(S99) INJECTION PAIN DECREASES WITH NEW 0.5-ML FORMULATION OF GLATIRAMER ACETATE

R. Murray,1 G. Anderson,2 D. Meyer,3 C. Herrman,4 C. Sheppard,5 E. Fox6

11st International Research Center, Centennial, CO; Multiple Sclerosis Clinic of Colorado, Lone Tree, CO; 2Associates in Neurology PSC, Lexington, KY; 3Triad Neurological Associates, Winston-Salem, NC; 4Josephson Wallack Munsbrough Neurology, PC, Indianapolis, IN; 5The Oak Clinic for MS, Uniontown, OH; 6Central Texas Neurology Consultants, Round Rock, TX

Background: Daily glatiramer acetate (GA) 20 mg/1.0 mL is a first-line treatment for relapsing-remitting multiple sclerosis. In an effort to reduce the occurrence of injection pain and injection site reactions, an injection volume of 0.5 mL was formulated.

Objectives: To compare the patient-reported pain and injection site reactions associated with a subcutaneous injection of a 20 mg/1.0 mL formulation of GA versus a 20 mg/0.5 mL GA formulation. Methods: Patients (N = 148) enrolled in an open-label, randomized, two-arm, single crossover study. Half of the patients (n = 76) were randomized to inject 20 mg/1.0 mL daily for the first 14-day period (period 1). The other half of the patient group (n = 72) injected 20 mg/0.5 mL daily during period 1. During the second 14-day period (period 2), the groups switched their injection volume formulation; the first group injected 20 mg/0.5 mL GA daily and the second group injected 20 mg/1.0 mL GA daily. Patients completed a home diary reporting pain occurring immediately after injection and at 5 minutes after injection, as well as the presence and severity of injection site reactions within 24 hours of injection. Safety, tolerability, clinical, and laboratory assessments occurred at the end of each period.

Results: Significant decreases in pain immediately after injection and at 5 minutes after injection were reported by patients when injecting 20 mg/0.5 mL GA compared with injecting 20 mg/1.0 mL GA (P < .0001). Patients also reported less severe injection site reactions (P < .0001) at 5 minutes and 24 hours post-injection of the 20 mg/0.5 mL GA formulation. Although the presence of injection site reactions (swelling, redness, itching, lumps) was not high for either formulation, a significant decrease was observed at 5 minutes and at 24 hours for the 20 mg/0.5 mL injections (P < .0001 and P < .0001, respectively). A total of 12.5% of patients when injecting 20 mg/1.0 mL and 18.1% when injecting 20 mg/0.5 mL reported adverse events; none reported serious adverse events. Conclusions: Patients reported less pain and fewer injection site reactions when using the 20 mg/0.5 mL GA formulation compared with the 20 mg/1.0 mL GA formulation. The lower-volume formulation offers a more tolerable option for patients using subcutaneous injections of GA.

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