



RWANDA FDA

Rwanda Food and Drugs Authority

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Kigali on, 28th May 2020
Ref. N^o: DIS/ 1060 /RwandaFDA/2020

MEDICINE SAFETY COMMUNICATION

Medicine: Ibuprofen

Re: Rwanda FDA warns on risk of renal toxicity by using Ibuprofen

Reference is made to the new safety information published in the WHO Pharmaceuticals NEWSLETTER NO. 1/2020, reference is also made to safety communication published by the New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE) on the risk of impaired renal function associated with the use of ibuprofen.

Ibuprofen is a Non-steroidal anti-inflammatory drugs (NSAIDs) that widely works by reducing hormones that cause inflammation and pain and is available over the counter and with a prescription. It is a type of medication with analgesic, fever-reducing, and, in higher doses, anti-inflammatory effects. Ibuprofen acts by blocking the production of prostaglandins, substances that the body releases in response to illness and injury. Ibuprofen is a non-selective inhibitor of an enzyme called cyclooxygenase (COX), which is required for the synthesis of prostaglandins. Prostaglandins cause pain and swelling, or inflammation. Ibuprofen is widely used for the temporary relief of pain or inflammation and is available over the counter and with a prescription.

When NSAIDs including ibuprofen are taken for long time and at high doses, they can lead to acute kidney injury due to reduced renal plasma flow caused by a decrease in prostaglandins, which regulate vasodilation at the glomerular level. NSAIDs disrupt the compensatory vasodilation response of renal prostaglandins to vasoconstrictor hormones released by the body. Inhibition of renal prostaglandins results in acute deterioration of renal function after

ingestion of NSAIDs. The second mechanism of acute kidney injury caused by NSAIDs is acute interstitial nephritis (AIN), which is characterized by the presence of an inflammatory cell infiltrate in the interstitium of the kidney especially in children or adolescents particularly those suffering from dehydration.

Information for healthcare professionals

- To ensure the steps to be taken in the proper and safe use of over-the-counter drugs like Ibuprofen
- Health-care professionals should consider whether the patient is adequately hydrated before prescribing ibuprofen
- Patients with high risk factors for renal toxicity should not be treated with Ibuprofen after careful consideration
- Pharmacists should advise on the appropriate dose to be taken
- Respect the prescribed dose, frequency and duration of treatment when ibuprofen is prescribed
- Patients and their care givers should contact their healthcare professionals right away if they experience any symptoms of renal toxicity like decrease urine output, swelling in legs, fatigue, nausea, weakness, muscle cramps
- Don't stop taking Ibuprofen without talking to your healthcare professionals first when prescribed

Rwanda FDA urges patients and healthcare professionals to report any suspected adverse drug events such as renal toxicity involving Ibuprofen and or other drugs 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-aeif reporting form .pdf](http://w.w.w.rwandafda.gov.rw/web/fileadmin/adr-aeif%20reporting%20form.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 Pharmaceuticals Newsletters No 1/2020, accessible on <https://www.who.int/publications-detail/who-pharmaceuticals-newsletter-978-92-4-000257-9>
2. MEDSAFE, Ibuprofen and impaired renal function, December 2019, accessible on <https://www.medsafe.govt.nz/profs/PUArticles/December2019/Ibuprofen-impaired-renal-function.htm>
3. Mehul Dixit et al, Significant Acute Kidney Injury Due to Non-steroidal Antiinflammatory Drugs: Inpatient Setting, *Pharmaceuticals* 2010, 3, 1279-1285; doi:10.3390/ph3041279 accessible on <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4034033/pdf/pharmaceuticals-03-01279.pdf>



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