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Direct Healthcare Professional Communication:

A reminder of important information to consider when prescribing and monitoring Quetiapine immediate (IR) and prolonged (XR) release tablets

Dear healthcare professional,

In agreement with the Medicines Authority; *Accord Healthcare Limited, Actavis Group PTC ehf, AstraZeneca UK Limited, Aurobindo Pharma, Central Procurement & Supplies Unit, 1 A Pharma GmbH, Sanofi Malta Limited and Fair-Med Healthcare GmbH* would like to remind doctors and pharmacists of information relating to medicinal products containing Quetiapine IR/Quetiapine XR.

The use of Quetiapine XR for the treatment of major depressive disorder (MDD).
Prolonged release preparations of Quetiapine should only be prescribed together with an antidepressant. There is no licensed indication as monotherapy for major depressive disorder. Quetiapine prolonged release preparations are indicated as add-on treatment of major depressive episodes in patients with MDD who have had sub-optimal response to antidepressant monotherapy.

Please also note that Quetiapine in immediate release form is not indicated for the treatment of MDD.

Monitoring Quetiapine IR/ Quetiapine XR patients for metabolic parameters.
When treating patients with Quetiapine IR/ Quetiapine XR it is important to monitor metabolic parameters as described in the following sections of the SmPC. SmPC Section 4.4. “Special Warnings and Precautions”:

<u>Weight:</u>
Weight gain has been reported in patients who have been treated with quetiapine, and should be monitored and managed as clinically appropriate as in accordance with utilised antipsychotic guidelines.

<u>Hyperglycaemia:</u>
Hyperglycaemia and/or development or exacerbation of diabetes occasionally associated with ketoacidosis or coma has been reported rarely, including some fatal cases (see section 4.8). In some cases, a prior increase in body weight has been reported which may be a predisposing factor. Appropriate clinical monitoring is advisable in accordance with utilised antipsychotic guidelines. Patients treated with any antipsychotic agent including quetiapine, should be observed for signs and symptoms of hyperglycaemia, (such as polydipsia, polyuria, polyphagia and weakness) and patients with diabetes mellitus or with risk factors for diabetes mellitus should be monitored regularly for worsening of glucose control. Weight should be monitored regularly.

Lipids:
Increases in triglycerides, LDL and total cholesterol, and decreases in HDL cholesterol have been observed in clinical trials with quetiapine. Lipid changes should be managed as clinically appropriate.

Metabolic Risk
Given the observed changes in weight, blood glucose (see hyperglycemia) and lipids seen in clinical studies, there may be possible worsening of the metabolic risk profile in individual patients, which should be managed as clinically appropriate.
SmPC Section 4.8. "Undesirable effects":

The following metabolic adverse drug reactions are listed for Quetiapine:

- Elevations in serum triglyceride levels
- Elevations in total cholesterol (predominantly LDL cholesterol)
- Decreases in HDL cholesterol
- Weight gain as
- Blood glucose increased to hyperglycaemic levels
- Diabetes mellitus
- Exacerbation of pre-existing diabetes

The above information can be found in the Summary of Product Characteristics (SmPC). The Medicines Authority database http://www.medicinesauthority.gov.mt/advanced-search can be used to retrieve full SmPCs. For both new and existing prescribers of Quetiapine products, the SmPC remains the best resource when making prescribing decisions.

Call for reporting
Any suspected adverse reactions and medication errors can be reported to the Medicines Authority or to the license holders of Quetiapine containing products. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or sent by email to postlicensing.medicinesauthority@gov.mt

Company contact points
Contact point details for further information and ADR reporting are given in the product information of the medicine (SmPC and Package Leaflet).

Yours Sincerely,

The Post Licensing Directorate
Medicines Authority

Disclaimer

This Direct Healthcare Professional Communication has been submitted to you on behalf of company's *Accord Healthcare Limited, Actavis Group PTC ehf, AstraZenica UK Limited, Aurobindo Pharma, Central Procurement & Supplies Unit, 1 A Pharma GmbH, Sanofi Malta Limited and Fair-Med Healthcare GmbH.*