



## Safety of Copamer® in Relapsing Remitting Multiple Sclerosis

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**Introduction:** Glatiramer acetate is a synthetic amino acid polymer used for relapsing remitting multiple sclerosis. Glatiramer acetate 20, 40 mg/ml prefilled syringe produced by Zahravipharmaeaceutical Company (Copamer ®) are in the market for a few years. According to standard guidelines, assessment of safety of products after marketing authorization shall be accomplished by manufacturer. The objective of this study was to investigate occurrence and frequency of adverse drug reactions associated to Copamer used by patients with multiple sclerosis.

**Method:** A non-interventional, single group safety study was implemented to interview 186 patients whom Copamer® 20 and/or 40 mg/ml were administrated during last three years. Of note, they were visited by 37 different physicians in the city of Tehran. The sample size of at least 181 patients was calculated to estimate same frequency reported on Copaxone® as a Glatiramer acetate reference.

**Results:** The interviewed patients with multiple sclerosis received Copamer® 20mg and/or 40mg for an average of 550 days (5 days - 3 years). Among 32 (17%) patients reported adverse drug reaction, injection site reaction such as itching, pain, inflammation, erythema, and swelling was described by 13 (7%) patients in comparison with 35.5% reaction reported on Copaxone®. The immediate post-injection reaction was defined by 12 (6.4%) patients and it is comparable with Copaxone® 8% and product information 2% to 16%. The rate of immediate post-injection reaction including dyspnea 6%, flushing 2%, chest pain 1.6%, palpitation 0.53%, urticaria 0.53%, throat constriction 1.07%, and anxiety 0% was comparable with the product information. Five (2.6%) patients received emergency medical care due to adverse drug reaction though no death was reported. Meanwhile, the rate of other adverse drug reaction was low.

**Conclusion:** Safety profile of Copamer®, as a generic drug, has shown that injection site reaction and immediate post-injection reaction, common adverse drug reaction, are comparable with what reported in the product information in Drug Facts and Comparison. In actual fact, it shall provide the convenient consumption for patients.

**Key words:** Glatiramer acetate, Copamer, Relapsing Remitting Multiple Sclerosis, Safety, Adverse Drug Reaction.