

## **Encore Abstract**

### **Title:**

Pregnancy and breastfeeding outcomes after maternal exposure to glatiramer acetate

### Short Title:

Pregnancy outcomes after glatiramer acetate

### **Authors:**

Main author: Sigal Kaplan

Co-authors: Mikhail Zeygarnik, Tali Stern

### **Affiliations and address:**

Teva Pharmaceutical Industries Ltd., Netanya, Israel

## **ABSTRACT**

**Objective:** To assess pregnancy and foetal outcomes and breastfeeding practices for women reporting exposure to GA during pregnancy.

**Methods:** Postmarketing reports of in-utero GA exposed pregnancies were extracted from April 1, 2019 to February 28, 2021 from Teva global safety database. One- and 12-month follow-up questionnaires were sent to patients. Pregnancy exposure data acquired prior to the pregnancy outcome knowledge or prior to detection of a congenital malformation at prenatal examination were considered prospective pregnancy reports. Major congenital malformations (MCM) were classified based on the Metropolitan Atlanta Congenital Defects Program (MACDP) classification and the European Concerted Action on Congenital Anomalies and Twins (EUROCAT) and adjudicated by a physician. Pregnancy outcome rates were compared with the general population rate.

**Results:** A total of 2129 pregnancy cases were retrieved. In the prospective group, the majority of patients reported exposure to GA during the first trimester (95%, 1027/1086). Of 702 fetuses (691 pregnancies) with known pregnancy outcomes, there were 647 live

births, 47 spontaneous abortions, 4 induced abortions, 2 ectopic pregnancies and 2 foetal deaths at unknown gestational age. MCM rate (MACDP or EUROCAT) in live births was 1.08%, 7/647, which is below the background prevalence rate of 3% according to MACDP and 2.06% according to EUROCAT. The preterm birth rate was 7.2% and low birth weight rate was 4.8%, both rates are within the general population rates reported in the literature. Among 393 pregnancy cases completing any follow-up questionnaires, 75 reported breastfeeding. A total of 40 breastfeeding reports were obtained from the 12-month questionnaire, none of which reported infant developmental delay.

**Conclusions:** The MCM rate and other pregnancy outcomes in prospective GA exposed pregnancies is within the normal range compared with background rates. No infant developmental delay among breastfed infant was reported through the age of one year.

**Conference presented:** The 37th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIM). Digital congress. 13-15 October 2021

**Declaration of Funding:** This analysis was funded by Teva Pharmaceutical Industries Ltd.

**Conflict of Interest:** SK, MZ and TS are employees of Teva Pharmaceutical Industries Ltd.