

Risk of neural tube defects reported in infants born to women exposed to dolutegravir at the time of conception

EDA performs label update to include the following:

4.6 Fertility, pregnancy and lactation

Women of childbearing potential

Women of childbearing potential should be counselled about the potential risk of neural tube defects with dolutegravir, including consideration of effective contraceptive measures. If a woman plans pregnancy, the benefits and the risks of continuing treatment with dolutegravir should be discussed with the patient.

Background on the safety concerns

Dolutegravir is indicated in combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults, adolescents and children of at least 6 years of age or older and weighing at least 14 kg.

Advice for healthcare professionals:

- Counsel women of childbearing potential about the possible risk of neural tube defects with dolutegravir, including consideration of effective contraceptive measures.
- Discuss the benefits and the risks of continuing treatment with dolutegravir to women who are trying to become pregnant.
- If a pregnancy is confirmed in the first trimester while a patient is on dolutegravir, the benefits and risks of continuing dolutegravir versus switching to another antiretroviral regimen should be discussed with the patient, taking into account the gestational age and the critical time period of neural tube defect development.

References:

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