



Ruj. Tuan :
Ruj. Kami : KKM.600-34/4/04 Jld. 2 (39)
Tarikh : 30 Ogos 2019

SEPERTI SENARAI EDARAN

YBhg. Datuk/Dato' Seri/ Dato'/Datin/Tuan/Puan,

PEKELILING PINDAAN/TAMBAHAN KEPADA FORMULARI UBAT-UBATAN KEMENTERIAN KESIHATAN MALAYSIA BILANGAN 2/2019

Saya dengan segala hormatnya merujuk kepada perkara di atas.

2. Sukacita dimaklumkan bahawa Mesyuarat Panel Kaji Semula Senarai Ubat-ubatan KKM Bil. 2/2019 yang diadakan pada 31 Julai 2019 telah mempertimbangkan permohonan-permohonan pindaan/tambahan kepada Formulari Ubat KKM (FUKKM). Keputusan pindaan/ tambahan tersebut adalah seperti berikut:

Permohonan Pindaan/Tambahan kepada FUKKM yang diluluskan (Jadual A):

- **Lampiran A1:** Ubat-ubatan baru yang diluluskan untuk disenaraikan dalam FUKKM.
- **Lampiran A2:** Tambahan indikasi yang diluluskan bagi ubat-ubatan yang tersenarai dalam FUKKM.
- **Lampiran A3:** Tambahan formulasi/kekuatan/bentuk dosej yang diluluskan bagi ubat-ubatan yang tersenarai dalam FUKKM.
- **Lampiran A4:** Pindaan kategori preskriber yang diluluskan bagi ubat-ubatan yang tersenarai dalam FUKKM.
- **Lampiran A5:** Ubat-ubatan yang dimansuhkan daripada FUKKM.
- **Lampiran A6:** Pindaan-pindaan lain yang diluluskan oleh Panel Kaji Semula Senarai Ubat-Ubatan KKM.

3. Penggunaan ubat-ubatan yang terdapat dalam FUKKM perlu dipantau dengan rapi dan sebarang kesan advers hendaklah dilaporkan kepada Jawatankuasa Penasihat Kesan Advers Ubat Kebangsaan (MADRAC) di Bahagian Regulatori Farmasi Negara (NPRA).

4. Sebagai makluman, harga ubat yang terdapat dalam senarai di lampiran adalah harga yang diisytiharkan oleh pihak syarikat kepada bahagian ini yang dikemukakan bersama cadangan pindaan/tambahan kepada FUKKM. Sebarang perbezaan harga (melebihi harga yang ditawarkan) di peringkat hospital/ institusi KKM hendaklah dilaporkan kepada Cawangan Pengurusan Harga Ubat, Bahagian Amalan dan Perkembangan Farmasi, berserta dokumen sokongan berkaitan supaya tindakan selanjutnya dapat diambil.

5. Sehubungan dengan itu, diharapkan YBhg. Datuk/Dato' Seri/Dato'/Datin/Tuan/Puan dapat menyampaikan maklumat ini kepada fasiliti yang berkaitan di negeri atau jabatan masing-masing. Segala kerjasama yang diberikan amatlah dihargai.

Sekian, terima kasih.

“BERKHIDMAT UNTUK NEGARA”

Saya yang menjalankan amanah,



(DR. RAMLI BIN ZAINAL) RPh. 1045

Pengarah Kanan Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia

RL/rr/nsy

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s.k.

