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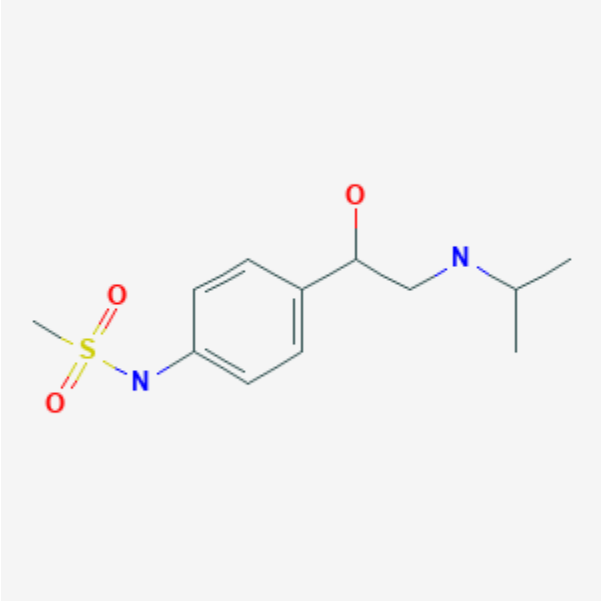
Sotalol

Revised: April 1, 2019.

CASRN: 3930-20-9



Drug Levels and Effects

Summary of Use during Lactation

Because of its extensive excretion into breastmilk, its renal excretion and minimal safety data in breastfed infants, other beta-adrenergic blocking drugs are preferred to sotalol, especially while nursing a newborn or preterm infant. Some authors recommend using sotalol during breastfeeding only while monitoring the infant closely for signs of beta-blockade.[1] Infants over 2 months of age have more mature kidney function and are less likely to be affected by sotalol in milk.

Drug Levels

The excretion of beta-adrenergic blocking drugs into breastmilk is largely determined by their protein binding. Those with low binding are more extensively excreted into breastmilk.[1][2]Accumulation of the drugs in the infant is related to the fraction excreted in urine. With 0% protein binding, 80 to 90% renal excretion and a

moderately long half-life, sotalol presents a high risk for accumulation in infants, especially neonates. It is estimated that a fully breastfed infant would receive 22% of the maternal weight-adjusted dosage of sotalol.[3]

Maternal Levels. Twenty milk samples from 5 mothers at various times during the first 7 days postpartum while taking sotalol 200 to 600 mg daily orally had average sotalol milk levels of 10.5 mg/L (range 4.8 to 20.2 mg/L).[4]

One woman taking sotalol 80 mg three times daily on day 5 postpartum had sotalol milk levels of 4.1 and 3.7 mg/L at 6.3 and 7 hours after a dose, respectively. She was restudied at 105 days postpartum while taking 80 mg twice daily. Her milk sotalol levels were 2.4 and 3.2 mg/L at 2.8 and 3.3 hours after a dose, respectively.[1]

A mother taking oral sotalol 80 mg twice daily had milk sotalol levels of 5 and 4.4 mg/L at 3 hours after the dose on days 5 and 7 postpartum.[5]

Infant Levels. Relevant published information was not found as of the revision date.

Effects in Breastfed Infants

A study of mothers taking beta-blockers during nursing found a numerically, but not statistically significant increased number of adverse reactions in those taking any beta-blocker. Although the ages of infants were matched to control infants, the ages of the affected infants were not stated. One of the mothers was taking sotalol.[6]

Bradycardia was not seen in one 12-day-old infant who was breastfed from birth during maternal use of 600 mg of sotalol daily.[4] In another breastfed infant whose mother was taking 80 mg 2 to 3 times daily for more than 3 months, no bradycardia was seen and developmental milestones were achieved normally.[1]

Beta-adrenergic blocking drugs with similar breastmilk excretion characteristics and renal elimination have caused adverse effects in breastfed newborns.[7][8]

Effects on Lactation and Breastmilk

Relevant published information on the effects of beta-blockade or sotalol during normal lactation was not found as of the revision date. A study in 6 patients with hyperprolactinemia and galactorrhea found no changes in serum prolactin levels following beta-adrenergic blockade with propranolol.[9]

Alternate Drugs to Consider

Propranolol, Labetalol, Metoprolol

References

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Substance Identification

Substance Name

Sotalol

CAS Registry Number

3930-20-9

Drug Class

Breast Feeding

Lactation

Antihypertensive Agents

Adrenergic Beta-Antagonists

Antiarrhythmics