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RWANDA FDA
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MEDICINE SAFETY COMMUNICATION

Medicine: **Erythromycin**

RE: **Rwanda FDA warns on risk of infantile hypertrophic pyloric stenosis in infants following exposure to Erythromycin**

Reference is made to the new safety information published in the WHO Pharmaceutical NEWSLETTER N^0 1/2021, and further reference is made to the safety notice of Ireland Health Products Regulatory Authority (HPRA) on warning risk of infantile hypertrophic stenosis regarding erythromycin.

Erythromycin is a macrolide antibiotic, active against gram-positive cocci, bacilli, some gram-negative cocci and some gram-negative bacilli. It is widely used to treat chest infections such as pneumonia, skin problems and sexually transmitted diseases.

Recent studies support an association between exposure to erythromycin in infants and the risk of infantile hypertrophic pyloric stenosis that makes the condition the most cause of surgical intervention in first 6 months of life. It is identified as eight to ten fold particularly in those exposed to erythromycin during the first 14 days of life. Frequently reported risk factors for hypertrophic pyloric stenosis include prematurity, smoking during pregnancy and infant bottle-feeding.

This risk was already included in the Summary of Product Characteristics (SmPC) for erythromycin medicines, however the magnitude of the increased risk should be considered.
Erythromycin interacts with the receptors of motilin, an intestinal peptide that stimulates contraction of gut smooth muscle. This interaction could therefore produce contraction of the gastric and pyloric bulb, resulting in hypertrophy of the pylorus resulting in gastric outlet obstruction, leading to the infant presenting with projectile vomiting and severe dehydration.

After conducting literature review and analysis of above safety information, Rwanda FDA is recommending health professionals , patients and Marketing authorization holders to consider the following on Erythromycin in infants due to the risk of infantile hypertrophic pyloric stenosis.

Information for healthcare professionals

- ✓ Healthcare providers should be aware of significant increased risk and weight the benefits of prescribing Erythromycin to infants because of a potential increased risk of infantile hypertrophic pyloric stenosis
- ✓ Health-care professionals should advise parents to seek advice from their doctor if vomiting or irritability with feeding occurs in infants during treatment with erythromycin.
- ✓ Health-care professionals should educate parents how to recognize the signs and symptoms of infantile hypertrophic pyloric stenosis

Information for caregivers and patients

- ✓ Rwanda FDA recommends parents to watch closely for signs of vomiting or irritability with feeding in infants when they are taking Erythromycin

Information for Marketing Authorization Holders

- ✓ Rwanda FDA requests Marketing Authorization Holders to update the product information to reflect the magnitude of the increased risk of infantile hypertrophic pyloric stenosis for infants on Erythromycin.

Rwanda FDA urges patients and healthcare providers to report the suspected adverse drug events related to Erythromycin and other medicines to Rwanda FDA by filling information in online reporting system https://pvims.rwandafda.gov.rw/public/spontaneous or 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 and copy to info@rwandafda.gov.rw

Sincerely,

Dr. Charles KARANGWA
Ag. Director General

REFERENCES

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2. Health Products Regulatory Authority (HPRA) accessible on https://www.hpra.ie/docs/default-source/default-document-library/erythromycin-updated-warnings-regarding-cardiovascular-risks-and-infantile-hypertrophic-pyloric-stenosis.pdf?sfvrsn=0

3. Medicines and Healthcare products Regulatory Agency accessible on https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/945824/Dec-2020-DSU-PDF-1712.pdf