- 1. Ketua Setiausaha**
Kementerian Kesihatan Malaysia
- 2. Ketua Pengarah Kesihatan**
Kementerian Kesihatan Malaysia
- 3. Setiausaha Bahagian (Perolehan & Penswastaaan)**
Kementerian Kesihatan Malaysia
- 4. Pengarah Kanan (Kesihatan Pergigian)**
Kementerian Kesihatan Malaysia
- 5. Pengarah**
Bahagian Perkembangan Perubatan
Kementerian Kesihatan Malaysia
- 6. Pengarah**
Bahagian Pembangunan Kesihatan Keluarga
Kementerian Kesihatan Malaysia
- 7. Pengarah**
Bahagian Kawalan Penyakit
Kementerian Kesihatan Malaysia
- 8. Pengarah Kesihatan Negeri**
Johor/ Kedah/ Kelantan/ Melaka/ Negeri Sembilan/ Pahang/ Perak/ Pulau
Pinang/ Perlis/ Sabah/ Sarawak/ Selangor/ Terengganu/ Wilayah Persekutuan
Kuala Lumpur dan Putrajaya/ Wilayah Persekutuan Labuan
- 9. Semua Pengerusi JK Kerja Ubat-ubatan**
Kementerian Kesihatan Malaysia
- 10. Semua Ahli Panel Kaji Semula Senarai Ubat-ubatan**
Kementerian Kesihatan Malaysia
- 11. Pengarah**
Bahagian Regulatori Farmasi Negara
Kementerian Kesihatan Malaysia
- 12. Pengarah**
Bahagian Dasar dan Perancangan Strategik Farmasi
Kementerian Kesihatan Malaysia

13. Semua Timbalan Pengarah

Bahagian Amalan & Perkembangan Farmasi
Kementerian Kesihatan Malaysia

14. Ketua Penolong Pengarah Kanan

Sektor Bekalan Farmasi
Cawangan Dasar Polisi Perkhidmatan
Bahagian Perkembangan Kesihatan Awam
Kementerian Kesihatan Malaysia

15. Timbalan Pengarah

Cawangan Teknologi Maklumat & Informatik Farmasi
Bahagian Dasar dan Perancangan Strategik Farmasi
(bagi tujuan pengemaskinian sistem PhIS).

16. Ketua Pustakawan

Kementerian Kesihatan Malaysia

17. Unit Teknikal Bantuan Perubatan

Pejabat Timbalan Ketua Pengarah Kesihatan (Perubatan)
Kementerian Kesihatan Malaysia

18. Pengarah Farmasi

Bahagian Perkhidmatan Kesihatan
Kementerian Pertahanan Malaysia

19. Ketua Jabatan Farmasi

Hospital Canselor Tuanku Mukhriz
Pusat Perubatan Universiti Kebangsaan Malaysia

20. Ketua Pegawai Farmasi

Pusat Perubatan Universiti Malaya

21. Ketua Pegawai Farmasi

Hospital Universiti Sains Malaysia

22. Ketua Pegawai Farmasi

Pusat Perubatan Universiti Islam Antarabangsa Malaysia (PPUIAM)

23. Pegawai Farmasi

Institut Jantung Negara

SENARAI EDARAN

1. Timbalan Pengarah Kesihatan Negeri (Farmasi)

Johor/ Kedah/ Kelantan/ Melaka/ Negeri Sembilan/ Pahang/ Perak/ Pulau Pinang/ Perlis/ Sabah/ Sarawak/ Selangor/ Terengganu/ Wilayah Persekutuan Kuala Lumpur dan Putrajaya/ Wilayah Persekutuan Labuan

2. Ketua Jabatan Farmasi

Hospital Kuala Lumpur

3. Ketua Jabatan Farmasi

Institut Kanser Negara

4. Ketua Jabatan Farmasi

Hospital Wanita dan Kanak-kanak Kuala Lumpur

5. Pegawai Farmasi y/m

Institut Perubatan Respiratori.

