פייזר פי אף אי פרמצבטיקה ישראל בע"מ
רח' שנקר 9, ת.ד. 12133
הרצליה פיתוח, ישראל 46725
טל: 972-9-9700500 פקס: 972-9-9700501

אוקטובר 2021

רופא/ה, רוקח/ת נכבד/ה,

חברת פייזר פי אף אי ישראל בע"מ, מבקשת להודיעכם על על עדכון בעלון לרופא של התכשירים

Prostin E2 Vaginal gel 1mg/3g ו- Prostin E2 Vaginal gel 2mg/3g

הודעה זו מפרטת את העדכונים המהווים החמרה במידע הבטיחותי בלבד, למידע מלא יש לעיין בעלון.

העלון לרופא מפורסם במאגר התרופות שבמשרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום:

חברת פייזר פי אף אי פרמצבטיקה ישראל בע"מ, שנקר 9, ת.ד. 12133, הרצליה פיתוח, 46725.

שם התכשיר: Prostin E2 Vaginal Gel 1mg/3g, Prostin E2 Vginal Gel 2mg/3g

הרכב וחוזק: Each 3 g gel (2.5 ml) contains 1mg/2mg dinoproston

התוויה מאושרת:

For labour induction in term and near term pregnant women who have favorable induction features and who have a singleton pregnancy with vertex presentation

להלן עדכוני הבטיחות בעלון (מסומנים בצהוב):

4.2 Posology and method of administration

Usage is restricted to qualified health care professionals and to hospitals and clinics with specialised obstetric units with facilities for continuous monitoring.

The recommended dose should not be exceeded, and the dosing interval should not be shortened as this increases the risk of uterine hyperstimulation, uterine rupture, uterine haemorrhage, foetal and neonatal death.

4.4 Special warnings and precautions for use

As with any oxytocic agent, the risk of uterine rupture should be considered. Concomitant medication, maternal and foetal status should be taken into consideration in order to minimise the risk of uterine hyperstimulation, uterine rupture, uterine haemorrhage, foetal and neonatal death. Continuous electronic monitoring of uterine activity and foetal heart rate should be conducted during use of dinoprostone. Patients who develop uterine hypertonus or hypercontractility, or in whom unusual foetal heart rate patterns develop, should be managed in a manner that addresses the welfare of the foetus and mother.

Caution should be exercised in the administration of Prostin E2 Vaginal Tablets for the induction of labour in patients with:

- asthma or a history of asthma
- epilepsy or a history of epilepsy
- glaucoma or raised intra-ocular pressure

- compromised cardiovascular, hepatic, or renal function
- hypertension.
- ruptured chorioamniotic membranes.

Dinoprostone should be used with caution in patients with multiple pregnancy.

4.8 Undesirable effects

Pregnancy, puerperium and perinatal conditions: Foetal death, stillbirth, neonatal death*
(Frequency not known- cannot be estimated from the available data)

Maternal-related conditions*:* Uterine hypertonus, uterine rupture, abruptio placenta, pulmonary amniotic fluid embolism, rapid cervical dilatation
Foetus-related conditions: Uterine hypercontractility with/without foetal bradycardia foetal distress/altered foetal heart rate (FHR)
Neonatal conditions: Neonatal distress, neonatal death, stillbirths, low Apgar score
*Foetal death, stillbirth, and neonatal death have been reported after application of dinoprostone, especially following the occurrence of serious events such as uterine rupture (see sections 4.2, 4.3 and 4.4).