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Cervidil (Dinoprostone)

??? ??????: 30 ?????2/????? 2017

Cervidil (dinoprostone) is well tolerated. In placebo-controlled trials in which 658 women were entered and 320 received active therapy (218 without retrieval system, 102 with retrieval system), the following events were reported.

Table 1 : Total Cervidil (dinoprostone) - Treated Drug Related Adverse Events

| ¹ Controlled Studies | | |
|---|--------|---|
| Placebo | Active | |
| 0.3% | 2.8% | Uterine hyperstimulation with fetal distress |
| 0% | 4.7% | Uterine hyperstimulation without fetal distress |
| 1.2% | 3.8% | Fetal Distress without uterine hyperstimulation |
| 338 | 320 | N |
| ² STUDY 101-801 | | |
| Placebo | Active | |
| 0% | 2.9% | Uterine hyperstimulation with fetal distress |
| 0% | 2.0% | Uterine hyperstimulation without fetal distress |
| 1.0% | 2.9% | Fetal Distress without uterine hyperstimulation |
| 104 | 102 | N |
| Controlled Studies (with and without retrieval system) ¹ | | |
| Controlled Study (with retrieval system) ² | | |

Drug related fever, nausea, vomiting, diarrhea, and abdominal pain were noted in less than 1% of patients who received Cervidil (dinoprostone) .

In study 101-801 (with the retrieval system) cases of hyperstimulation reversed within 2 to 13 minutes of removal of the product. Tocolytics were required in one of the five cases.

In cases of fetal distress, when product removal was thought advisable there was a return to normal rhythm and no neonatal sequelae.

Five minute Apgar scores were 7 or above in 98.2% (646/658) of studied neonates whose mothers received Cervidil (dinoprostone) . In a report of a 3 year pediatric follow-up study in 121 infants, 51 of whose mothers received Cervidil (dinoprostone) , there were no deleterious effects on physical examination or psychomotor evaluation (18).

Post-marketing surveillance

Hypersensitivity **Immune System Disorders:**

WARNINGS Section Disseminated Intravascular Coagulation (See **Blood and lymphatic system disorders:**

Reports of uterine rupture have been reported in association with use of Cervidil (dinoprostone) some required a hysterectomy and some **Reproductive system:** resulted in subsequent fetal or neonatal death.

Hypotension **Vascular Disorders:**

Amniotic fluid embolism **Pregnancy, Puerperium and Perinatal Conditions:**

Drug Abuse And Dependence

No drug abuse or dependence has been seen with the use of Cervidil (dinoprostone) .