6. Pegawai Farmasi y/m

Pusat Darah Negara

PINDAAN/TAMBAHAN KEPADA FORMULARI UBAT KKM (FUKKM) BIL. 2 TAHUN 2019

JADUAL A: PERMOHONAN PINDAAN/TAMBAHAN KEPADA FUKKM YANG DILULUSKAN

BIL	NAMA UBAT	PINDAAN	LAMPIRAN
1.	Abiraterone acetate 250mg tablet	Penyenaraian ubat baru	<u>A1</u>
2.	Degarelix 120mg & 80mg injection		
3.	Mometasone Furoate 50mcg aqueous nasal spray	Tambahan Indikasi	<u>A2</u>
4.	Empaglifozin 10mg & 25mg Tablet	Tambahan Indikasi	
5.	Diltiazem HCl 100mg sustained release capsule	Tambah formulasi	<u>A3</u>
6.	Enoxaparin 40mg & 60mg Injection	Pindaan kategori preskriber A* kepada A/KK	<u>A4</u>
7.	Azithromycin 250mg tablet	Pindaan kategori preskriber A* kepada A/KK	
8.	Azithromycin 200mg/5ml granules	Pindaan kategori preskriber A* kepada A/KK	
9.	Etoricoxib 90mg tablet	Pindaan kategori preskriber A* kepada A/KK	
10.	Gabapentin 300mg capsule	Pindaan kategori preskriber A* kepada A/KK	
11.	Ketoprofen 2.5% gel	Pindaan kategori preskriber A kepada A/KK	
12.	Ketoprofen 200mg Slow Release Capsule	Pemansuhan daripada FUKKM	<u>A5</u>
13.	Adefovir Dipivoxil 10mg tablet		
14.	Olodaterol HCl 2.5mcg/puff, solution for inhalation		
15.	Rotigotine transdermal patch (2mg/24 hr; 4mg/24hr; 6mg/24hr; 8mg/24hr)		
16.	*Metformin/Glibenclamide 500mg/2.5mg tablet		

* Pemansuhan telah diluluskan dalam Mesyuarat Panel Kaji Semula Senarai Ubat FUKKM Bil.2/2018

UBAT-UBATAN BARU YANG DILULUSKAN UNTUK DISENARAIKAN DALAM FUKKM

BIL.	MAKLUMAT UBAT	KETERANGAN UBAT
1.	<p>Abiraterone acetate 250mg Tablet</p> <p><u>MDC:</u> L02BX03-000-T10-01-001</p> <p><u>Cost/unit (RM):</u> RM50.83* per tablet</p> <p>*This is applicable to the product Zytiga® marketed by Johnson & Johnson Sdn Bhd.</p> <p>Remarks: This is a multisource drug (generics), marketed by more than one pharmaceutical manufacturer.</p> <p><u>Prescriber Category:</u> A* (Consultant/Specialists from disciplines of Oncology and Urology only)</p>	<p><u>Approved Indication(s):</u> With prednisone or prednisolone, for the treatment of metastatic castration-resistant prostate cancer (mCRPC) in adult men.</p> <p><u>Prescribing restriction:</u></p> <ol style="list-style-type: none"> Those who have progressed on OR failed prior docetaxel chemotherapy Those who are contraindicated or unsuitable for chemotherapy <p><u>Dose:</u> 1,000mg once daily</p> <p><u>Precaution(s):</u> Hypertension, hypokalaemia, fluid retention due to mineralocorticoid excess, hepatotoxicity, hepatic impairment, decreased bone density, prior use of ketoconazole</p> <p><u>Adverse reaction(s):</u> Peripheral oedema, hypokalemia, hypertension, urinary tract infection, hematuria, aspartate aminotransferase increased, alanine aminotransferase increased, dyspepsia, fractures</p> <p><u>Contraindication(s):</u></p> <ul style="list-style-type: none"> Hypersensitivity to the active substance or to any of the excipients Women who are or may potentially be pregnant Severe hepatic impairment (Child-Pugh Class C) <p><u>Interaction(s):</u> Food, CYP3A4 inducers, drugs activated by or metabolised by CYP2D6 and CYP2C8</p>
2.	<p>Degarelix 120mg & 80mg Injection</p> <p><u>MDC:</u> 80mg: L02BX02-000-P40-01-002</p> <p>120mg: L02BX02-000-P40-01-001</p>	<p><u>Approved Indication(s):</u> Treatment of adult male patients with advanced hormone-dependent prostate cancer</p> <p><u>Prescribing restriction:</u> Patients who are contraindicated to Gonadotrophin Releasing Hormone (GnRH) agonist</p>

