolair®) is white to off- white lyophilisate, contained in a 6 ml vial with rubber stopper and an aluminium seal with plastic flip-off cap. It comes with water for injection for dilution.
- ❖ It is a humanized monoclonal antibody manufactured from a mammalian cell line.
- ❖ It is indicated for allergic asthma in both adults and adolescents (12 years of age and above) with moderate to severe persistent allergic asthma. In children age 6 to <12 years old, it is used as add-on therapy to improve asthma control with severe persistent allergic asthma.

B. REGISTRATION NUMBER

MAL20091873ARZ

C. PRICE

RM 1,451.45/VIAL

D. DEPARTMENT

RESPIRATORY

E. PRESCRIBER CATEGORY

A*
Consultant/ Specialists for specific Indications only

F. PREGNANCY CATEGORY

No adequate and well- controlled studies in pregnant women

G. MECHANISM OF ACTION

- ❖ Omalizumab is a recombinant DNA- derived humanized IgG monoclonal antibody that selectively binds to human immunoglobulin (IgE).
- ❖ It inhibits the binding of IgE to the high infinity IgE receptor (RI) on the surface of mast cells and basophils.
- ❖ Reduction in surface bound IgE on RI bearing cells limit the degree of release of mediators of the allergic response.
- ❖ Treatment with Omalizumab also reduces number of RI receptors on basophils in atopic patients.

H. INDICATION IN FUKKM

- ❖ **ADULT & ADOLESCENT (> 12 YEARS):**
Severe persistent allergic asthma whose symptoms are inadequately controlled with inhaled corticosteroids.
- ❖ **CHILDREN (6 TO < 12 YEARS) :**
As add-on therapy to improve asthma control with severe persistent allergic asthma

I. DOSE AND ADMINISTRATION

- ❖ **ADULT & ADOLESCENT (> 12 YEARS):**
150-375 mg SC every 2-4 weeks, according to body weight & baseline serum total IgE level.
- ❖ **CHILDREN (6 TO < 12 YEARS) :**
Appropriate dose & dosing frequency determined by baseline IgE & body weight. Do not administer if the measurements are outside the limit of the dosing table. Based on these measurements, 150-375 mg SC in 1-3 injections may be needed for each administration.

J. ADVERSE DRUG REACTION

❖ COMMON ADVERSE REACTION

- Headache
- Upper abdominal pain
- Pyrexia
- Injection site reactions such as pain, erythema, pruritus, swelling

❖ UNCOMMON ADVERSE REACTION

- Pharyngitis
- Dizziness, somnolence, paraesthesia, syncope
- Postural hypotension, flushing
- Coughing, allergic bronchospasm
- Nausea, diarrhea, dyspeptic signs & symptoms
- Weight increase, fatigue, swelling arms, influenza-like illness
- Urticaria, rash, pruritus, photo sensitivity

❖ RARE ADVERSE REACTIONS

- Parasitic infections
- Anaphylactic reaction and other allergic conditions, anti-therapeutic antibody development
- Laryngoedema
- Angioedema

K. WARNING AND PRECAUTIONS

- ❖ Omalizumab is intended for long-term treatment. Discontinuation generally results in a return to elevated free IgE levels and associated symptoms.
- ❖ Anaphylaxis and anaphylactoid reactions have been reported following the first or subsequent administrations of Omalizumab
- ❖ Increase in infection rates with Omalizumab, although the course, severity, and response to treatment of infection were unaltered.
- ❖ Not indicated for the treatment of acute asthma exacerbations, acute bronchospasm or status asthmaticus

L. CONTRAINDICATIONS

Hypersensitivity to the active substance or to any of the excipients

M. USE IN SPECIAL POPULATION

- ❖ **Pregnancy:** There are no adequate and well-controlled studies of Omalizumab in pregnant women.
- ❖ **Lactation:** While presence in human milk has not been studied, IgG is excreted in human milk and therefore it is expected to be present in human milk.
- ❖ **Renal and Hepatic impairment:** No pharmacokinetic or pharmacodynamic data in patients with renal or hepatic impairment.
- ❖ **Paediatric:** Safety and efficacy in paediatric patients below age 6 have not been established and use in such patients is therefore not recommended.
- ❖ **Geriatric:** There are limited data available on the use of Omalizumab in patients older than 65 years old

N. MONITORING PARAMETER

- ❖ Closely monitor for anaphylactic/hypersensitivity reaction (2 hours after first 3 injections and 30 minutes after subsequent injections)
- ❖ Also monitor baseline serum total IgE, peak flow and/or other pulmonary function tests
- ❖ Monitor for signs of infection

O. STORAGE

Store at 2-8°C, do not freeze. Store in the original package.

