



**RWANDA FDA**  
Rwanda Food and Drugs Authority

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Kigali; 28/04/2022  
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## **MEDICINE SAFETY COMMUNICATION**

### **Medicine: DICLOFENAC**

#### **RE: Warning on the risk of cardiovascular events (heart attack and stroke) in patients using Diclofenac**

Reference is made to the new safety information on Diclofenac published in the WHO Pharmaceuticals Newsletter - N° 03/2015 warning on the significant risk of cardiovascular events (heart attack and stroke) following inappropriate use or overuse of the non-steroidal anti-inflammatory drugs (NSAIDs) including Diclofenac.

Being cognizant of the safety information published by U.S. Food and Drug Administration (USFDA) and New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE) warning on the risk of cardiovascular events (heart attack and stroke) associated with Diclofenac.

Considering the study published by the Lancet on vascular and upper gastrointestinal effects of NSAIDs that confirmed the vascular risks associated with high-dose of Diclofenac.

Diclofenac is non-steroidal anti-inflammatory drug (NSAID) indicated for pain and inflammation in rheumatic disease (including juvenile idiopathic arthritis) and other musculoskeletal disorders; acute gout and postoperative pain. Non-steroidal anti-inflammatory drugs (NSAIDs) include Naproxen, Ibuprofen, and Diclofenac among others.

Rwanda FDA warns about the significant risk of cardiovascular events (heart attack and stroke) associated with inappropriate use or overdose of Diclofenac such as high dose (150mg daily) and for long-term treatment. In addition, NSAIDs are safe if used according to the recommended doses for short duration as instructed on the label.

#### **Information to Healthcare professionals**

- Pharmacists are encouraged to provide detailed medical information to patients and encourage them to report any cardiovascular events encountered.

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- Health care professionals are advised to use the lowest effective dose of Diclofenac for shortest possible duration.
- Health care professionals should not use Diclofenac for patients with a recent medical history of myocardial infarction (within the last 6-12 months).
- Periodic review for effectiveness, adverse effects and development of cardiovascular risk factors should be done for patients receiving long-term Diclofenac in addition to monitoring of blood pressure, haemoglobin levels and renal function.
- Relevant risk factors for cardiovascular events associated with Diclofenac (and other NSAIDs) include hypertension, ischaemic heart disease, hyperlipidaemia, diabetes, and smoking.

#### **Information to patients/consumers and caregivers**

- Patients and caregivers are encouraged to report any suspected adverse events following Diclofenac use.
- If smoking, present high blood pressure, high cholesterol, diabetes, or kidneys which do not work very well; patients/consumers are advised to check with their healthcare professionals that Diclofenac is appropriate.
- Patients are advised to use the recommended dose of Diclofenac as per the instructions provided by healthcare professionals and stop as soon as they can.

#### **Information to Marketing Authorization Holders (MAH)**

- Marketing authorization Holders (MAH) are advised to update the patient information leaflet to more appropriately convey the risk even if the overall risk/benefit ratio remains favourable; and the following additions are recommended:
  - Adding Patient with severe heart failure to the contraindications list
  - Adding stronger warning about cardiovascular events to the precaution section together with the need to consider carefully the risk and benefits of treatment in individuals at higher risk of cardiovascular disease.

**Note:** Patients and Healthcare Professionals are urged to report any suspected serious adverse drug reactions associated with Diclofenac and other medicines to Rwanda FDA by completing ADR/AEFI reporting form accessible on the Rwanda FDA website via the link <https://www.rwandafda.gov.rw/index.php?eID=dumpFile&t=f&f=38447&token=f8d1aed5592f83285b9b15f614818cf1a892349> and the filled form should be sent to the email: [pv\\_sm@rwandafda.gov.rw](mailto:pv_sm@rwandafda.gov.rw)

Sincerely,

*S. Casimir*  
28/04/2022

**Dr. Emile BIENVENU**  
**Director General**





## References

1. Australian Government-Therapeutic Goods Administration (2014) *Safety review of diclofenac*. Available at: <https://www.tga.gov.au/sites/default/files/medicines-review-safety-diclofenac.pdf>
2. European Medicines Agency (2013) *New safety advice for diclofenac-CMDh endorses PRAC Recommendation-New measures aim to minimise cardiovascular risks*. Available at: [https://www.ema.europa.eu/en/documents/press-release/new-safety-advice-diclofenac-cmdh-endorses-prac-recommendation\\_en.pdf](https://www.ema.europa.eu/en/documents/press-release/new-safety-advice-diclofenac-cmdh-endorses-prac-recommendation_en.pdf)
3. New Zealand Medicines and Medical Devices Safety Authority (2013) *Diclofenac (Voltaren) and risk of cardiovascular events (heart attack and stroke)*. Available at: <https://www.medsafe.govt.nz/safety/ews/2013/diclofenac-cardio.asp>
4. The Lancet (2013) *Vascular and upper gastrointestinal effects of non-steroidal anti-inflammatory drugs: meta-analyses of individual participant data from randomised trials*. Available at: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(13\)60900-9/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)60900-9/fulltext)
5. U.S. Food and Drug Administration (2015) *FDA Drug Safety Communication: FDA strengthens warning that non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs) can cause heart attacks or strokes*. Available at: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-strengthens-warning-non-aspirin-nonsteroidal-anti-inflammatory>
6. World Health Organization (2015) *WHO Pharmaceuticals Newsletter - N° 03/2015*. Available at: <https://www.who.int/publications/i/item/who-pharmaceuticals-newsletter---n-3-2015>

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