Ritodrine (Systemic)

VA CLASSIFICATION
Primary: AU100
Secondary: GU900

Commonly used brand name(s): Yutopar; Yutopar S.R.

Note: For a listing of dosage forms and brand names by country availability, see Dosage Forms section(s).

Category:

Tocolytic—

Indications

Accepted

Premature labor (prophylaxis and treatment)—Intravenous ritodrine is indicated in the treatment of preterm labor in patients with a pregnancy of 20 or more weeks’ gestation. Preterm labor is defined as rhythmic uterine contractions less than 10 minutes apart accompanied by progressive cervical effacement and/or dilation before the end of the 37th week of gestation. By prolonging gestation, ritodrine may reduce the incidence of neonatal mortality and respiratory distress syndrome by allowing time for the fetus to age and the fetal lung to mature or time for corticosteroids to be administered to the mother to enhance lung maturity in the fetus. Suitable patients must have intact amniotic membranes, cervical dilation usually but not always less than 4 centimeters (cm), and cervical effacement less than 80%. Use is not recommended prior to the 20th week of pregnancy.

—For intravenous ritodrine to be most effective, it is recommended that therapy begin as soon as the diagnosis of preterm labor is confirmed. Due to the potential risks for the patient and fetus, a physician experienced in the use of intravenous ritodrine should be present to intervene in case of an emergency.

—Intravenous ritodrine is less likely to inhibit labor when labor is advanced (cervical dilation more than 4 cm or effacement more than 80%) or when patient is close to term; its use, according to one study, may be best in pregnancies of less than 28 weeks. Risk-benefit should be cautiously assessed for those women in advanced labor or whose amniotic membranes have ruptured as safety and efficacy have not been established for these patients; use of ritodrine
is not recommended. Risk of intrauterine infection when amniotic membranes are ruptured must be considered. (03) (17)
—Although oral ritodrine is indicated in the treatment of preterm labor in Canada, it is the opinion of the USP Obstetrics and Gynecology Advisory Panel that oral ritodrine cannot be recommended because its efficacy has not been established to be more effective than a placebo and alternative therapies may be more beneficial. (15) (16) Bed rest at home and early admission may be better alternatives than using oral ritodrine in treatment of preterm labor, including retreatment of recurrent preterm labor. (26)

Pharmacology/Pharmacokinetics

Physicochemical characteristics:
Molecular weight—
323.82 (02)

Mechanism of action/Effect:
Ritodrine, a beta-2–adrenergic agonist, relaxes the uterus by stimulating the beta-2–adrenergic receptors of the uterine muscle, which causes a decrease in the intensity and frequency of uterine contractions. Specifically, ritodrine decreases uterine myometrial contractility by increasing cellular cyclic adenosine monophosphate (cAMP) and increasing cell membrane cytokines that increase and sequester intracellular calcium. Without intracellular calcium, the activation of contractile protein of smooth muscle is prevented and the uterus relaxes. (03)

Other actions/effects:
In addition to stimulating the beta-2–adrenergic receptors of the uterine smooth muscle, ritodrine stimulates beta-adrenergic receptors of bronchial and vascular smooth muscles. The cardiostimulatory effects, including increased cardiac output, increased maternal and fetal heart rates, and widening of the maternal pulse pressure, are probably due to relaxation of vascular smooth muscle. Relaxation of vascular smooth muscle stimulates the beta-1–adrenergic receptors and the reflex response to blood pressure. (03) (18) Also, during intravenous administration, ritodrine transiently increases maternal and fetal blood glucose and maternal plasma insulin concentrations. Other metabolic changes include increased cAMP, lactic acid, and free fatty acids, and decreased serum potassium concentration. (03) (18)

Distribution:
Ritodrine and its conjugates transfer via placenta into the fetal circulation; fetal and maternal concentrations may be equal. (03) (11) (19)
**Protein binding:**

Low (almost exclusively to albumin).

**Biotransformation:**

Hepatic (inactive metabolites); metabolized to conjugates by both the mother and the fetus. \(^{(12)}\)

**Half-life:**

Intravenous—Nonpregnant females:

Distribution: 6 to 9 minutes \(^{(03)} \(20\).

Elimination: 1.7 to 2.6 hours \(^{(03)} \(20\).