P. REFERENCES

Product leaflet, FUKKM, Medscape, UpToDate, FDA Drug Information

PREPARED BY: NURUL SYAHIRAH ASMAA BINTI MOHD ZAIN



PHARMACY R&D

TITLE: ASSESSMENT ON MEDICATION ERRORS DETECTION AMONG PHARMACISTS IN A PHARMACY DEPARTMENT OF A GOVERNMENT HOSPITAL SETTING (ADAPT)

Author: Sohaimi NF, Rosli M, Mohd Sabri M, Khairul Fadzil S, Ahmad Bashir NH, Abd Majid MZ, Ali RA

Department of Pharmacy, Hospital Tengku Ampuan Afzan, Kuantan, Pahang.

Background: Medication error is defined as ‘any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. In 2016, there were 40 medication error cases reported to pharmacy department and pharmacists detected 35% of the reported cases.

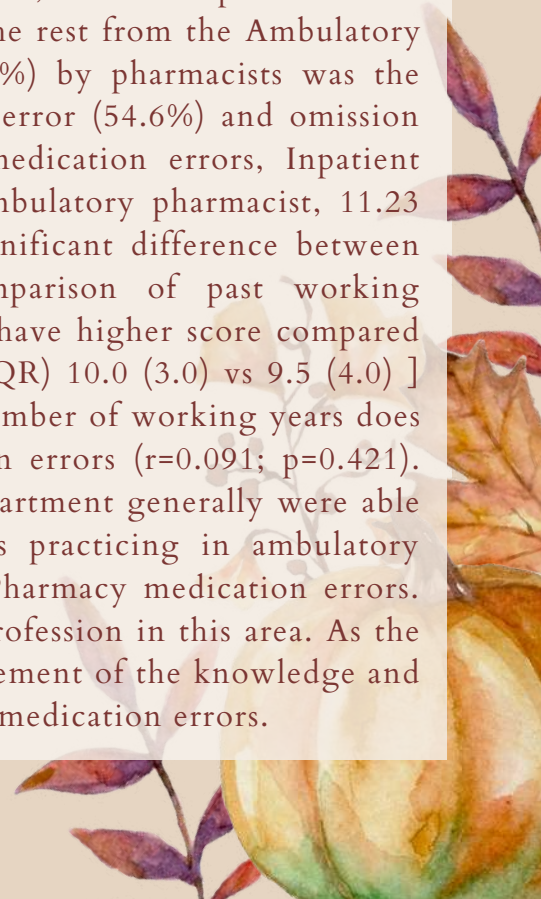
Objectives: This study aimed to assess the ability of pharmacists in Hospital Tengku Ampuan Afzan (HTAA) in detecting medication errors and to explore the factors that influenced their performance as well as the pattern of detection rate of medication errors involved.

Method: A cross-sectional study was conducted among all registered pharmacists in HTAA using a validated online questionnaire. It consisted of 2 parts: 1) 10 domains of 20 medication errors simulated questions; 2) Demographic background. The links to access the questionnaires were distributed to all subjects via their email together with the standard Participant Information Sheet and Informed Consent. Analysis of data was carried out using Statistical Package for the Social Sciences (SPSS).

Results: A total of 81 pharmacists answered the questionnaire, with a response rate of 88%. They were 48.1% from the Inpatient Pharmacy while the rest from the Ambulatory Pharmacy. Overall, the detection rate of filling error (76.3%) by pharmacists was the highest, followed by transcribing error (59.3%), prescribing error (54.6%) and omission error (23.5%) respectively. In terms of ability to detect medication errors, Inpatient pharmacists with means (SD) scored higher compared to ambulatory pharmacist, 11.23 (2.32) vs 9.93 (2.76) ($p=0.025$). Generally, there was no significant difference between education background of pharmacists ($p=0.915$). In comparison of past working experiences, pharmacists who worked at hospital exclusively have higher score compared to pharmacists who had extra hospital experience [Median (IQR) 10.0 (3.0) vs 9.5 (4.0)] ($p<0.05$). In terms of years of service and performance, the number of working years does not influence the ability of pharmacists to detect medication errors ($r=0.091$; $p=0.421$).

Conclusion: Pharmacists who are practicing in inpatient department generally were able to detect more medication errors compared to pharmacists practicing in ambulatory department for simulated situations based on the Inpatient Pharmacy medication errors.

Exposure to different working units may help to grow the profession in this area. As the occurrence of medication errors can be multifactorial, enhancement of the knowledge and competency of pharmacists plays a vital roles in prevention of medication errors.





PHARMACY R&D

TITLE: AWARENESS AMONG PATIENTS AT OUTPATIENT PHARMACY ON GENERIC MEDICINES IN HOSPITAL TENGKU AMPUAN AFZAN, KUANTAN

Author: Mohd Sopian MA, Rusli ANZ, Matsor NAL, Ahmad Hamedon S, Abdullah US, Torng TW, Yi CJ, Dalim RA, Zameram AM

Department of Pharmacy, Hospital Tengku Ampuan Afzan, Kuantan.

