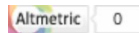


Effects of Safety-Related Alerts on Aliskiren Use Trends: An Observational Study from Portugal

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fully known before marketing

Application of aliskiren safety-related alerts (SA) have clinical and economic consequences. This study sought to assess the impact of aliskiren SA on consumption trends of all medicines containing aliskiren available in Portugal.

Methods

An ecological study was conducted using monthly-aggregated consumption data (January 2011 to December 2012). A search was made about aliskiren SA published by the National Authority of Medicines and Health Products, IP (INFARMED), and consumption data was provided by IMS Health Portugal. We studied the SA impact on the country-wide sales of all available medicines containing aliskiren (aliskiren and aliskiren/hydrochlorothiazide). The Anatomical Therapeutic Chemical (ATC) classification and DID (Defined daily doses per 1000 inhabitants per day) were used. Segmented regression was performed.

Results

During the period of study, INFARMED published, in their website, two SA about aliskiren (December 2011 and February 2012).

It was observed that aliskiren consumption increased immediately after both SA (Figure 1). However, long period analysis revealed a decreasing of DID consumed, also confirmed with the statistical analysis. It is also evident that the decreasing of sales is major in the medicines of single aliskiren comparing with aliskiren/hydrochlorothiazide.

Conclusion

After a global safety-related alert it is expected that the consumption of medicines containing aliskiren decreases. Immediately after both alerts, consumption of aliskiren seems to increase, but statistical analysis revealed a long period decreasing which could be related with health professionals concerns about the safety profile of aliskiren.

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Disclosure of Interest

Nothing to disclose.

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