

DRUG INFORMATION

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SAFETY OF TRAMADOL IN PREGNANCY

Question:

What is the safety of tramadol in the first-trimester of pregnancy?

Answer:

First-trimester

Humans: We found no reports describing first-trimester use of tramadol in humans^[1-4].

Animals: Embryo and fetal toxicity (decreased foetal weight, skeletal ossification, increased supernumerary ribs) have been reported in studies in rats and mice with toxic maternal doses (3-15 times the maximum human dose on a mg/kg basis). Toxicity was not observed with lower doses that were not maternally toxic. Teratogenicity (malformations) were not reported with any of the doses used in these studies^[1]. Interspecies differences render translation from animals to humans difficult.

Second and third trimesters

Tramadol has been used in the treatment of labour pain with some studies suggesting it may be associated with less respiratory depression than pethidine. In contrast, other studies failed to support this conclusion and suggested neonatal outcomes were similar with tramadol, pethidine or morphine^[1].

Conclusion:

We are not aware of any information describing the use of tramadol in the first-trimester of human pregnancy. Therefore, we would advise against its use. In general, it is preferable to avoid all forms of drug exposure in pregnancy, especially in the first-trimester. However, if analgesia is required, it would be preferable to consider paracetamol +/- codeine. These agents have been used more extensively in pregnancy and are not considered to be overtly teratogenic.

References:

1. Briggs GG *et al.* Drugs in pregnancy and lactation (5th ed), 1999
2. Drugdex, Micromedex database
3. Embase database 1988-2001
4. Medline database 1966-2001

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