



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

Ruj. Kami : (31) dim.BPFK/ 02 / 5 / 1.3
Tarikh : 20. 07. 04

Semua Pemegang Pendaftaran

Tuan,

KEPUTUSAN MESYUARAT PBKD

TAMBAHAN AMARAN BERKAITAN DENGAN HYPERGLYCEMIA BAGI KELUARAN "ATYPICAL ANTIPSYCHOTIC AGENTS"

Pihak Berkuasa Kawalan Dadah, dalam mesyuaratnya yang ke 160 pada 1hb. Julai 2004 telah membuat keputusan berikut:

2. PBKD telah bersetuju agar amaran berkaitan dengan kesan advers "hyperglycemia" wajib untuk dimuatkan pada sisip bungkusan bagi semua keluaran yang merupakan agen "atypical antipsychotic".
3. Keluaran yang terlibat adalah keluaran yang mengandungi bahan aktif seperti berikut:
 - a. Clozapine
 - b. Olanzapine
 - c. Risperidone
 - d. Quetiapine
 - e. Ziprasidone
 - f. Aripiprazole
4. Amaran yang perlu dimuatkan di bawah bahagian "Warning" adalah seperti berikut:

WARNINGS:

Hyperglycemia and Diabetes Mellitus

Hyperglycemia in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given this confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.

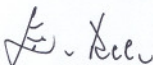
Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

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)

Setiasaha

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 & Surveillans, BPFK.
 5. Ketua Bahagian Pembangunan Organisasi dan Teknologi Maklumat, BPFK
 6. Fail BPFK/ 02 / 5 / 1.3