experience with atosiban in patients with impaired liver or kidney function.

2.1 Onset and Duration

Onset

1) Initial Response

PRETERM LABOR, INTRAVEOUS INFUSION: A decline (not cessation) in uterine activity has occurred within 60 minutes of initiation of a 300-mcg/minute infusion (no preceding bolus)

2) Peak Response

PRETERM LABOR, INTRAVEOUS: Cessation of uterine contractions has occurred in about a fourth of patients within 2 hours of initiation of an intravenous bolus/continuous infusion regimen (2 or 6 mg followed by 100 or 300 mcg/minute). Without an initial bolus dose, control of uterine activity is somewhat slower

2.2 Drug Concentration Levels

Time to Peak Concentration

INTRAVENOUS INFUSION: within 60 minutes

Mean steady-state plasma concentrations of 442 ng / mL were achieved within one hour of initiation of a 300-mcg/minute infusion (no initial bolus). After infusion discontinuation, plasma levels declined to less than 10 ng/mL after 4 hours (Goodwin et al, 1995). Data for bolus/infusion regimens are lacking.

CONTRAINDICATIONS/ PRECAUTIONS:

Atosiban should not be administered to pregnant women with any of the following conditions:

- Gestational age below 24 or over 33 completed weeks.
- Premature rupture of the membranes at >30 weeks of gestation
- Intrauterine growth retardation
- Abnormal fetal heart rate
- Antepartum uterine haemorrhage requiring immediate delivery
- Eclampsia and severe pre-eclampsia requiring delivery
- Intrauterine fetal death
- Suspected intrauterine infection
- Placenta praevia or abruptio placenta
- Any other conditions of the mother, or fetus, where continuation of pregnancy is hazardous.
- Any known hypersensitivity to the active substance or any of the excipients.

There is only limited experience in the use of atosiban in multiple pregnancies or in the gestational age group between 24 and 27 weeks. Although retreatment with atosiban is possible, there is only limited clinical experience with up to 3 retreatments No interaction studies have been performed.