



RWANDA FDA

Rwanda Food and Drugs Authority

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Kigali , 12/01/2021

Ref N°:DIS/ 004 /FDA/2021

MEDICINE SAFETY COMMUNICATION

Medicine: Tramadol

Re: Rwanda FDA warns on the risk of opioid effects in breastfeeding babies among mothers being treated with Tramadol

Reference is made to the new safety information published in the WHO Pharmaceutical NEWSLETTER N°.1/2020 [1], and further reference is made to the MEDSAFE and US FDA drug safety communication about the risk of opioid effects in infant and babies while their mother taking Tramadol [2];

Tramadol is well known as an analgesic that produces opioid-like effects by acting mainly on the central nervous system with a multimode of action. It acts on serotonergic (5-HT) and noradrenergic nociception, while its metabolite O-desmethyltramadol (M1) acts as a mu (μ) agonist on the opioid receptor.

Tramadol is used for the relief of moderate to severe pain in adults. It is sometimes used to help to manage pain after a caesarean section. When used by breastfeeding women, tramadol and its metabolite are found in breast milk and may produce effect in babies that are being breastfed. Numerous cases were reported and manifested by excess sleepiness, serious breathing problems, difficulty breastfeeding and Limpness; [3,4]

These analgesia properties and sedation effect of tramadol arise from the fact that they inhibit serotonin (5-HT) and norepinephrine reuptake augmenting 5-HT concentration on the synaptic cleft. Its metabolite into breast milk and may produce effect in babies that are being breastfed. [3,4]

Therefore, Rwanda FDA is recommending health professionals, marketing authorization holders and patients to consider the following when using tramadol in breastfeeding mothers due to the possible harm to their infants.

Information for healthcare professionals

- ✓ Healthcare providers should be aware that the use of Tramadol during breastfeeding is not recommended due to the risk of serious adverse reactions in breastfed infants such as excess sleepiness, difficulty breastfeeding, and serious breathing problems;
- ✓ Healthcare providers should avoid prescribing tramadol to the mother during breastfeeding because its safety in infants and new-borns has not been established;
- ✓ The benefits and risks of harm of treatment with tramadol in both the mother and baby should be considered as well as the benefits and risks of harm of not treating;
- ✓ Advise parents and caregivers to watch closely for signs of breathing problems in infants and new-borns exposed to tramadol through breast milk;

Information for carers givers and patients

- ✓ Rwanda FDA recommends breastfeeding mothers or caregivers to watch closely for signs of problems in infants when the mothers are taking any opioid especially tramadol for pain management

Information for Marketing Authorization Holders

- ✓ Rwanda FDA is requiring Marketing Authorization Holders to add boxed warning to the prescribing information for tramadol describing the risk of opioid effects in breastfed babies. The boxed warning will remind practitioners that due to that risk of opioid effects in breastfed babies the tramadol is contraindicated for mothers breastfeeding. [3, 4]

Rwanda FDA urges patients and healthcare providers to report the suspected serious adverse drug events related to Tramadol and others medicines to Rwanda FDA by completing ADR/AEFI reporting form accessible on Rwanda FDA website on the link <http://w.w.w.rwandafda.gov.rw/web/fileadmin/adr-aeFI> reporting form .pdf and the filled form should be sent to the email: pv-sm@rwandafda.gov.rw and copy to info@rwandafda.gov.rw

Sincerely,

Dr. Charles KARANGWA
Ag. Director General

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References

1. WHO, Pharmaceutical Newsletter NO 1/2020, accessible <https://www.who.int/medicine>
2. MEDSAFE, Use of Tramadol During Breastfeeding 7 July 2017. Accessible on: www.medsafe.govt.nz/safety/EWS/2017/UseOfTramadolDuringBreastfeeding.asp
3. USFDA, restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women Accessible on <https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-restricts-use-prescription-codeine-pain-and-cough-medicines>
4. Greta M Palmet et al. Tramadol, breastfeeding and safety in new born. Accessible on <http://adc.bmj.com/> on March 29,2018.

