Association of Oxcarbazepine with neurodevelopmental disorders, congenital

EDA performs label update to include the following:

Fertility ,pregnancy and Lactetion

Pregnancy

Risk related to oxcarbazepine

There is moderate amount of data on pregnant women (300-1000 pregnancy outcomes). However, the data on oxcarbazepine associated with congenital malformation is limited. There is no increase in the total rate of malformations with [product name] as compared with the rate observed with general population (2-3%). Nevertheless, with this amount of data, a moderate teratogenic risk cannot be completely excluded. **Study** results related to the risk of neurodevelopmental disorders in children exposed to oxcarbazepine during pregnancy are conflicting and a risk cannot be excluded.

Breastfeeding

Oxcarbazepine and its active metabolite (MHD) are excreted in human breast milk. A milk-to-plasma concentration ratio of 0.5 was found for both. The effects on the infant exposed to [product name] by this route are not known. Therefore, [product name] should not be used during breast-feeding.

Limited data indicate that the breastfed infants´MHD plasma concentrations are 0.2-0.8 µg/ml, corresponding to up to 5% of the maternal MHD plasma concentration.

Although exposure appears to be low, a risk to the infant cannot be excluded. Therefore, a decision whether to breastfeed while using [product name] should take into consideration both the benefit of breastfeeding and the potential risk of side effects in the infant. If breastfed, the infant should be monitored for adverse effects such as drowsiness and poor weight gain.

Birth defects

Studies have not shown an increased risk of birth defects associated with oxcarbazepine use during pregnancy, however, a risk of birth defects for your unborn child cannot be completely ruled out.

Neurodevelopmental disorders.

Some studies have shown that exposure to oxcarbazepine in the womb negatively affects the development of brain function (neurodevelopment) in children, while other studies have not found such an effect. The possibility of an effect on neurodevelopment cannot be ruled out.

Background

Theraputic Indications:

Oxacarbazepine is indicated for use as monotherapy or adjunctive therapy for the treatment of partial seizures and generalised tonic-clonic seizures, in adults and children.

Maximum recommended dose for adults:

In a controlled hospital setting, dose increases up to 2400 mg/day have been achieved over 48 hours.

Daily doses above 2400 mg/day have not been studied systematically in clinical trials.

There is only limited experience with doses up to 4200 mg/day.

Maximum recommended dose for paeiatrics

If clinically indicated, the dose may be increased by a maximum of 10 mg/kg/day at approximately weekly intervals from the starting dose, to a maximum daily dose of 60 mg/kg/day, to achieve the desired clinical response

References: *EMA (Click here)*