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Kigali, 20th April, 2020

Ref N°: DIS/ 733 /Rwanda FDA/2020

MEDICINE SAFETY COMMUNICATION

Medicine: Paracetamol (Acetaminophen)

Re: Rwanda FDA warns on the risk of severe liver injury associated with overdose of Paracetamol/Acetaminophen

Reference is made to the new safety information published by WHO Pharmaceutical Newsletter No 5/2017, further reference is also made to the French health agency (ANSM) warning about dangers of paracetamol overdose, Rwanda FDA is warning about the risks of severe liver injury associated with overdose of paracetamol/acetaminophen.

Paracetamol, the most widely used analgesic, is an active ingredient in hundreds of over-the-counter (OTC) and prescription medicines. It relieves pain and fever, and is also combined with other active ingredients in medicines that treat allergy, cough, colds, flu, and sleeplessness.

Paracetamol is safe if used appropriately at a maximum of **4 grams per day** in adults but larger amounts overwhelms the body ability to process it safely; this can lead to build up of a toxic metabolite, N-acetyl-p-benzoquinone imine (NAPQI) which binds to liver cells, causing these cells to die thus resulting in severe hepatic necrosis leading to acute liver failure (ALF).

In Rwanda, we have different brands of medicine containing paracetamol as one of the active ingredients, among others there are Ibupar syrup (Paracetamol 120mg/Ibuprofen 100mg) Ibupar tablets (Ibuprofen 400mg/Paracetamol 325mg), Lotem syrup (Paracetamol 250mg/ Ibuprofen 200mg), Sekalgic tablets (Ibuprofen 400mg/Paracetamol 500mg/Cafein 30mg), Trialgic cap

(Ibuprofen 200mg/Paracetamol 325mg/Cafein 30mg), Relief tablets (Paracetamol 500mg/Diclofenac 50mg/Chlorpheniramine 4mg), Antalgex-T (Paracetamol 325mg/Tramadol37.5mg), Efferalgan Codeine (Paracetamol 500mg/Codeine 30mg), Efferalgan Vit C (Paracetamol 500mg/vitamin C 200mg), ParaCo-denk tablet (Paracetamol 500mg/Codeine 30 mg), Hedex tablet (Paracetamol 200mg/Aspirin 400mg/Cafein 30mg), Action (Paracetamol 300mg/Aspirin 600mg/Cofein 50mg), Coldcap capsules (Paracetamol 400mg/Cafein 30mg), Dacold capsules (Paracetamol 400mg/cafein 30mg/Chlorpheiniramine 4mg), Fevarol tablet (Paracetamol 500mg/Cafein 30mg/Phenylephrine5mg/chlorpheniramine 2mg) , Flucoldex tablet (Paracetamol 500mg /Cafein 30mg), Flucoldex capsules (Paracetamol 500mg/cofein 30mg), Antigrippince (Paracetamol 350mg/codein 12.5mg/cafein 10mg/vitamin C 50 mg), Febrilex tablet (Paracetamol 500mg/chlorpheniramine maleate 2mg/ phenylephrine hydrochloride 5mg), Sinarest tablets (Paracetamol 500mg/phenylephrine hydrochloride 10 mg/chlorpheniramine 2 mg/caffeine anhydrous 10 mg), Fervex sachet (Paracetamol 500mg/Pheniramine 25mg/Vitamin C 200mg) and Coldarest tablets contain Paracetamol 500mg) and others.

It is important to remember that, when used at therapeutic levels, paracetamol is usually safe and effective. However, taking >100mg/kg or >4 g per day for a few days has been known to result in hepatotoxicity. Paracetamol overdose may occur intentionally and accidentally, the latter due to the high number of combination products available over the counter and or prescription medicines.

Safety information for healthcare professionals

- Prescribe the right dose of paracetamol in right duration of treatment
- Don't prescribe two or more brands of medicine concomitantly with paracetamol as one of the active ingredient
- Review the medications that patients are taking before prescribing Paracetamol to avoid overdose once other medications contain paracetamol ingredient
- Educate patients about the importance of reading all prescription and OTC labels to ensure they are not prescribing multiple acetaminophen-containing products
- Advise patients not to exceed the Paracetamol maximum total daily dose of 4 grams/day
- Advise patients not to drink alcohol while taking acetaminophen-containing medications

- Advise patients to seek medical help immediately if they have taken more paracetamol than directed or experience swelling of the face, mouth, and throat, difficulty breathing, itching, and rash

Safety information for patients

- Carefully read all labels for prescription and OTC medicines and ask the pharmacist if your prescription pain medicine contains paracetamol
- Do not take more than one product that contains paracetamol at any given time
- Do not take more of paracetamol -containing medicine than directed
- Do not drink alcohol when taking medicines that contain paracetamol

Rwanda FDA urges patients and healthcare professionals to report any suspected serious adverse drug reactions associated with Paracetamol and other medicines to Rwanda FDA by completing ADR/AEFI reporting form accessible on Rwanda FDA website on the link following [http://w.w.w.rwandafda.gov.rw/web/fileadmin/adr-aeft-reporting-form .pdf](http://w.w.w.rwandafda.gov.rw/web/fileadmin/adr-aeft-reporting-form.pdf) and the filled form should be sent to the email: pv_sm@rwandafda.gov.rw

Sincerely,

Dr. Charles KARANGWA
Ag. Director General



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Rwanda Food and Drugs Authority

References

1. Dr Laurence Knott, Paracemol Poisoning, 2019 accessible on <https://patient.info/doctor/paracetamol-poisoning>
2. ANSM, Paracétamol et risque pour le foie : un message d’alerte ajouté sur les boîtes de médicament – Communiqué, July 2019; accessible on <https://ansm.sante.fr/S-informer/Communiques-Communiques-Points-presse/Paracetamol-et-risque-pour-le-foie-un-message-d-alerte-ajoute-sur-les-boites-de-medicament-Communique>

