הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך 19.11.2017

שם תכשיר באנגלית ומספר הרישום Propess

Reg.no. **131-89-29517**

שם בעל הרישום Ferring Pharmaceutical Ltd.

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות

פרק בעלון	טקסט נוכחי	טקסט חדש
Posology and method of administration		לתשומת לבכם, רק מידע בטיחותי שהתווסף לעלון בעדכון זה מופיע מטה מסומן בצהוב. למידע מלא על פרק זה יש לעיין בעלון The vaginal delivery system should be removed after 24 hours irrespective of whether cervical ripening has been achieved. A dosing interval of at least 30 minutes is recommended for the sequential use of oxytocin following the removal of the vaginal delivery system. *Paediatric population* The safety and efficacy of PROPESS in pregnant woman aged less than 18 years has not been established. No data are available. ……. *Method of administration* Removal It is necessary to remove the vaginal delivery system to terminate drug administration when cervical ripening is judged to be complete or for any of the reasons listed below. 1. Onset of labour. For the purposes of induction of labour with PROPESS, the onset of labour is defined as the presence of regular painful uterine contractions occurring every 3 minutes irrespective of any cervical change. There are two important points to note: (i) Once regular, painful contractions have been established with PROPESS they will not reduce in frequency or intensity as long as PROPESS remains in situ because dinoprostone is still being administered. (ii) Patients, particularly multigravidae, may develop regular painful contractions without any apparent cervical change. Effacement and dilatation of the cervix may not occur until uterine activity is established. Because of this, once regular painful uterine activity is established with PROPESS in-situ, the vaginal delivery system should be removed irrespective of cervical state to

avoid the risk of uterine hyperstimulation. 2. Spontaneous rupture of the membranes or amniotomy. 3. Any suggestion of uterine hyperstimulation or hypertonic uterine contractions. 4. Evidence of fetal distress. 5. Evidence of maternal systemic adverse dinoprostone effects such as nausea, vomiting, hypotension or tachycardia. At least 30 minutes prior to starting an intravenous infusion of oxytocin., as there is a much greater risk of hyperstimulation if the dinoprostone source is not removed before administration of oxytocin.		
לתשומת לבכם, רק מידע בטיחותי שהתווסף לעלון בעדכון זה מופיע מטה מסומן בצהוב. למידע מלא על פרק זה יש לעיין בעלון PROPESS should not be used or left in place: 1. When labour has started. 2. When oxytocic drugs are being given/or other labour induction agents are being given. 3. When strong prolonged uterine contractions would be inappropriate such as in patients: a. who have had previous major uterine surgery, e.g. caesarean section, myomectomy etc (see sections 4.4 and 4.8) b. with cephalopelvic disproportion c. with fetal malpresentation d. with suspicion or evidence of fetal distress ~~e. who have had more than three full term deliveries~~ f. who have had previous surgery (e.g. other than biopsies and cervical abrasion) or rupture of the cervix 4. When there is current pelvic inflammatory disease, unless adequate prior treatment has been instituted. 5. When there is hypersensitivity to dinoprostone or to any of the excipients listed in section 6.1. 6. When there is placenta previa or unexplained vaginal bleeding during the current pregnancy.		
לתשומת לבכם, רק מידע בטיחותי שהתווסף לעלון בעדכון זה מופיע מטה מסומן בצהוב. למידע מלא על פרק זה יש לעיין בעלון PROPESS should not be used during pregnancy prior to 37 completed weeks of gestation. Breast-feeding No studies have been performed to investigate the amount of dinoprostone in colostrum or breast milk following the use of PROPESS. Dinoprostone may be excreted in colostrum and breast milk, but the level and duration is expected to be very limited and should not hinder breastfeeding. No effects on the breastfed newborns have been observed in the clinical studies conducted with PROPESS.		**Fertility, pregnancy and lactation**

Commented [ZO1]: עבר לפרק אזהרות, בהתאם לעלון במדינת ייחוס

לתשומת לבכם, רק מידע בטיחותי שהתווסף לעלון בעדכון זה מופיע מטה מסומן בצהוב. למידע מלא על פרק זה יש לעיין בעלון Because adrenal function may be suppressed, an ACTH stimulation test for diagnosing pituitary insufficiency might show false results (low values).		**Interaction with other medicinal**
לתשומת לבכם, רק מידע בטיחותי שהתווסף לעלון בעדכון זה מופיע מטה מסומן בצהוב. למידע מלא על פרק זה יש לעיין בעלון The most commonly reported adverse drug reactions in placebo-controlled and active comparator efficacy clinical trials (N=1116) were "foetal heart rate disorder" (6,9%), "uterine contractions abnormal" (6,2%) and "abnormal labour affecting foetus" (2.6 %). The table below displays the main ADRs distributed by system organ classes (SOC) and frequency. Further, the ADRs seen during post-marketing experience are mentioned with unknown frequency. Adverse reactions observed in clinical studies are presented according to their incidence, post authorisation reported adverse reactions are presented in the column frequency unknown.		**Undesirable effects**