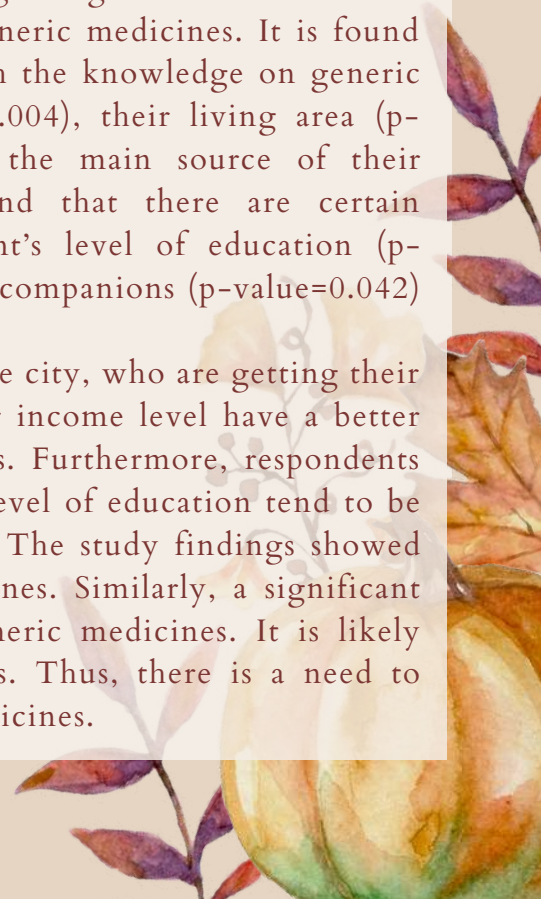
Background: The use of generic medicines has increased significantly in recent years as they have the same quality, safety and efficacy as their counterpart original brand medicines. However, some patients considered them to be inferior medicines and were viewed with poorer qualities and less effectiveness. Some had also claimed that side effects experiences were more prominent when taking generic medicines.

Objective: This study aimed to assess patients' awareness on generic medicines and also to determine the associated risk factor influencing patients' awareness and knowledge on generic medicines at the outpatient pharmacies setting in HTAA.

Method: A cross-sectional study was conducted in HTAA, Kuantan to assess the patients' awareness on generic medicines and the risk factors associated to patients' awareness and knowledge on generic medicines. A set of questionnaire consisting of 3 sections that make up a total of 28 questions (7 background-related, 11 awareness-related and 10 knowledge-related) was distributed to various patients attending the outpatient pharmacies in HTAA.

Results: A total of 380 questionnaires were answered completely. The mean total score of the patient's knowledge and awareness on generic medicines were 4.46 and 23.81 respectively. Most patients (n=175,46.1%) have poor knowledge on generic medicines and most of them (n=358,94.2%) have moderate awareness on generic medicines. It is found that there are 4 factors that have significant associations with the knowledge on generic medicine which are patient's level of education (p-value=0.004), their living area (p-value=0.030), one's monthly income (p-value=0.001) and the main source of their medication information (p-value=0.023). It was also found that there are certain significant associations that existed between the participant's level of education (p-value=0.000), monthly income (p-value=0.007) and the living companions (p-value=0.042) to the level of awareness on generic medicine.

Conclusion: It is shown that respondents who are living in the city, who are getting their information through health-care providers and with a higher income level have a better knowledge about generic medicines comparing to the others. Furthermore, respondents who are not living alone, with a higher income and higher level of education tend to be more aware about generic medicines compare to the others. The study findings showed that most respondents were not aware about generic medicines. Similarly, a significant proportion of respondents hold negative perceptions of generic medicines. It is likely these attitudes present barriers to the wider use of generics. Thus, there is a need to provide patients with adequate information about generic medicines.



World Pharmacists' Day 2020 Celebration

25th September 2020



KETUA JABATAN FARMASI
Hjh Pn. Samehah Almuna
Bt Hj Ismail



FARMASI MAKMUR



**FARMASI WAD &
PRIC**



FARMASI LOGISTIK



FARMASI SATELIT



FARMASI BEKALAN WAD



**FARMASI KLINIK
PAKAR**

KURSUS MEDICATION SAFETY JABATAN FARMASI

26/9/2020

BILIK MESYUARAT NILAM 1, BANGUNAN PUSAT
RAWATAN HARIAN, HTAA

Participants concentrating
on the talk



Pn. Aisyah giving a talk
on Adverse Drug
Reactions





MALAYSIA FOODIE RACE

**1ST OCTOBER - 15TH OCTOBER
2020**



Vice Chairperson of PharmCare,
Puan Falahiah presenting a token of
appreciation to Puan Zaidah for her
participation and completion in the event.

One of the participants, Puan Liyana
Hamiza, receiving her T-shirt and medal
as appreciation for her achievement in the
event



Kursus Kesedaran Projek QA & KIK

21/10/2020

BILIK MESYUARAT TOPAZ, UFL, HTAA

Dr. Farawahida from Ophthalmology department as one of the speakers of this course.



Dr. Sahimi, Timbalan Ketua Jabatan Farmasi presenting a token of appreciation to Sr. Anisah from O&G department.

Dr. Farawahida sharing on the methods of implementing and choosing projects, as well as solving problems of QA projects.



Dr. Sahimi presenting a token of appreciation to Dr. Farawahida.



**3RD PHARMACY
BULLETIN**