RWANDA FDA
Rwanda Food and Drugs Authority
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Kigali, 20th April, 2020
Ref N° : DIS/ **732** /Rwanda FDA/2020

MEDICINE SAFETY COMMUNICATION

Medicine: Promethazine Hydrochloride injection

Re: Rwanda FDA warns on the risk of severe tissue injury including gangrene associated with the use of Promethazine Hydrochloride injection

Promethazine is a phenothiazine agent with antihistaminic, sedative, antiemetic, anticholinergic and anti-motion sickness properties, it is used also to treat stuffy runny nose from allergy, watery, itchy eyes due to inhaled allergies and foods, mild allergic skin reactions.

Reference made to the new safety information published in the WHO Pharmaceuticals NEWSLETTER NO.5/2009, further reference is also made to the U.S. FDA safety communication about warning of severe tissue injury, including gangrene associated with the use of Promethazine Hydrochloride injection. Rwanda FDA warns about the risks of severe tissue injury, including gangrene which may require amputation following intravenous administration of promethazine where Perivascular extravasation, unintentional intra-arterial injection and intraneuronal or perineuronal infiltration of the drug may result in irritation and tissue damage, including gangrene.

Information for healthcare professionals

- Healthcare professionals should respect the dose and recommended route of administration of Promethazine injection

- Rwanda FDA advises healthcare professionals to be alert for signs and symptoms of potential tissue injury including burning or pain at the site of injection, phlebitis, swelling, and blistering

Information for Patients

- Patients should be advised of the risk of severe tissue injury, including gangrene
- Patients should be advised to immediately report persistent or worsening pain or burning at the injection site.

Information for Marketing Authorization Holders

Rwanda FDA is requesting Marketing Authorization Holders to add Boxed Warning to the prescribing information for Promethazine Hydrochloride injection products, describing the risks of severe tissue injury, including gangrene, which may require amputation following intravenous administration of promethazine. The Boxed Warning will remind practitioners that due to the risks of intravenous injection, the preferred route of administration is deep intramuscular injection and that subcutaneous injection is contraindicated

Rwanda FDA urges patients and healthcare professionals to report any suspected serious adverse drug reactions associated with Promethazine Hydrochloride injection 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,

Dr. Charles KARANGWA
Ag. Director General

References

1. USFDA, FDA Requires Boxed Warning For Promethazine Hydrochloride Injection, 2009, accessible on https://www.bioprocessonline.com/doc/fda-requires-boxed-warning-for-promethazine-0001
2. Andrew Lee F., Andrew Bozeman P., Waldo Floy E, Necrosis Caused by Intra-arterial Injection of Promethazine: Case Report, 2009, accessible on https://www.sciencedirect.com/science/article/pii/S0363502309000458#!
3. WHO, Pharmaceutical Newsletters NO 5/2019 accessible on https://www.who.int/medicines/publications/newsletter/PharmNewsletter09_5.pdf?ua=1

Photos

Phenergan extravasation caused gangrene in a young woman's fingers.
(Courtesy of The Daily World, Aberdeen, WA)