

Carbamazepine risk of Interaction with brivaracetam, warnings and recommendations on use during pregnancy and in women of childbearing potential and addition of hyperammonemia to undesirable effects

EDA performs label update to include the following:

4.4 Special warnings and precautions for use

Women of childbearing potential

Carbamazepine may cause foetal harm when administered to a pregnant woman. Prenatal exposure to carbamazepine may increase the risks for major congenital malformations and other adverse development outcomes. Carbamazepine should not be used in women of childbearing potential unless the benefit is judged to outweigh the risks following careful consideration of alternative suitable treatment options. Women of childbearing potential should be fully informed of the potential risk to the foetus if they take carbamazepine during pregnancy. Before the initiation of treatment with carbamazepine in a woman of childbearing potential, pregnancy testing should be considered. Women of childbearing potential should use highly effective contraception during treatment and for at least two weeks after stopping treatment. Due to enzyme induction, carbamazepine may result in a failure of the therapeutic effect of hormonal contraceptives, therefore, women of childbearing potential should be counselled regarding the use of other effective contraceptive methods. Women of childbearing potential should be counselled regarding the need to consult their physician as soon as they are planning a pregnancy to discuss switching to alternative treatments prior to conception and before contraception is discontinued (see Section 4.6). Women of childbearing potential should be counselled to contact the doctor immediately if they become pregnant or thinks they might be pregnant and are taking carbamazepine.

4.5 Interaction with other medicinal products and other forms of interaction

Antiepileptics: progabide, valproic acid, valnoctamide, valpromide, primidone, **brivaracetam**.

4.8 Undesirable effects:

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| Metabolism and nutrition disorders | |
| <i>Rare:</i> | folate deficiency, decreased appetite. |
| <i>Very rare:</i> | porphyria acute (acute intermittent porphyria and variegate porphyria), porphyria non-acute (porphyria cutanea tarda). |
| <i>Not Known:</i> | Hyperammonaemia |

Background on the safety concerns

Carbamazepine is an anti-epileptic drug indicated in generalized tonic-clonic and partial seizures. It also indicated in paroxysmal pain of trigeminal neuralgia and prophylaxis of manic-depressive psychosis in patients unresponsive to lithium. Carbamazepine is not usually effective in absences (petit mal) and myoclonic seizures. Moreover, anecdotal evidence suggests that seizure exacerbation may occur in patients with atypical absences.

References:

1. MHRA ([Click here](#))
2. EMA ([Click here](#))