(S41) POSTMARKETING UTILIZATION AND SAFETY OF INTRAMUSCULAR INTERFERON BETA-1A
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Background: Intramuscular interferon beta-1a (IM IFNβ-1a) was first approved by the US Food and Drug Administration for multiple sclerosis (MS) in May 1996 and is now authorized in 77 countries. Since first approval, an estimated 375,450 patients have been treated with IM IFNβ-1a, with 1,239,934 cumulative years of exposure. Objectives: To report utilization and safety data for IM IFNβ-1a in the postmarketing setting. Methods: Suspected adverse events (AEs) with IM IFNβ-1a that have been reported worldwide to Biogen Idec, Inc, since first approval have been maintained in a safety database. Terms have been classified in accordance with regulatory authorities. All suspected adverse drug reactions (ADRs) in the database from the most recent 3-year reporting period (May 2006–May 2009), including spontaneous reports, literature case reports, and serious suspected ADRs from clinical trials, were analyzed. ADRs of special interest and the safety profile in special populations (eg, pediatric, elderly, pregnant women) were also evaluated. Results: During the reporting period, an estimated 51,950 new patients with 373,971 person-years of exposure were treated with IM IFNβ-1a. The most frequent ADR was flu-like symptoms, as indicated on the package insert. Reporting rates of malignancies were consistent with background incidence rates, and there was no indication of a causal relationship with IM IFNβ-1a. ADRs in children and adolescents (age <18 years) suggest that the safety profile of IM IFNβ-1a in this population is consistent with that in adults. ADRs reported in elderly patients (age ≥65 years) were in agreement with those in patients aged <65 years. The nature and character of pregnancy-related events did not indicate that IM IFNβ-1a produced any teratogenicity or maturation defect. Conclusions: The overall safety profile of IM IFNβ-1a in MS is consistent with current prescribing information, and no new safety issues were identified during this reporting period. The nature of ADRs over time has remained constant, and there has been no increased risk in the occurrence of any unexpected AEs not seen with shorter-term use.

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