TERHAD - Edaran dalaman sahaja

BIL	UBAT DALAM FUKKM	PINDAAN	KETERANGAN UBAT
2.	Empagliflozin 10mg & 25mg Tablet	<p><u>Approved to add indication(s):</u> Indicated in patients with type 2 diabetes mellitus (T2DM) and established cardiovascular disease (CVD) to reduce the risk of cardiovascular (CV) death: As an adjunct to diet, exercise and standard of care, to reduce the risk of cardiovascular (CV) death.</p> <p><u>Prescribing Restriction:</u> Patients must meet all the following criteria:</p> <ul style="list-style-type: none"> i. Patients have inadequate glycaemic control (HbA1c between 7% -10%) despite an adequate trial of metformin; ii. Creatinine clearance 45ml/min or EGFR 45ml/min/1.73m² and above <p><u>Cost/unit (RM):</u> RM 51.00 / pack of 's (RM 1.70/ tablet)</p> <p><u>Prescriber Category:</u> A* (Consultant/ Specialists from disciplines related to the listed indication only)</p>	<p><u>Dose:</u> Starting dose is 10 mg empagliflozin once daily for monotherapy and add-on combination therapy with other glucose-lowering medicinal products including insulin. In patients tolerating empagliflozin 10 mg once daily and need tighter glycaemic control, the dose can be increased to 25 mg once daily. The maximum daily dose is 25 mg</p> <p><u>Precaution(s):</u> Should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Use with cautions in patients with renal impairment, hepatic impairment, pregnancy & lactation, diabetic ketoacidosis, urinary tract infections, cardiac failure patients at risk for volume depletion & patients who are lactose intolerance.</p> <p><u>Adverse reaction(s):</u> Hypoglycaemia (when used with sulphonylurea or insulin), vaginal moniliasis, vulvovaginitis, balanitis and other genital infection, urinary tract infection, pruritus (generalised), increase urination.</p> <p><u>Interaction(s):</u> Diuretics may add to the diuretic effect & increase the risk of dehydration and hypotension. Insulin and insulin secretagogues may increase the risk of hypoglycaemia.</p> <p><u>Contraindication(s):</u> Hypersensitivity to the active substance or to any of the excipients in tablet core and film coating.</p>

TAMBAHAN FORMULASI/KEKUATAN YANG DILULUSKAN BAGI UBAT-UBATAN YANG TERSENARAI DALAM FUKKM.

BIL	UBAT DALAM FUKKM	PINDAAN	KETERANGAN UBAT
1.	Diltiazem HCl 100mg sustained release capsule	<p><u>Approved to add dosage formulation:</u> Diltiazem HCl 100mg sustained release capsule</p> <p><u>MDC:</u> C08DB01-110-C20-05-001</p> <p><u>Cost/unit (RM):</u> RM 58.00 / pack of 100's (RM 0.58 / tablet)</p> <p><u>Prescriber Category:</u> A/KK (Family Medicine Specialists)</p>	<p><u>Approved indication(s):</u> Treatment of angina pectoris in the following cases:</p> <ol style="list-style-type: none"> Inadequate response or intolerance to beta-blockers and Isosorbide Dinitrate Contraindication to beta-blockers Coronary artery spasm <p><u>Dose:</u> Usually, for adults, 100 mg to 200 mg to be administered orally once daily. If the effect is insufficient, the dosage may be increased to 200 mg once daily.</p> <p><u>Precaution(s):</u> Administered with care in the following patients:</p> <ul style="list-style-type: none"> Patients with congestive cardiac failure Patients with severe bradycardia (less than 50 beats/min) or first grade atrioventricular block. Patients with excessively low blood pressure. Patients with severe hepatic or renal impairment. <p><u>Other precautions:</u></p> <ul style="list-style-type: none"> Avoid abrupt cessation - may aggravate patient's symptoms. Patient should avoid engaging in potentially hazardous activities such as working at altitude or driving motor vehicles if dizziness occurs. Prolonged QT and ventricular arrhythmia have been reported in coadministration of terfenadine with other antiarrhythmic agents (disopyramide phosphate).

