

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Seroquel XR/IR

ACTIVE INGREDIENT: Quetiapine extended release, quetiapine immediate release

Study No: VD-NS-1101; NCT01455961
An Epidemiological Registry Study to Evaluate Clinical Practice Treatment in Patients With Bipolar Disorder (REED)

Developmental Phase: Observational study

Study Completion Date: 30 April 2012

Date of Report: 17 April 2013

OBJECTIVES:

Bipolar disorder is a psychiatric disease characterized by recurring mood episodes. One pharmacological treatment for bipolar disorder is quetiapine fumarate, which exists in two formulations; extended release (XR) and immediate release (IR). The aim of the present epidemiological register study was to describe patient characteristics and clinical practice treatment patterns in an observational, real life setting for bipolar disorder patients treated with quetiapine IR continuously versus patients who were switched to XR.

METHODS:

Data from patients with bipolar disorder was extracted from the mandatory Swedish National Patient Registry and linked to the Prescribed Drug Register, and to data on socioeconomic factors from Statistics Sweden. Linkage was based on the unique personal identification number allocated to all Swedish citizens. The bipolar disorder (ICD-9 296.0, 296.4-8, 296A, 296C-E, 296W and/or ICD-10 F30, F31) was defined as the most recent diagnose in connection with in- or out-patient visits at hospital.

Index date was defined as first dispense date of quetiapine XR or first dispense date of IR after 1st January 2009. End of observation was 31st December 2011. Data were analysed by descriptive methods, and data management and statistical analyses were performed using SAS version 9.2 (SAS Institute Inc.) and R version 2.14.1.

RESULTS:

Fifteen percent of the Swedish population of patients with bipolar disorder (5 219 patients) was prescribed quetiapine XR or quetiapine IR during the study period. Of these, 1 761 patients were all initially prescribed quetiapine IR and could thus be included; and of these, 1 303 patients were switched to treatment with quetiapine XR during the study (XR Switch). The remaining 458 patients were continuously prescribed quetiapine IR (IR Continuous). Patients' age at baseline (standard deviation) was 43.6 (15.8) and 46.9 (16.4) years for XR Switch and IR Continuous, respectively.

Prior to index date, patients who switched from quetiapine IR to quetiapine XR had more single depressive episodes (47.1% vs. 40.4%) and other anxiety disorders (36.1% vs. 30.3%) compared to patients who continued their quetiapine IR. Concomitant treatment with anti-psychotic drugs was seen more frequently for XR Switch vs. IR Continuous patients.

Prior to the switch from quetiapine IR to quetiapine XR, the XR Switch patients were prescribed a lower mean daily quetiapine IR dose (218 vs. 270 mg), and fewer of these patients were receiving medications for somatic diseases (39.0% vs. 46.5%) compared to the IR Continuous patients.

Following switch to quetiapine XR, the number of concomitant atypical antipsychotic and antidepressant medications was reduced by 5.9% and 6.0% in the XR Switch group; while it increased by 3.0% and 0.7% in the IR Continuous group, respectively. The quetiapine dose following switch was higher in the XR Switch group compared to the IR Continuous treatment group; 305 vs. 252 mg per day, respectively.