ANALYSIS OF THE ADVERSE DRUG REACTIONS FOR FINGOLIMOD IN THE POST-MARKETING PHASE

1)Auricchio F. 2)Scavone C. 3)Cimmaruta D. 4)Larato A. 5)Fiorentino S. 6)Rossi F. 7)Capuano A. 8)Bernardi F.F.

University of Campania "L. Vanvitelli"

Introduction

Multiple sclerosis (MS) is a chronic inflammatory disorder of the central nervous system (CNS) characterized by inflammation, demyelination, and axonal degeneration. Even though the pharmacological armamentarium for the MS treatment is considerably improved in the last 20 years, safety data specially for the second-line treatment are lacking.

Aims

To analyze the Adverse drug reactions for fingolimod in the post-marketing phase.

Methods

We performed a descriptive analysis of the reports of suspected ADRs inserted in the National Network of Pharmacovigilance (RNF) of Italian Medicines Agency (AIFA) from the date of approval until April 2017.

Results

To date, 121 reports of suspected ADRs have been included in the National Network of Pharmacovigilance (RNF) of Italian Medicines Agency (AIFA) for Campania region for fingolimod/Gilenya. 98.3% of the reports were received from hospital, the mean age of patients was 37.94 years (Δs= 12.00) and 65.23% were female. Since each report form may contain more than one ADR and more than one drug, a total of 906 ADRs were reported. ADRs referred mainly to investigations (27.60%), blood and lymphatic system disorders (18.2%), infections and infestations (16.20%), cardiac disorders (14.20%) and nervous system disorders (11.10%).

Conclusions

The analysis of the ADRs reported in the Italian safety database (RNF) shows that the safety profile of fingolimod is consistent with literature and clinical data. During the pivotal phase urinary tract infection was the most common serious adverse drug reaction reported followed by macular edema and elevation in liver-enzyme levels.

Due to the several limitations, which are mainly related to under-reporting, observational studies and post-marketing surveillance activities will be necessary in order to improve the knowledge about the safety profile of these drugs.