◈ Propofol in Pregnancy

- **Pregnancy category**
  - **FDA : B**

    Either animal-reproduction studies have not demonstrated a fetal risk but there are no controlled studies in pregnant women or animal-reproduction studies have shown adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the first trimester (and there is no evidence of a risk in later trimesters).

  - **Australian Drug Evaluation Committee's (ADEC) Category : C**

    Drugs which, owing to their pharmacological effects, have caused or may be suspected of causing harmful effects on the human fetus or neonate without causing malformations. These effects may be reversible. Accompanying texts should be consulted for further details.

- **태반통과여부 : Yes**
  - **→ 태아의 CNS, respiratory depression을 가져 올 수 있음**
  - **→ 임신 중 투여에 신중을 기해야 하며, 반드시 투여의 필요성에 대한 명확한 판단 하에 사용되어야 함**

FDA pregnancy category : B	
제품설명서	임신 중 약물투여지침 (미국 FDA 분류) : B등급 성분 : Propofol 원문정보 보기 B 등급 B 등급 A B C D X 위험도 낮음 ◀ ▶ 위험도 높음 사람에서 위험하다는 증거가 없다. 동물연구에서는 위험성을 보였으나 사람에서는 보이지 않았다; 또는 사람에 대한 적절한 연구가 실시되지 않았다면, 동물연구에서 태자에 대한 위험성을 보이지 않았다.
DI handbook	*Pregnancy risk factor : B *Pregnancy Considerations : Propofol should only be used in pregnancy if clearly needed. Propofol is not recommended for obstetrics, including cesarean section deliveries. Propofol crossed the placenta and may be associated with neonatal CNS and respiratory depression.
Drugs in Pregnancy and Lactation	*Risk factor : B_M : 상세설명 → If the **manufacturer rated its product** in its professional literature, the Risk Factor will be shown with a **subscript M.** *Fetal risk recommendation

	: **Limited Human Data – Animal Data suggest Low Risk** :상세설명 → Either there is no human pregnancy experience or the few pregnancy exposures have not been associated with developmental toxicity (growth retardation, structural defects, functional/behavioral deficits, or death). The drug does not cause decelopmental toxicity (at doses that did not cause maternal toxicity) in all animal species studied at doses ≤ 10 times the human dose based on body surface area (BSA) or AUC.
CCIS	1. Teratogenicity/Effects in Pregnancy/Breastfeeding A) Teratogenicity/Effects in Pregnancy **1) U.S. Food and Drug Administration's Pregnancy Category: Category B** (Prod Info DIPRIVAN(R) IV injectable emulsion, 2008) (All Trimesters) a) Either animal-reproduction studies have not demonstrated a fetal risk but there are no controlled studies in pregnant women or animal-reproduction studies have shown adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the first trimester (and there is no evidence of a risk in later trimesters). **2) Crosses Placenta: Yes** **3) Clinical Management** a) Propofol has been shown to cross the placenta. As with other general anesthetic agents, administration of propofol may be associated with neonatal depression. Therefore, propofol should be used during pregnancy only if clearly needed (Prod Info DIPRIVAN(R) IV injectable emulsion, 2008). **4) Literature Reports** a) A case report described the successful use of propofol for induction of anesthesia during an elective Cesarean section in a 45-year-old woman with cerebral palsy. Propofol was used in this mother due to the risk of athetotic reaction. She received propofol 1 mg/kg IV and succinylcholine 120 mg IV. Due to hypertension and tachycardia, additional propofol 1 mg/kg, 50% nitrous oxide-oxygen, and sevoflurane (under 1%) were administered. Time between induction and delivery was 15 minutes. A total dose of propofol 2 mg/kg was used. A healthy boy was delivered with Apgar scores of 8 at one minute and 10 at five minutes. No maternal respiratory depression was observed (Kariya et al, 1999). b) In 19 patients undergoing cesarean section receiving propofol 6 or 9 mg/kg/hour, maternal vein propofol concentrations ranged from 1.91 to 3.82 mcg/mL; umbilical vein concentrations ranged from 1 to 2 mcg/mL; and umbilical artery concentrations ranged from 0.53 to 1.66 mcg/mL. Lower neurologic scores were noted in neonates with high umbilical vein

	concentrations (Gin et al, 1991). c) A comparative study evaluated induction with thiopental 5 mg/kg and propofol 2.8 mg/kg in 40 women undergoing cesarean section. The infants who received propofol had lower Apgar scores at 1 and 5 minutes; 25% had muscular hypotonus at 5 minutes. Depression in alert state, pinprick, and placing reflexes were noted 1 hr after birth in the newborns receiving propofol. Depression was not observed after 4 hours. These effects were not observed as frequently in those newborns who had received thiopental (Celleno et al, 1989). By contrast, other studies demonstrated no significant difference in Apgar scores of newborns delivered from patients receiving either propofol or thiopental during cesarean sections (Valtonen et al, 1989; Moore et al, 1989). d) Propofol concentrations in neonates born to women receiving propofol as a 2.5 mg/kg induction dose and 5 mg/kg/hr maintenance infusion ranged from 0.029 to 0.14 mcg/mL in a blood sample taken 2 hours after birth (Dailland et al, 1989). e) In one case, no apparent ill effects were seen in a neonate born to a mother who had been sedated with propofol for 48 hours (Bacon & Razis, 1994).

Australian Drug Evaluation Committee's (ADEC) Category: C **(Australian Drug Evaluation Committee, 1999)**	
CCIS	a) Drugs which, owing to their pharmacological effects, have caused or may be suspected of causing harmful effects on the human fetus or neonate without causing malformations. These effects may be reversible. Accompanying texts should be consulted for further details.