**Onset of action:**

Intravenous—5 minutes (at effective dose). \(^{(03)}\)

**Peak serum concentration**

Intravenous—32 to 52 nanograms per mL after infusion of 9 mg over 60 minutes in nonpregnant females. \(^{(03)}\)

**Elimination:**

Renal (71 to 93%; conjugated metabolites; with 90% of dose eliminated within 24 hours). \(^{(19)}\)

In dialysis—Removable by dialysis. \(^{(03)}\)

**Precautions to Consider**

**Cross-sensitivity and/or related problems**

Patients sensitive to sulfites may be sensitive to intravenous ritodrine because of the sulfite preservative present.

**Carcinogenicity/Tumorigenicity**

Studies in rats receiving ritodrine orally found no increased risk of carcinogenicity or tumorigenicity. \(^{(03)}\)
Pregnancy/Reproduction

Pregnancy—
Adequate and well-controlled studies in humans have not been done in women with a pregnancy of less than 20 weeks' gestation. A small number of children 7 to 9 years of age who had been exposed to ritodrine prenatally were studied for up to 2 years and did not show increased risk of abnormalities. Risk-benefit to the fetus must be considered since ritodrine crosses the placenta. Neonatal hypoglycemia, tachycardia, and ileus have been reported; ketoacidosis has resulted in fetal death. Neonatal hypocalcemia and hypotension have occurred with other beta-adrenergic stimulants, although they have not been reported with ritodrine.

Studies in animals have not shown that ritodrine causes adverse effects on the fetus.

FDA Pregnancy Category B.

Drug interactions and/or related problems
The following drug interactions and/or related problems have been selected on the basis of their potential clinical significance (possible mechanism in parentheses where appropriate)—not necessarily inclusive (» = major clinical significance):

Note: Combinations containing any of the following medications, depending on the amount present, may also interact with this medication.

Anesthetics, potent, general or
Diazoxide, parenteral or
Magnesium sulfate or
Meperidine (may potentiate cardiovascular effects of intravenous ritodrine, especially cardiac arrhythmias or hypotension)

» Beta-adrenergic agonists, other or
Parasympatholytic agents, such as atropine or
Sympathomimetics (concurrent use may cause an additive sympathomimetic effect and greatly increase the likelihood of developing side effects, including hypertension from a parasympatholytic agent or cardiac problems from another tocolytic agent. A sufficient time interval should elapse prior to administering another sympathomimetic agent [90% of an intravenous dose is eliminated within 24 hours])
» Beta-adrenergic blocking agents (these agents antagonize the effects of ritodrine, and although agents with greater beta-1–adrenergic selectivity may be less antagonistic, concurrent use is not recommended)

» Corticosteroids, long-acting (corticosteroids are often used concurrently to enhance fetal lung maturity; however, intravenous ritodrine and, to a lesser extent, corticosteroids each expand plasma volume by causing sodium retention. Intravenous ritodrine further increases plasma volume and may cause overhydration. One possible result of overhydration is maternal pulmonary edema, which has occurred with or without corticosteroid administration. Restricting and monitoring fluids helps prevent maternal pulmonary edema; however, on occurrence, discontinuance of ritodrine should be considered. Maternal ketoacidosis has also been reported with concurrent use of high doses of corticosteroids)

**Laboratory value alterations**
The following have been selected on the basis of their potential clinical significance (possible effect in parentheses where appropriate)—not necessarily inclusive (» = major clinical significance):

**With physiology/laboratory test values**
Alanine aminotransferase (ALT [SGPT]) or Aspartate aminotransferase (AST [SGOT]) (increased serum concentrations have been reported in less than 1% of patients receiving ritodrine and other beta-adrenergic agonists)

Blood pressure, maternal and Cardiac output, maternal and Heart rate, fetal and maternal (increased maternal heart rate, increased maternal systolic blood pressure, and decreased maternal diastolic blood pressure occur in 80 to 100% of patients treated with intravenous ritodrine; oral ritodrine frequently causes small increases in maternal heart rate but usually does not affect fetal heart rate or maternal blood pressure)

Free fatty acid, serum and Glucose, blood and Insulin, serum (concentrations may be transiently increased during intravenous infusion but usually return to pretreatment concentrations within 48 to 72 hours, even with continued infusion)
Potassium\(^{(03)}\) (serum concentration may be decreased during intravenous infusion; related to changes in glucose and insulin; maximum effect occurs within 2 hours after infusion is started and concentrations return to normal 30 minutes to 48 hours after withdrawal)

**Medical considerations/Contraindications**
The medical considerations/contraindications included have been selected on the basis of their potential clinical significance (reasons given in parentheses where appropriate)—not necessarily inclusive (» = major clinical significance).

