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SAFETY INFORMATION COMMUNICATION

Medical Product	Title
Lidocaine (injection form)	**Risk of anaphylactic reaction.**

1. Introduction

Reference is made to the law No 003/20218 of 09/02/2018 establishing Rwanda FDA, and to the regulations governing pharmaceutical products and medical devices including IVDs, especially in Article 23 on safety information and communication. Rwanda FDA warns about the Risk of an Anaphylactic reaction associated with the use of Lidocaine injection.

Referring to the safety information published in WHO Pharmaceuticals Newsletters No.3, 2025(1), further reference is also made to the Ministry of Food and Drug Safety (MFDS) of the Republic of Korea and the Korea Institute of Drug Safety and Risk Management (KIDS), which has announced that the product information for lidocaine (injection form) will be updated to include the risk of anaphylactic reaction. Additionally, it reviewed a case report of an anaphylactic reaction in a patient who received lidocaine as a local anesthetic, and the foreign product information MFDS concluded that a causal relationship between the medicine and the adverse event could not be excluded. Although allergic reactions are not rare complications in drug use, anaphylaxis or anaphylactoid reactions to some widely used drugs can embarrass clinicians because anaphylaxis is not easily diagnosed at the time of the event, and treatment is unfamiliar to many. Lidocaine is a very popular drug in different procedures, and an anaphylactoid reaction to it has been rarely reported. Clinicians who use lidocaine daily should, however, be aware of the possibility of anaphylaxis after its use. Once it occurs, anaphylaxis can be fatal, but if it is quickly diagnosed or suspected, treatment is simpler than most clinicians believe. (2)
It is against this background that Rwanda FDA warns about the risk of an anaphylactic reaction associated with the use of Lidocaine injection.

2. Description

Lidocaine (or 2-(diethylamino)-N-(2.6-dimethylphenyl) acetamide) is the main prototype of amino-amide local anesthetics (LA). It has analgesic effect, antihyperalgesic and anti-inflammatory properties, which make it useful as a general anesthetic adjuvant. Lidocaine is capable of reducing nociception and/or cardiovascular responses to the surgical stress, and postoperative pain and/or analgesic requirements. However, its mechanisms of action remain unclear, despite its different known properties(3).
Lidocaine, the most frequently applied local anesthetic of the amide group, is used broadly in different fields of medicine, e.g., antiarrhythmic therapy, in addition to its administration as a local anesthetic(4).

Lidocaine was shown to provide analgesia by blocking both peripheral and central voltage-dependent sodium channels(5). In the IV administration route, it can also relieve both deafferentation and central pain. The antinociceptive properties of lidocaine seem to be derived from a more multifaceted process, rather than simple inhibition of neuronal ectopic discharges(6).

Anaphylaxis is a rapid and severe allergic reaction that can be life-threatening. According to the World Allergy Organization, anaphylaxis is characterized by typical skin symptoms and at least one additional systemic symptom, such as respiratory and/or cardiovascular symptoms, acute hypotension, bronchospasm, or laryngeal involvement(7).

Anaphylactic reactions to lidocaine are extremely rare. When they do occur, the mechanism is typically an IgE-mediated (Type 1) hypersensitivity reaction involving the immune system (8).

Therefore, Rwanda FDA recommends the following:

3. *Information for the Patients and Caregivers*

Seek urgent medical help if, shortly after receiving lidocaine, you or the person in your care develops any of the following symptoms:

- Sudden swelling of the face, lips, tongue, or throat
- Difficulty breathing, wheezing, or shortness of breath
- Severe itching, rash, or hives
- Dizziness, fainting, or rapid heartbeat
- If these symptoms occur, **call emergency services immediately**.
- Inform healthcare professionals that lidocaine was recently used.
- Do not use lidocaine again unless a doctor confirms it is safe.
- Always tell your healthcare provider if you have had allergies to medicines or local anesthetics in the past.

4. *Information to Healthcare Professionals*

Healthcare professionals are therefore required to:

- Obtain detailed allergy history, especially previous reactions to local anesthetics, preservatives, or other drugs.
- Consider preservative-free formulations if excipient allergy is suspected.
- Always ensure resuscitation equipment and emergency drugs (including intramuscular epinephrine) are immediately available whenever lidocaine is administered.
- Staff should be trained to recognize and promptly manage anaphylaxis.

Immediate management of suspected anaphylaxis:

- Stop lidocaine administration.
- Administer **epinephrine IM (first-line treatment)** without delay.
- Provide airway support, oxygen, IV fluids, and additional treatments as clinically indicated.
- Refer the patient for further allergy evaluation before any future use.

- Report all suspected adverse events associated with Lidocaine to the Rwanda FD

5. *Information for the Marketing Authorization Holders/Manufacturers*

Rwanda FDA is requesting Marketing Authorization Holders to submit an updated SmPC for Lidocaine to include the risk of anaphylaxis as an adverse drug reaction. The product label and/or box warning should also be updated to remind healthcare professionals of the potential effects of Lidocaine.

6. *Reporting channel*

Patients and Healthcare Professionals are urged to report any suspected adverse drug event/reaction associated with Lidocaine or any other medical product to the Rwanda FDA by using an online reporting tool called VigiMobile for medicines, which is available on the Rwanda FDA website at *https://vigiflow-eforms.who-umc.org/rw/adr* or using online reporting system (PViMS) accessible on *https://pvims.rwandafda.gov.rw/security/landing*

Sincerely,

Prof. Emile BIENVENU
Director General

7. *References*

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