ATOSIBAN

Class: Tocolytic Agent

Indications: Inhibit uncomplicated premature labor

Available dosage form in the hospital:

ATOSIBAN 7.5 MG/ML [0.9ML VIAL]

ATOSIBAN 7.5 MG/ML [5 ML VIAL]

Trade Names:

Dosage:

Inhibition of preterm birth: Females: I.V.: Initial: Administer 6.75 **mg** bolus by slow injection over 1 minute, immediately followed by continuous infusion of 300 **mcg**/minute for 3 hours. Then decrease infusion rate to 100 **mcg**/minute for up to 45 hours. Maximum total dose/duration: 330.75 **mg**/48 hours. **Note:** If retreatment is deemed necessary, the full 48-hour regimen (including initial bolus injection) may be repeated; data for multiple retreatments (≤3) is very limited.

Renal Impairment:
No dosage adjustment provided in manufacturer's labeling (has not been studied); need for dosage adjustment appears unlikely due to minimal renal excretion.

Hepatic Impairment:
No dosage adjustment provided in manufacturer's labeling (has not been studied); use caution.

Common side effect: >10%: Gastrointestinal: Nausea (14%)

1% to 10%:

Cardiovascular: Hot flush, hypotension, tachycardia

Central nervous system: Dizziness, headache

Endocrine & metabolic: Hyperglycemia

Gastrointestinal: Vomiting

Local: Injection site reaction

<1%, postmarketing, and/or case reports: Allergic reaction, atrial fibrillation (Cheun, 2013), dyspnea, insomnia, fever, pruritus, pulmonary edema, rash, uterine atony, uterine hemorrhage

Pregnancy Risk Factor: Adverse effects have not been observed in animal reproduction studies from implantation up to late-stage pregnancy (fertility and early embryonic development not studied); atosiban crosses the placenta with a fetal/maternal concentration ratio of 0.12 for healthy women at term. No direct physiologic effects (heart rate, blood flow) or abnormal fetal movement were observed during in utero exposure in a controlled study of 17 women (de Heus, 2009). Data on long-term outcomes from *in utero* exposure is insufficient (RCOG, 2011).

Atosiban is only indicated for use in women between completed weeks 24-33 of gestation. Tocolytic therapy, including atosiban, has not been clearly shown to improve perinatal/neonatal morbidity or mortality (Haas, 2012; RCOG, 2011). The decision to initiate therapy should take into account potential harms to the fetus as well as possible benefits of delaying labor (eg, increased access to specialized care, antepartum corticosteroids [RCOG, 2011]).