

Trimethoprim

- For products with an existing contraindication in place, PRAC recommended that the stricter advice may remain (therefore, products on the Irish market will maintain the existing contraindication throughout pregnancy), however for products marketed elsewhere, the PRAC recommended the addition of a contraindication during the first trimester of pregnancy in section 4.3.
- The PRAC recommended the following updates section 4.6 and corresponding package leaflet updates. Regarding the contraindication, the existing stricter text will remain for Irish products.

SmPC section 4.6

New information with regards to the risk(s) of the product when used during pregnancy should be added as follows (stricter existing advice may remain):

Pregnancy:

Trimethoprim is contraindicated during the first trimester of pregnancy (see section 4.3). Studies in animals have shown a teratogenic effect.

Epidemiological studies have shown an increased risk of spontaneous abortion and congenital malformations, in particular neural tube defects, oral clefts and cardiovascular defects, in children of mothers treated with trimethoprim during the first trimester of pregnancy. The presumed mechanism of action is thought to be interference with folates.

In the second and third trimesters, use should be avoided, unless clinically necessary.

Package Leaflet Section 2 “Pregnancy and breast-feeding” (stricter existing advice may remain):

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This medicine should not be taken during first three months of pregnancy. Treatment with trimethoprim in the first three months of pregnancy may increase the risk of miscarriage. Children born to mothers treated with trimethoprim during the first trimester of pregnancy may have an increased risk of birth defects, in particular neural tube defects (where the spine and spinal cord do not form properly), oral clefts (where the lip and palate do not form properly) and defects affecting the heart.