PHARMACY AND POISONS BOARD
HONG KONG
香港藥劑業及毒藥管理局

Your Ref. :
貴處檔號

Our Ref. : DH DO PRIE/1-55/1
本局檔號

Tel. No. : 3974 4133
電　話

Fax No. : 2803 4962
圖文傳真

C/O Drug Office
Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon, Hong Kong
香港九龍觀塘巧明街100號
Landmark East 友邦九龍大樓
20樓2002-05室

19th April 2021

To: Certificate holders of
registered pharmaceutical products

Dear Sir / Madam,

New Warnings for Products containing Montelukast

On 12th April 2021, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) considered the latest new warnings on neuropsychiatric risks associated with montelukast, and the restriction of its use on patients with allergic rhinitis imposed by the drug regulatory authorities of the United States, United Kingdom, Canada and Singapore, and decided that the sales pack labels and / or package inserts of such registered products should be updated to include the following new safety information or equivalent as appropriate:

(I) Restriction of use in allergic rhinitis

Allergic Rhinitis

Because the benefits of montelukast may not outweigh the risk of neuropsychiatric symptoms in patients with allergic rhinitis, reserve use for patients who have an inadequate response or intolerance to alternative therapies.

(II) Warning on neuropsychiatric risks

Neuropsychiatric Events

Serious neuropsychiatric (NP) events have been reported with use of montelukast. These postmarketing reports have been highly variable and included, but were not limited to, agitation, aggressive behavior or hostility, anxiousness, depression, disorientation, disturbance in attention, dream abnormalities, dysphemia (stuttering), hallucinations, insomnia, irritability, memory impairment, obsessive-compulsive symptoms, restlessness, somnambulism, suicidal thoughts and behavior (including suicide), tic, and tremor. NP events have been reported in adult, adolescent, and pediatric patients with and without a previous history of psychiatric disorder. NP events have been reported mostly during montelukast treatment, but some were reported after montelukast discontinuation. Based upon the available data, it is difficult to identify risk factors for or quantify the risk of NP events with montelukast use.

Discuss the benefits and risks of montelukast use with patients and caregivers when prescribing montelukast. Advise patients and/or caregivers to be alert for changes in behavior or for new NP symptoms when taking montelukast. If changes in behavior are observed, or if new NP symptoms or suicidal thoughts and/or behavior occur, advise patients to discontinue montelukast and contact a healthcare provider immediately. In many cases, symptoms resolved after stopping montelukast therapy; however, in some cases symptoms persisted after discontinuation of montelukast. Therefore, continue to monitor and provide supportive care until symptoms resolve. Re-evaluate the benefits and risks of restarting treatment with montelukast if such events occur.

Postmarketing Experience

The following adverse reactions related to psychiatric disorders which include but not limited to, agitation, aggressive behavior or hostility, anxiousness, depression, disorientation, disturbance in attention, dream abnormalities, dysphemia (stuttering), hallucinations, insomnia, irritability, memory impairment, obsessive-compulsive symptoms, restlessness, somnambulism, suicidal thinking

and behavior (including suicide), tic, and tremor have been identified during post-approval use of montelukast.

You are therefore required to review and revise, if necessary, the sales pack labels and / or package inserts of the concerned products registered by your company to ensure that the products comply with the above new requirements. The revised sales pack labels and / or package inserts should be submitted to the Committee for approval within 2 months from the date of this letter. Failing to comply with the above requirements may result in de-registration of the products or registration not renewed by the Committee.

If you have any enquiries on the above issue, please contact Ms. Queenie CHAN at 3974 4147.

Yours faithfully,

(T.K. YIM)
Secretary,
Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee

c.c. 7-15/3, Product Files

TK/QC