RWANDA FDA
Rwanda Food and Drugs Authority
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Kigali on; 15/03/2021
Ref Nº:DIS/ 923 /FDA/2021

MEDICINE SAFETY COMMUNICATION

Medicine: AMINOPHYLLINE

Re: Rwanda FDA warns on the risk of urinary retention in elderly patients by using Aminophylline

In reference to the new safety information published in WHO Pharmaceutical Newsletter No.4/2020, reference is also made to the National Pharmaceutical Regulatory Agency (NPRA Malaysia) safety communication about warning of overdose of aminophylline.

Aminophylline is a complex of theophylline and ethylenediamine. Both aminophylline and theophylline are methylxanthines and are derived from the group called xanthines. Drugs in the Xanthine group relax smooth muscle particularly bronchial muscle, stimulate cardiac muscle, the central nervous system and produce diuresis. Aminophylline acts by increasing intracellular cyclic adenine monophosphate (cAMP), and contributes to detrusor muscle relaxation of the urinary bladder leading to urinary retention, especially in elderly patients. Aminophylline is indicated for relief of bronchospasm associated with asthma and in chronic obstructive pulmonary disease.

Rwanda FDA warns about aminophylline overdose, which causes urinary retention in elderly patients including inability to urinate and lower abdominal pain.

The dosage for aminophylline should be reduced in geriatric population and patients on aminophylline therapy should be monitored for symptoms of urinary retention or difficulty urinating. The recommended intravenous dosage for elderly patients is 5.5mg/kg over 30 minutes as loading dose followed by a maintenance dose of 0.38 mg/kg/hour.

Information to Healthcare Professionals

- Rwanda FDA advises healthcare professionals to give adjusted aminophylline dosage to geriatric population as compared to normal adult dosing to avoid theophylline toxicity
- Healthcare professionals should monitor the signs and symptoms of urinary retention including difficulty in urinating for the patients on aminophylline therapy, particularly elderly male patients with risk of prostatism
- Healthcare professionals should check the clearance of elderly patients while administering aminophylline.

Information to patients

- Patients are advised about the risk of urinary retention including inability to urinate and lower abdominal pain
- Patients are also advised to immediately contact their healthcare professionals when they experience any of the above mentioned symptoms.

Information for Marketing Authorization Holders

- Rwanda FDA is requesting Marketing Authorization Holders to add Boxed Warning to the prescribing information for aminophylline describing the risks of urinary retention.
- Rwanda FDA also urges patients and healthcare professionals to report any suspected serious adverse drug reactions associated with aminophylline and other 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

Sincerely,

Digitally signed by Rwanda FDA
(Ag DG)
Date: 2021.03.16 17:15:32 +02'00'

Dr. Charles KARANGWA
Ag. Director General

Reference

1. WHO, WHO Pharmaceutical newsletter N0.4/2020 accessible on http://www.who.int/medicines
2. Ayyoub Barzegarnezhad, Abolfazl Firouzian, The Effects of Local Administration of Aminophylline on Transureteral Lithotripsy accessible on https://doi.org/10.1155/2012/727843
3. Anoosh Zafar Gondal; Hassam Zulfiqar, aminophylline accessible on https://www.ncbi.nlm.nih.gov/books/NBK545175/
4. Madrac Bulletin, NPRA,01/2020 aminophylline overdose: risk of urinary retention accessible on www.npra.gov.my/