Direct Healthcare Professional Communication

January 2022

DINOPROSTONE

ADD A RESTRICTION ON USE AND UPDATE OF DOSAGE RECOMMENDATIONS, WARNINGS AND ESPECIALLY ADDING RECOMMENDATIONS ON THE RISKS OF HYPERSTIMULATION UTERINE, UTERINE RUPTURE AND FETAL / NEONATAL MORTALITY

Dear Healthcare Professional,

The Egyptian Pharmaceutical Vigilance Center of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

Summary

EPVC wish to inform you of the next update of the Summary of Product characteristics (SPC) and package leaflet for dinoprostone-based medicinal products mentioned above, on the recommendation of the Committee for the Assessment of Risks in pharmacovigilance (PRAC: Pharmacovigilance Risk Assessment Committee), the European Medicines Agency (EMA), and the Group of coordination for mutual and decentralized recognition procedures — human (CMDh: Coordination group for Mutual Recognition and Decentralised Procedures - Human).

Abstract

The SPCs and instructions for the aforementioned medicinal products will be updated in order to:

- Reserve their use for qualified health professionals and hospitals and clinics with specialized and equipped obstetric units' facilities for continuous monitoring.
- Highlight the warning and recommendations regarding risks of uterine hyperstimulation and uterine rupture as well as their serious complications, such as fetal **and** neonatal mortality.
- Highlight the warning and recommendations on the maximum dose (for Dinoprostone vaginal tablet), and the dosing interval (for Dinoprostone vaginal tablet).
- Reinforce the contraindications (for Dinoprostone), the warnings and precautions for use, including those concerning concomitant use and / or sequential of dinoprostone and oxytocin.

21st Abdel-Aziz Al-Saud, Manial Al-Roda,Cairo
pv.head@edaegypt.gov.eg; pv.safety@edaegypt.gov.eg;
Tel.: 237484988 Ext.:1470

- Add "fetal mortality", "stillbirth" and "neonatal death" as side effects with frequency not known.

Indications:

- Dinoprostone concentrate for solution for infusion can be used for induction artificial labor in the absence of contraindications in mother and fetus, or in case of fetal death in uterus.
- Dinoprostone concentrate for solution for infusion can be used to obtain evacuation of uterine contents in case of fetal retention (miscarriage) or is useful for the non-surgical evacuation of the hydatidiform mole.
- Dinoprostone tablets are indicated for induction of labor in women full term and near term pregnant with a mature cervix and pregnancy single with presentation by the head. Vaginal tablets are used as alternative to oral or parenteral administration of dinoprostone.
- Dinoprostone endocervical gel is indicated for the maturation of an unfavorable cervix in pregnant women who have reached or near term and who have medical or obstetric necessity of inducing labor.
- Dinoprostone vaginal delivery system is indicated for the induction of cervical maturation in term patients (from 37 weeks gestation gone).

General information on the security issue and recommendations

As part of a procedure for monitoring a PSUSA (Periodic Safety Update Single Assessment) relating to dinoprostone (SE / H / PSUFU / 00001104/201909) which was closed on April 27, 2021, an analysis of post-market data showed that cases of uterine hyperstimulation and uterine rupture leading to serious complications including fetal and neonatal mortality have been reported with medication errors and for off-indication use (dosage, frequency and / or mode of administration) of Dinoprostone, in specific patients (with a history of caesarean section or scarred uterus for any other reason).

Despite rare serious complications that may appear after uterine hyperstimulation or uterine rupture, the benefits of giving dinoprostone to women pregnant in accordance with the recommendations of the SPC and the medication leaflet concerned outweigh these possible risks. This communication is currently being distributed at the request of the Egyptian Pharmaceutical vigilance Centre (EPVC).

References:

Belgium

https://www.fagg.be/sites/default/files/DHPC%20Dinoprostone%20Nl%20-%20Website.pdf

Call for reporting

21st Abdel-Aziz Al-Saud, Manial Al-Roda,Cairo
pv.head@edaegypt.gov.eg; pv.safety@edaegypt.gov.eg;
Tel.: 237484988 Ext.:1470
Address : 8 Abd El Hamid Abd El Wahab St., Nasr City, Cairo

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: Egyptian Pharmaceutical Vigilance Center

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt, And PO Box: 11451 Telephone: +202- 25354100, Extension: 1470 Fax: +202 – 23610497

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://primaryreporting.who-umc.org/EG

QR Code:

Hotline: 15301

21st Abdel-Aziz Al-Saud, Manial Al-Roda,Cairo
pv.head@edaegypt.gov.eg; pv.safety@edaegypt.gov.eg;
Tel.: 237484988 Ext.:1470