System organ class	**Common** **(≥ 1/100 and < 1/10)**	**Uncommon** **(≥ 1/1000 and ≤ 1/100)**	**Not known: frequency cannot be estimated from the available data**
Blood and lymphatic system disorders			Disseminated intravascular coagulation
Immune system disorders			Anaphylactic reaction Hypersensitivity
Nervous system disorders		Headache	
Cardiac disorders	Foetal heart rate disorder [1*]		
Vascular disorders		Hypotension	
Respiratory, thoracic and mediastinal disorders		Neonatal respiratory distress related conditions	

System organ class	Common (≥ 1/100 and < 1/10)	Uncommon (≥ 1/1000 and ≤ 1/100)	Not known: frequency cannot be estimated from the available data
Gastrointestinal disorders			Abdominal pain, Nausea, vomiting, diarrhoea
Hepatobiliary disorders		Neonatal hyperbilirubinaemia	
Skin and subcutaneous tissue disorders		Pruritus	
Pregnancy, puerperium and perinatal conditions	Abnormal labour affecting foetus [2*] Uterine contractions abnormal [4*] Meconium in amniotic fluid	Postpartum haemorrhage, Premature separation of placenta, Apgar score low Arrested labour Chorioamnionitis Uterine atony	Anaphylactoid syndrome of pregnancy Foetal distress syndrome [3*]
Reproductive system and breast disorders		Vulvovaginal burning sensation	Genital oedema
General disorders and administration site conditions		Febrile disorders	
Injury, poisoning and procedural complications			Uterine rupture

1 "Foetal heart rate disorder" was in clinical studies reported as "foetal heart rate abnormalities", "foetal bradycardia", "foetal tachycardia", "unexplained absence of normal variability", "foetal heart rate decreased", "foetal heart rate deceleration", "early or late decelerations", "variable decelerations", "prolonged decelerations".*

2 "Abnormal labour affecting foetus" as expression for hyperstimulation syndrome was in clinical studies reported as "uterine tachysystole" combined with "late decelerations", "foetal bradycardia", or "prolonged decelerations "*

3 "Foetal distress syndrome" was also reported as "foetal acidosis" , "pathological CTG", "foetal heart rate abnormalities", "intrauterine hypoxia" or "threatening asphyxia". The term itself is unspecific, has a low positive predictive value and is often associated with an infant who is in good condition at birth.*

4 "Uterine contractions abnormal" were reported as "uterine hyperstimulation" and "uterine hypertonus".*

מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב (עדכונים מעלון שוויצרי) ועל רקע סגול (עדכונים מעלון גרמני המתייחסים להתוויה חדשה)
שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע שונה. יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט.

הועבר בדואר אלקטרוני בתאריך.....19/11/2017.....

☒ כל השינויים עולים בקנה אחד עם תנאי הרישום (תעודת הרישום, תעודת האיכות וטופס פרטי התכשיר העדכני).
☒ כל הכתוב בהצעת העלון, תואם את תנאי הרישום.
☐ ~~קיים עלון לצרכן והוא מעודכן בהתאם.~~
☒ אסמכתא לבקשה: ___ עלון לרופא מאושר על ידי UK **האסמכתא מצ"ב**.
☒ השינוי הנ"ל אושר על ידי רשויות הבריאות ב UK
☒ אני, הרוקחת הממונה של חברת _ פרינג_פרמצאוטיקלס בע"מ___ מצהירה בזה כי אין שינויים נוספים , מלבד אלה שסומנו בהצעת העלון.
☒ אני מצהיר כי למיטב הבנתי השינויים אינם יוצרים סתירה פנימית במידע בעלון.

☒ עלון זה לא מטופל במקביל במסגרת אחרת (כגון: עדכון עלון במסגרת בקשה לתוספת התוויה, החמרה וכו') במידה וקיים טיפול מקביל במסגרת אחרת- יש לציין זאת.

חתימת הרוקח הממונה (שם וחתימה): אורית זוזוט