



SAFETY COMMUNICATION

2 May 2018

Potential Respiratory Risks of Using Tramadol in Children and Breast-Feeding Women

The Saudi Food and Drug Authority (SFDA) added new restrictions to the use of tramadol in children under 18 years of age and breast-feeding women. Tramadol is a narcotic medication approved for the treatment of moderate to severe pain.

The National Pharmacovigilance and Drug Safety Center (NPC) has prepared a comprehensive safety review to evaluate the potential risks of using tramadol in children under 18 years of age and in breast feeding women. The findings of this review have been reassessed by the Higher Pharmacovigilance Advisory Committee's fourth meeting in February 2018.

The committee concluded that the current evidence showed that the use of tramadol in children under 18 years of age could cause life threatening respiratory depression. Children under 12 years of age may be more susceptible to the respiratory depressant effects of tramadol. Some reported cases occurred in children between 12-18 years of age who used tramadol to treat pain after surgery to remove the tonsils (tonsillectomy) and/or adenoids (adenoidectomy). In addition, tramadol is excreted in the breast milk and may lead to potentially excessive sleepiness or fatal respiratory depression in breastfed infants.

Another concern is that some individuals (mostly children) with "ultra-rapid" metabolism may end up having high level of tramadol due to a variation in enzyme called cytochrome P450 isoenzyme 2D6 (CYP2D6) that converts tramadol to its active metabolite.

The committee recommended labeling changes to protect the children from the serious risks associated with tramadol use. Accordingly, the SFDA instructs the marketing authorization holders to amend the label for all products containing tramadol as follows:

- Tramadol is contraindicated in children under 12 years of age.
- Tramadol is contraindicated for treating pain following tonsillectomy or adenoidectomy in children under 18 years of age.

- Tramadol should be avoided in children between 12 to 18 years of age who are obese, or have severe lung disease or obstructive sleep apnea. These conditions may increase the risk for respiratory problems.
- Breastfeeding is not recommended while taking tramadol due to the potential risk of serious adverse reactions in breastfed infants.
- Ultra-rapid metabolizers should not use tramadol.

Report Adverse Drug Events (ADEs) to the SFDA

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

National Pharmacovigilance and Drug Safety Center (NPC)

Saudi Food and Drug Authority-Drug sector

3292 Northern Ring Road

Al Nafal District

Riyadh 13312 – 6288

Kingdom of Saudi Arabia

Reporting hotline: **19999**

Fax: 01 2057662

Email: NPC.Drug@sfd.gov.sa

Webpage: www.sfd.gov.sa/npc