BIL	UBAT DALAM FUKKM	PINDAAN	KETERANGAN UBAT
			<p><u>Adverse reaction(s):</u> <i>Bradycardia, atrioventricular block, facial flushing, dizziness, malaise, headache, headache dull, increased AST [GOT], increased ALT [GPT]), hypersensitivity rash, stomach discomfort, constipation, abdominal pain, heartburn, anorexia, nausea.</i></p> <p><u>Contraindication(s):</u></p> <ul style="list-style-type: none"> • <i>Patients with severe congestive cardiac failure.</i> • <i>Patients with second- or third-degree atrioventricular block or sick sinus syndrome [persistent sinus bradycardia (less than 50 beats/minute), sinus arrest, sinoatrial block, etc.]</i> • <i>Patients with a history of hypersensitivity to any of the ingredients of this product.</i> • <i>Pregnant women and women who may possibly be pregnant.</i> <p><u>Interaction(s):</u> <i>Antihypertensives, fingolimod, drugs which causes depression of cardiac stimulation and cardiac conduction (e.g. beta-blockers, digitalis preparations, anti-arrhythmic agents), drugs which are metabolized through cytochrome (CYP) P450 (e.g. simvastatin, theophylline, cyclosporin, tacrolimus, phenytoin), CYP P450 inducers (e.g. rifampicin), CYP P450 inhibitors (e.g. cimetidine, HIV protease inhibitors), muscle relaxants (e.g. pancuronium bromide, vecuronium bromide).</i></p>

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

BIL	NAMA GENERIK	KETERANGAN PINDAAN
1.	Enoxaparin 40mg & 60mg Injection	<p>The change of the category of prescriber from A* to A/KK is <u>specifically</u> for the indication - "Prevention of DVT in antenatal and/or postnatal women with <u>VTE risk scoring of 3 or more</u>" only.</p> <p>A written consent form by the patient is necessary prior treatment initiation. Healthcare facilities are advised to refer to "Panduan Penggunaan Ubat-Ubatan yang Mengandungi Unsur Tidak Halal" at https://www.pharmacy.gov.my/v2/sites/default/files/document-upload/garis-panduan-penggunaan-ubatan-dengan-kandungan-tidak-halal.pdf</p> <p>Other indications and their corresponding categories of prescriber remain unchanged.</p>
2.	Azithromycin 250mg tablet	<p>The change in the category of prescriber from A* to A/KK is <u>specifically</u> for the indication - "<u>Treatment of pertussis</u>" only.</p> <p><u>Revised indication in the MOHME:</u> Treatment of complicated respiratory tract infections (A*).</p>
3.	Azithromycin 200mg/5ml granules	<p>Other indications and their corresponding categories of prescriber remain unchanged</p>
4.	Etoricoxib 90mg tablet	Change of the category prescriber from A* to A/KK.
5.	Gabapentin 300mg capsule	<p>Change of the category prescriber from A* to A/KK for the following indication:</p> <ul style="list-style-type: none"> Treatment of various types of neuropathic pain, both peripheral (which includes diabetic neuropathy, post-herpetic neuralgia, trigeminal neuralgia) in adult more than 18 years. <p>The use of gabapentin for indication, "Add-on therapy for intractable partial epilepsy, refractory to standard anti-epileptic drugs" is still categorised as A*.</p>
6.	Ketoprofen 2.5% gel	Change of prescriber category from A to A/KK

Nota:

A* (Consultant/ Specialists from disciplines related to the listed indication only)

A (Consultant/Specialists)

A/KK (Consultant/ Specialists/ Family Medicine Specialists)

