



Pihak Berkuasa Kawalan Dadah  
Drug Control Authority  
KEMENTERIAN KESIHATAN MALAYSIA  
MINISTRY OF HEALTH MALAYSIA

Ruj. Kami : ( 14 ) dlm.BPFK/ 02 / 5 / 1.3  
Tarikh :

12 SEP 2003

Semua Pemegang Pendaftaran

Tuan,

KEPUTUSAN MESYUARAT PBKD

Keluaran yang mengandungi bahan aktif Dopaminergik : Tambahan amaran berkaitan dengan 'Sudden Sleep Onset'.

Pihak Berkuasa Kawalan Dadah, dalam mesyuaratnya yang ke 149 pada 24hb. Julai 2003 telah membuat keputusan berikut:

2. PBKD telah bersetuju agar amaran berkaitan dengan "Sudden Sleep Onset" dimuatkan pada sisip bungkusan bagi semua keluaran yang mengandungi bahan aktif dopaminergik supaya dapat mengurangkan risiko kejadian kesan advers serius kepada pengguna.
3. Keluaran yang mengandungi bahan aktif jenis dopaminergik yang terlibat ialah:
  - a. Levodopa (termasuk kombinasi dengan carbidopa/benserazide/entacapone).
  - b. Apomorphine.
  - c. Bromocriptine.
  - d. Cabergoline.
  - e. Alpha-dihydroergocryptine.
  - f. Lisuride
  - g. Pergolide.
  - h. Piribedil.
  - i. Pramipexole.
  - j. Quinagolide.
  - k. Ropinirole.
4. Amaran yang disyorkan adalah pada ruangan seperti berikut:
  - i) **Special warning & Special Precautions For Use:**  
.....has been associated with somnolence and episodes of sudden sleep onset, particularly in patients with Parkinson's disease. Sudden onset of sleep during daily activities, in some cases without awareness or warning signs, has been reported very rarely. Patients must be informed of this and advised to exercise caution while driving or operating machines during treatment with ..... Patients who have experienced somnolence and/or an episode of sudden sleep onset must refrain from driving or operating machines. Futhermore a reduction of dosage or termination of therapy may be considered.

ii) **Effects on Ability to Drive and Use Machines:**

Patients being treated with ..... and presenting with somnolence and/or sudden sleep episodes must be informed to refrain from driving or engaging in activities where impaired alertness may put themselves or others at risk of serious injury or death (e.g. operating machines) until such recurrent episodes and somnolence have resolved (see also section on special warnings and special precautions for use).

iii) **Undesirable Effects:**

..... is associated with somnolence and has been associated very rarely with excessive daytime somnolence and sudden sleep onset episodes.

5. Pihak tuan adalah disarankan agar mengambil maklum dan mematuhi keperluan di atas.

Sekian, terima kasih.

**"BERKHIDMAT UNTUK NEGARA"**

**"UTAMAKAN KUALITI, EFIKASI DAN KESELAMATAN"**

Saya yang menurut perintah,



**(EISAH BT. A. RAHMAN)**

Setiausaha

Pihak Berkuasa Kawalan Dadah

Kementerian Kesihatan Malaysia

- Sk.
1. Pengarah Perkhidmatan Farmasi, Bhg. Farmasi, KKM.
  2. Pharmaceutical Association of Malaysia (PhAMA)
  3. Malaysian Organisation of Pharmaceutical Industries (MOPI)
  4. Ketua Bahagian Farmakovigilans & Surveilans, BPFK.
  5. Fail BPFK/ 02 / 5 / 1.3