Safety Alert June 2025

Carbamazepine - risks of Microcephaly, Small for gestational age (SGA), Neuro-developmental disorders (Autism spectrum disorder, Intellectual disability, ADHD) in Neonates

EDA performs label update to include the following:

Special warnings and precautions for use (for carbamazepine containing propylene glycol):

Propylene glycol : This medicine contains propylene glycol. Co-administration with any substrate for alcohol dehydrogenase such as ethanol may induce serious adverse effects in neonates.

Fertility, pregnancy and lactation:

Pregnancy
Risk related to carbamazepine
Malformations such as neural tube defects (spina bifida), craniofacial defects such as cleft lip/palate, cardiovascular malformations, hypospadias, hypoplasia of the fingers, microcephaly and other anomalies involving various body systems, have been reported in the offspring of women who used carbamazepine during pregnancy.
Data from an epidemiological study suggests an increased risk for infants of being born small for gestational age (potentially associated with fetal growth restriction) in pregnant women receiving antiepileptic drugs (including carbamazepine) during pregnancy compared to unexposed pregnant women with epilepsy.
Neurodevelopmental disorders (such as developmental delay, Autism spectrum disorder, Intellectual disability, ADHD, etc.) have been reported among children born to women with epilepsy treated with carbamazepine alone or in combination with other antiepileptic drugs during pregnancy. Studies related to the risk of neurodevelopmental disorders in children exposed to carbamazepine during pregnancy are contradictory and a risk cannot be excluded.

Background:

THERAPEUTIC INDICATIONS
Carbamazepine is indicated for treatment of:
- Epilepsy
- Trigeminal neuralgia
- Mania and bipolar affective disorders

References:
EMC (Click here)