UBAT-UBATAN YANG DIMANSUHKAN DARIPADA FUKKM

BIL	NAMA GENERIK	JUSTIFIKASI PEMANSUHAN	ALTERNATIF DALAM FUKKM (KATEGORI PRESKRIBER)
1.	Ketoprofen 200mg Slow Release Capsule	<ul style="list-style-type: none"> Product is no longer use in the MOH setting and not registered with the Drug Control Authority. Sufficient alternatives are available in the MOHMF. 	<ul style="list-style-type: none"> Diclofenac 50 mg Tablet (B). Ibuprofen 200 mg Tablet (B). Indomethacin 25mg Capsule (B). Mefenamic Acid 250 mg Capsule (C). Tramadol HCl 50 mg Capsule (A/KK). Meloxicam 7.5 mg Tablet (A/KK).
2.	Adefovir Dipivoxil 10mg tablet	<ul style="list-style-type: none"> Product withdrawn from Malaysian market and not registered with the Drug Control Authority Sufficient alternatives are available in the MOHMF 	<ul style="list-style-type: none"> Entecavir 0.5mg Tablet Lamivudine 100mg Tablet Telbivudine 600mg Tablet Tenofovir Disoproxil Fumarate 300mg Tablet Peginterferon Alfa-2b 50mcg, 80mcg, 100mcg, 120mcg, & 150mcg Injection Peginterferon Alfa-2a 135mcg & 180mcg Injection
3.	Olodaterol HCl 2.5mcg/puff, solution for inhalation	Product is no longer manufactured worldwide by the pharmaceutical company	Indacaterol Maleate 150 mcg Inhalation Capsule
4.	Rotigotine transdermal patch (2mg/24 hr; 4mg/24hr; 6mg/24hr; 8mg/24hr)	Product is no longer manufactured worldwide by the pharmaceutical company	<ul style="list-style-type: none"> Pramipexole Tablet (multiple strengths) Levodopa Tablet (multiple strengths)
5.	*Metformin/Glibenclamide 500mg/2.5mg Tablet	<ul style="list-style-type: none"> Risk of hypoglycaemia especially in the elderly Sufficient alternatives are available in the MOHMF 	<ul style="list-style-type: none"> Gliclazide 80mg Tablet Gliclazide MR 30mg Tablet Gliclazide MR 60mg Tablet

* Telah dipersetujui dalam Mesyuarat Panel Kaji Semula Senarai Ubat FUKKM Bil. 2/2018

PINDAAN-PINDAAN LAIN YANG DILULUSKAN OLEH PANEL KAJI SEMULA SENARAI UBAT-UBATAN KKM

BIL.	NAMA GENERIK	PINDAAN	KETERANGAN PINDAAN
A) Addition of indication:			
1.	Gamma Benzene Hexachloride (GBH) 1% Lotion	<i>Addition of indication: For treatment of head lice Dosage: Leave lotion on hair for exactly 4 minutes. Then wash off the hair and the skin with warm water.</i>	<i>To allow use of GBH 1% Lotion in treatment of head lice</i>
B) Amendment of the current generic name to:			
1.	Cisplatin 10 mg Injection Cisplatin 50 mg Injection	Cisplatin 1mg/ml Injection	<i>To enable flexible procurement at central and/or local facility level.</i>
2.	Carboplatin 150mg Injection Carboplatin 450mg Injection	Carboplatin 10mg/ml Injection	
3.	Cytarabine 100mg Injection Cytarabine 500mg Injection Cytarabine 1g Injection	Cytarabine 100mg/ml Injection	
4.	Fluorouracil 50mg/ml in 5 ml Injection Fluorouracil 1g/20ml Injection	Fluorouracil 50mg/ml Injection	
5.	Idarubicin 5mg Injection Idarubicin 10mg Injection	Idarubicin 1mg/ml Injection	
6.	Irinotecan HCl Trihydrate 20 mg/ml Injection Irinotecan HCl Trihydrate 40 mg/2 ml Injection	Irinotecan HCl Trihydrate 20 mg/ml Injection	
7.	Methotrexate 1000mg Injection Methotrexate 50 mg Injection Methotrexate 500 mg/20 ml Injection	Methotrexate 100mg/ml Injection Methotrexate 25mg/ml Injection	
8.	Paclitaxel 100mg/16.6ml Injection Paclitaxel 30mg/5ml Injection	Paclitaxel 6mg/ml Injection	
9.	Vinorelbine 10mg Injection Vinorelbine 50mg Injection	Vinorelbine 10mg/ml Injection	
10.	Doxorubicin 10mg Injection Doxorubicin 50mg Injection	Doxorubicin 2mg/ml Injection	
11.	Epirubicin 10mg Injection Epirubicin 50mg Injection	Epirubicin 2mg/ml Injection	
12.	Oxaliplatin 50mg Injection	Oxaliplatin 5mg/ml Injection	