

Safety Alert

Sep. 2025

Oxcarbazepine – Risk of infants being small for gestational age (SGA)

EDA performs label update to include the following:

FERTILITY, PREGNANCY AND LACTATION

Pregnancy:

Data from an observational population-based registry study from the Nordic countries suggests an increased risk for children being born small for gestational age (SGA; defined as birth weight below the 10th percentile for their sex and gestational age) following prenatal exposure to oxcarbazepine. The risk of SGA in children of women with epilepsy receiving oxcarbazepine was 15.2% compared with 10.9% in children of women with epilepsy not receiving an anti-seizure medication.

Background:

Small for gestational age (SGA):

refers to an infant with a birth weight below the 10th percentile for their gestational age, meaning they are smaller than most babies at that stage of pregnancy. While some SGA babies are simply smaller due to genetics, others experience intrauterine growth restriction from factors like placental issues, maternal health problems, or substance use. Although many SGA infants catch up in growth by age two, some are at increased risk for later health problems, including obesity, type 2 diabetes, and high blood pressure.

Therapeutic Indication

Treatment of partial seizures with or without secondarily generalised tonic-clonic seizures. It is indicated for use as monotherapy or adjunctive therapy in adults and in children of 6 years of age and above.

Reference

EMA ([click Here](#))