KEMENTERIAN KESIHATAN MALAYSIA
(Ministry of Health Malaysia)
Bahagian Regulatori Farmasi Negara (NPRA)
Lot 36, Jalan Universiti
46200 Petaling Jaya
Selangor
MALAYSIA

No. Telefon : 03-7883 5400
No. Faksimili : 03-7956 2924
Portal Rasmi : http://www.npra.moh.gov.my
E-mel Rasmi : npra@npra.gov.my

Ruj. Kami: (6) dlm. BPFK/PPP/07/25 Jld. 4
Tarikh : 12 Mei 2020

SEMUA PEMEGANG PENDAFTARAN

SEMUA PERSATUAN BERKENAAN
(SEPERTI DI SENARAI EDARAN)

Tuan/ Puan,

PERATURAN-PERATURAN KAWALAN DADAH DAN KOSMETIK 1984
ARAHAN PENGARAH PERKHIDMATAN FARMASI BILANGAN 6 TAHUN 2020: DIREKTIF UNTUK SEMUA PRODUK YANG MENGANDUNGI DOMPERIDONE: PENGEMASKINIAN SISIP BUNGKUSAN DAN RISALAH MAKLUMAT UBAT UNTUK PENGGUNA (RiMUP) DENGAN MAKLUMAT BERKAITAN PENGGUNAAN DALAM KALANGAN GOLONGAN PEDIATRIK

Adalah saya merujuk kepada Arahan Bilangan 6 Tahun 2020 oleh Pengarah Perkhidmatan Farmasi.

2. Dimaklumkan bahawa Pengarah Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia dalam Arahan Bilangan 6 Tahun 2020 telah bersetuju untuk memasukkan maklumat keselamatan berkaitan penggunaan dalam kalangan golongan pediatrik bagi produk yang mengandungi domperidone seperti pada surat arahan Bil.(6) BPFK/PPP/07/25 Jld.4.

3. Pihak pemegang pendaftaran adalah diarahkan untuk mematuhi keperluan tersebut.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(DR HASENAH BINTI ALI) (RPh 1517)
Pengarah
Bahagian Regulatori Farmasi Negara
Kementerian Kesihatan Malaysia

SAB/NB/PKPSR/NPRA/06052020

SAB/nb
suhailah@npra.gov.my/ nurhidayah@npra.gov.my
+603 – 7883 5463/5474

ARAHAN DI BAWAH PERATURAN 29 PERATURAN – PERATURAN KAWALAN DADAH DAN KOSMETIK 1984

BILANGAN 6 TAHUN 2020

DIREKTIF UNTUK SEMUA PRODUK YANG MENGANDUNGI DOMPERIDONE: PENGEMASKINIAN SISIP BUNGKUSAN DAN RISALAH MAKLUMAT UBAT UNTUK PENGGUNA (RiMUP) DENGAN MAKLUMAT BERKAITAN PENGGUNAAN DALAM KALANGAN GOLONGAN PEDIATRIK

TUJUAN

1.1 Arahan ini dikeluarkan oleh Pengarah Perkhidmatan Farmasi di bawah Peraturan 29 (1) Peraturan-peraturan Kawalan Dadah dan Kosmetik 1984.

1.2 Arahan ini ditujukan kepada semua pemegang pendaftaran produk yang mengandungi domperidone bagi mengemaskini sisip bungkusan dan risalah maklumat ubat untuk pengguna (RiMUP) dengan maklumat keselamatan berkaitan penggunaan dalam kalangan golongan pediatrik.

LATAR BELAKANG

2.1 Pihak Berkuasa Kawalan Dadah (PBKD) dalam mesyuarat kali ke **344** pada **30 April 2020** telah membuat keputusan untuk semua produk yang mengandungi domperidone bagi mengemaskini sisip bungkusan dan risalah maklumat ubat untuk pengguna (RiMUP) dengan maklumat keselamatan berkaitan penggunaan dalam kalangan golongan pediatrik.

PELAKSANAAN

3.1 Oleh itu arahan – arahan berikut perlu dipatuhi untuk semua produk yang mengandungi domperidone seperti berikut:-

3.1.1 Sisip bungkusan

Pada bahagian *Dosage and administration* [Menggantikan *specific labelling requirements – Domperidone* bahagian *Dosage and administration* dalam *Drug Registration Guidance Document]*

It is recommended to take [product name] 15-30 minutes before meals. If taken after meals, absorption of the drug is somewhat delayed.

