



DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 10 September 2020

EL (20)A/44

Our Ref: MDR 002-09/20

Dear Healthcare Professional,

Ratiopharm UK Limited

Zopiclone 3.75 mg Tablets

PL 15773/0028

Zopiclone 7.5 mg Tablets

PL 15773/0029

Generics [UK] Limited t/a Mylan

Zopiclone 3.75 mg Tablets

PL 04569/0450

Brief description of the problem

Ratiopharm UK Limited and Generics [UK] Limited t/a Mylan have confirmed that the Patient Information Leaflet (PIL) within all packs and the Summary of Product Characteristics (SmPC) for Ratiopharm is missing important safety information related to potential suicide risks:

Missing information from the Patient Information Leaflet:

- Suicidal ideation/suicide attempt/suicide and depression
 - Some studies have shown an increased risk of suicidal ideation, suicide attempt and suicide in patients taking certain sedatives and hypnotics, including this medicine.
 - However, it has not been established whether this is caused by the medicine or if there may be other reasons. If you have suicidal thoughts, contact your doctor as soon as possible for further medical advice.

Missing information from the Summary of Product Characteristics:

- Suicidal ideation/suicide attempt/suicide and depression
 - Some epidemiological studies show an increased incidence of suicidal ideation, suicide attempt and suicide in patients with or without depression, and treated with benzodiazepines and other hypnotics, including zopiclone. However, a causal relationship has not been established.
 - As with other hypnotics, zopiclone does not constitute a treatment for depression and may even mask its symptoms (suicide may be precipitated in such patients).
 - Zopiclone should be administered with caution in patients exhibiting symptoms of depression. Suicidal tendencies may be present therefore the least amount of zopiclone that is feasible should be supplied to these patients to avoid the possibility of intentional overdose by the patient. Pre-existing depression may be unmasked during use of zopiclone. Since insomnia may be a symptom of depression, the patient should be re-evaluated if insomnia persists.
 - Any underlying cause of the insomnia should also be addressed before symptomatic treatment to avoid under treating potentially serious effects of depression



It is important that any patients are provided with information on warnings and precautions whilst taking Zopiclone products. Additionally, patients who notice the symptoms/side effects or mood effects should seek immediate medical advice.

Advice for healthcare professionals

Patients should be made aware that the information on the possible risk of suicide is missing from the PIL provided in their packs. When dispensing this product, please check the Marketing Authorisation Holder; if any of the products listed below are being dispensed, ensure that patients are aware of the missing information by providing guidance in relation to the risk identified and by providing a copy of this alert.

Ratiopharm UK Limited - Zopiclone 3.75 mg and 7.5 mg Tablets, PL 15773/0028 and 15773/0029

- Please note the SmPC and PIL are undergoing a variation to include the missing information. In the event that this product is dispensed, please provide a copy of this drug alert to patients for information related to the suicide risks mentioned above.

Generics [UK] Limited t/a Mylan - Zopiclone 3.75 mg Tablets, PL 04569/0450

- In the event that this product is dispensed, please provide a copy of this drug alert to patients for information related to the suicide risks mentioned above.
- <https://www.medicines.org.uk/emc/product/2565/smpc> (Please note the SmPC has been updated, however the PIL is not up to date)

Further Information

For more information or medical information queries, please contact:

Ratiopharm UK Limited

- Teva UK Medical Information at: medinfo@teva.co.uk or Tel No: 0207 540 7117

Generics [UK] Limited t/a Mylan

- Medical Information Direct Line +44 (0)1707 853 000 select option 1, Customer Care direct line +44 (0)1707 853 000 select option 2 or via Medical Information e-mail info@mylan.co.uk

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this notice.

NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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