



Naloxone Pregnancy and Breastfeeding Warnings

Naloxone is also known as: **Evzio, Narcan Injection, Narcan Nasal Spray**

Naloxone Pregnancy Warnings

Administration during organogenesis to mice and rats at subcutaneous dose up to 6 and 12 times, respectively, the expected human exposure showed no evidence of embryotoxicity or teratogenicity. This drug does cross the placenta and therefore may precipitate withdrawal in the fetus. There are no adequate and well controlled studies in pregnant women. AU TGA pregnancy category B1: Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals have not shown evidence of an increased occurrence of fetal damage. US FDA pregnancy category B: Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women. US FDA pregnancy category C: Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks. US FDA pregnancy category Not Assigned: The US FDA has amended the pregnancy labeling rule for prescription drug products to require labeling that includes a summary of risk, a discussion of the data supporting that summary, and relevant information to help health care providers make prescribing decisions and counsel women about the use of drugs during pregnancy. Pregnancy categories A, B, C, D, and X are being phased out.

Use is recommended only if clearly needed and benefit outweighs risk. AU TGA pregnancy category: B1 US FDA pregnancy category (IV/IM/subcutaneously): B/C US FDA pregnancy category (nasal): Not assigned
Comments: -This drug can cause withdrawal symptoms in fetus as well as mother; both mother and fetus should be monitored for signs of distress until stable. -During labor, blood pressure should be monitored closely in mothers with moderate hypertension as severe hypertension may occur.

See references

Naloxone Breastfeeding Warnings

Use caution Excreted into human milk: Unknown Excreted into animal milk: Data not available
Comments: The effects in the nursing infant are unknown.

Because this drug is not orally bioavailable, it is unlikely to affect the breastfed infant. Studies in nursing mothers have shown that it does not affect prolactin or oxytocin hormone levels. Some labeling suggests breast-feeding should be avoided for 24 hours after receiving this drug; however, it is not a reason to discontinue breastfeeding.

See references

References for pregnancy information

1. Cerner Multum, Inc. "UK Summary of Product Characteristics." O O
2. Cerner Multum, Inc. "Australian Product Information." O O
3. "Product Information. Narcan (naloxone)." DuPont Pharmaceuticals, Wilmington, DE.

References for breastfeeding information

1. "Product Information. Narcan (naloxone)." DuPont Pharmaceuticals, Wilmington, DE.
2. United States National Library of Medicine "Toxnet. Toxicology Data Network. Available from: URL: <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT>." ([cited 2013 -]):
3. Cerner Multum, Inc. "Australian Product Information." O O
4. Cerner Multum, Inc. "UK Summary of Product Characteristics." O O

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