Adults and adolescents ≥ 12 years of age and weighing ≥35 kg & children <12 years of age and weighing ≥ 35 kg
The dose of [product name] should be the lowest effective dose for the individual situation (typically 30 mg/day) and can be increased if necessary to a maximum daily oral dose of 40 mg.

Usually, the maximum treatment duration should not exceed one week for the treatment of acute nausea and vomiting. If nausea and vomiting persists for longer than one week, patients should consult their physician. For other indications, the initial duration of treatment is up to four weeks. If treatment exceeds four weeks, patients should be reevaluated and the need for continued treatment reassessed.

Formulation (domperidone per unit)	***Dosage***	***Maximum dose per day***
Tablets (10 mg/tablet)	*1 tablet three to four times per day*	*40 mg (4×10 mg tablet).*
Oral suspension (1 mg/ml)	*10 mL three to four times per day*	*40 mg (40 mL of 1 mg/mL oral suspension)*

Adults and adolescents (≥ 12 years of age) weighing < 35 kg
The dose of [product name] should be the lowest effective dose. The total daily dose is dependent on weight (see table below).

Usually, the maximum treatment duration should not exceed one week for the treatment of acute nausea and vomiting. For other indications, the initial duration of treatment is up to four weeks. If treatment exceeds four weeks, patients should be reevaluated and the need for continued treatment reassessed. Due to the need for accurate dosing, tablets are unsuitable for use in adults and adolescents weighing less than 35 kg.

Formulation (domperidone per unit)	***Dosage***	***Maximum dose per day***
Oral suspension (1 mg/ml)	*0.25 mg/kg three to four times per day*	*35 mg (1 mg/kg but no more than 35 mL)*

Infants and children < 12 years of age and weighing < 35 kg
The efficacy of [product name] has not been established in infants and children < 12 years of age and weighing < 35 kg.

Renal impairment
Since the elimination half-life of domperidone is prolonged in severe renal impairment (serum creatinine > 6 mg/100 mL, i.e. > 0.6 mmol/L), the dosing frequency of [product name] should be reduced to once or twice daily, depending on the severity of the impairment, and the dose may need to be reduced. Patients with severe renal impairment should be reviewed regularly.

Hepatic impairment
[Product name] is contraindicated for patients with moderate (Child-Pugh 7 to 9) or severe (Child-Pugh >9) hepatic impairment. Dose adjustment is not required for patients with mild (Child-Pugh 5 to 6) hepatic impairment.

3.1.2 Risalah maklumat ubat untuk pengguna (RiMUP)

Pada bahagian *How to use [product name]:*

You should always take the lowest amount of [product name] that works for you and you should not take it for longer than is necessary. Although the amount of [product name] you should usually take is described below, your doctor may adjust your dose to your personal needs.

[Product name] is most effective if taken 15-30 minutes before meals.

Adults and adolescents (12 years of age and over) weighing 35 kg or more; children weighing 35kg or more:
Tablets: Take 1 tablet 3 to 4 times a day. Do not take more than 4 tablets per day (40 mg/day).
Oral suspension: Take 10mL of oral suspension 3 or 4 times a day. Do not take more than 40mL per day (40 mg/day).

Adults and adolescents weighing less than 35 kg:
Oral suspension: Give 0.25 milliliters of the oral suspension per kilogram of body weight 3 or 4 times a day. The maximum dose per day is 1 mg/kg but do not exceed 35 mg per day.

Infants and children less than 12 years of age and weighing less than 35kg: The effectiveness of [product name] has not been established in infants and children under 12 years of age with a body weight of <35 kg.

4. Tarikh pelaksanaan keperluan mengemaskini maklumat berkenaan pada semua produk yang mengandungi domperidone bagi:

(a) Permohonan baru dan produk yang sedang dalam proses penilaian : **1 Jun 2020**

(b) Produk berdaftar : **1 Januari 2021.**

5. Permohonan pindaan pada sisip bungkusan dan RiMUP bagi produk berdaftar perlu dikemukakan sebagai permohonan variasi.

6. Tarikh kuat kuasa arahan ini ialah mulai **1 Jun 2020.**

"BERKHIDMAT UNTUK NEGARA"

(DATIN DR. FARIDAH ARYANI BINTI MD YUSOF) (RPh 1197)
Pengarah Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia
SAB/NB/PKPSR/NPRA/04052020

s.k. 1. Pengarah
Bahagian Regulatori Farmasi Negara
Kementerian Kesihatan Malaysia

2. Pengarah
Bahagian Amalan dan Perkembangan Farmasi
Kementerian Kesihatan Malaysia

3. Pengarah
Bahagian Penguatkuasaan Farmasi
Kementerian Kesihatan Malaysia