

Title

Drug Utilization Study for azilsartan medoxomil in Germany

Keywords

Azilsartan medoxomil, drug utilization study, EMR database analysis, primary care setting

Rationale and background

Azilsartan medoxomil has been authorised in the European Union since December 2011 for treatment of essential hypertension in adults and was launched in Germany in March 2012. A Drug Utilisation Study (DUS) was conducted to assess the prescribing patterns of azilsartan medoxomil in a primary care population in Germany. While an interim analysis revealed useful information regarding the real-world use of azilsartan medoxomil in specific patients, including those with congestive heart failure, there remains limited data with regard to the use of this product in patients with severe renal or hepatic impairment, and those with an activated renin angiotensin aldosterone system (including patients with renal artery stenosis).

Research question and objectives

The current drug utilization study aimed to describe the population being prescribed azilsartan medoxomil and to evaluate drug utilization patterns in the primary care setting in Germany.

Study design

This is a retrospective cohort study using a patient level Electronic Medical Records (EMR) database for Germany.

Subjects and study size, including dropouts

The study was conducted among patients initiated on azilsartan medoxomil in the primary care setting in Germany. Overall, 811 subjects prescribed azilsartan medoxomil between January 2014 and November 2016 were considered.

Variables and data sources

Demographic characteristics of azilsartan medoxomil users and prescription patterns including use in the elderly, in non-approved indications, patient populations with missing information, concomitant prescribing of other antihypertensive drugs and drugs, which may cause drug interaction, were analysed. The primary care physicians' (PCP) panel of IMS[®] Disease Analyzer database was used as the data source for the study.

Results

In total, 696 patients from the IMS[®] Disease Analyzer met the study inclusion criteria and were included in the analysis. About 24% of patients were aged 75 or older, no patients were younger

than 18 years; about 46% were women. Azilsartan medoxomil was prescribed for the label indication (essential hypertension, ICD-10 I10) in 68% of users; 5.9% patients started exposure in study for other diagnoses, including other forms of hypertension (0.5%). In 26% of users information on prescription indication at the exposure start was missing. The proportion of azilsartan medoxomil users with documented history of severe renal impairment was 0.3%, with unspecified renal failure 4.6%, renal artery stenosis 0.6%, with hepatic injury 5.7%. Simultaneous prescription of azilsartan medoxomil and other antihypertensive drugs at the exposure start was recorded in 37.2% of patients with beta blockers and calcium antagonists being most common. Drugs, which may cause a drug interaction were simultaneously prescribed in 3.0% of the study population. Overlapping prescription periods of the study first azilsartan medoxomil prescription with other antihypertensive drugs were identified in 59% of users (overlap at least 7 days). The overlap with drugs potentially causing a drug interaction was detected in 8% of patients initiated on azilsartan medoxomil.

Discussion

The final study results show that azilsartan medoxomil has been used in the appropriate population, as per the approved indication in adults, with a high proportion of patients with essential hypertension. No evidence was found of use in paediatrics or off label use of azilsartan medoxomil to treat heart failure. The diagnoses of renal or hepatic impairment were not commonly reported in azilsartan medoxomil users. The findings indicate that the substantial proportion of patients received co-prescription of other antihypertensive drug classes. The concomitant use with drugs, which may cause a drug interaction was not infrequent during the first administration of azilsartan medoxomil.