*Except under special circumstances, this medication should not be used when the following medical problems exist:*
» Cardiovascular diseases, maternal, especially those associated with arrhythmias or\(^{(03)}\)
» Hyperthyroidism\(^{(03)}{[15]}\), uncontrolled or
» Hypovolemia\(^{(03)}\) or
» Pheochromocytoma\(^{(03)}\) (ritodrine may precipitate arrhythmias or heart failure; occult cardiac disease may be unmasked)

» Chorioamnionitis or\(^{(03)}{[21]}\)
» Intrauterine fetal death\(^{(03)}{[21]}\) or
» Nonreassuring fetal status\(^{(27)}\) (premature labor should not be suppressed for these problems or conditions\(^{(21)}\))

» Eclampsia and severe preeclampsia\(^{(03)}{[21]}\) or
» Hypertension, uncontrolled or\(^{(03)}{[21]}\)
» Pulmonary hypertension\(^{(03)}\) (ritodrine may aggravate these conditions and, if these conditions cannot be controlled, preterm labor should not be suppressed\(^{(21)}\))

**Risk-benefit should be considered when the following medical problems exist**
» Abruptio placentae\(^{(27)}\) or
» Hemorrhage, maternal or\(^{(03)}{[15]}{[21]}\)
» Placenta previa\(^{(27)}\) or
» Preeclampsia, mild to moderate\(^{(03)}{[21]}\) (ritodrine may aggravate these conditions and, if they cannot be controlled, premature labor should not be suppressed\(^{(21)}\))

Allergy or sensitivity to ritodrine or sulfites\(^{(03)}\)
» Diabetes mellitus\textsuperscript{(03)(21)} (may be aggravated; maternal ketoacidosis has also been reported, especially in patients with poorly controlled diabetes; insulin dose may need to be increased\textsuperscript{(14)}; neonatal glucose should be checked after delivery)

Hypertension or\textsuperscript{(03)(21)}
Migraine headaches, or history of\textsuperscript{(10)} (these conditions may be aggravated; also, transient cerebral ischemia has been reported with the use of other beta-adrenergic agonist therapy in patients who had migraines during ritodrine administration\textsuperscript{(03)})

Patient monitoring
The following may be especially important in patient monitoring (other tests may be warranted in some patients, depending on condition; » = major clinical significance):

Assessment of gestational age and fetal maturity\textsuperscript{(03)} (to diagnose preterm labor)

» Blood count determinations\textsuperscript{(04)} (patients using ritodrine long-term, especially intravenous use for 2 or 3 weeks, should be monitored for development of leukopenia or agranulocytosis\textsuperscript{(04)})

» Blood glucose, maternal and neonatal and\textsuperscript{(03)}
» Fluid and electrolyte status, maternal and neonatal\textsuperscript{(03)} (should be monitored carefully during prolonged intravenous administration, especially in diabetic patients or those receiving corticosteroids, potassium-depleting diuretics, or digitalis glycosides; neonatal blood glucose should be determined promptly after delivery)

Cardiac function monitoring, maternal, such as electrocardiogram (ECG) and/or\textsuperscript{(03)}
Pulmonary function monitoring, maternal\textsuperscript{(03)} (baseline ECG should be done to rule out occult maternal cardiac disease\textsuperscript{(03)}; pulmonary function monitoring and an ECG should also be done immediately in patients complaining of chest pain or tightness during ritodrine therapy and ritodrine should be temporarily discontinued until ECG is assessed; a persistent high tachycardia [over 140 beats per minute] may be related to impending pulmonary edema\textsuperscript{(03)})

Heart rate, fetal and\textsuperscript{(03)}
Heart rate and blood pressure, maternal and \(^{(03)}\)
Uterine activity (should be monitored frequently during intravenous administration \(^{(03)}\))

**Side/Adverse Effects**

**Note:** Most adverse effects of ritodrine are related to its beta-adrenergic stimulating activity and are usually dose-related. \(^{(03)}\)

Maternal ketoacidosis has been reported, especially in patients also receiving high doses of corticosteroids or in patients with poorly controlled diabetes mellitus \(^{(03)}\).

The following side/adverse effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate)—not necessarily inclusive:

**Those indicating need for medical attention**

**Incidence more frequent**

*Angina or cardiac disease, previously undiagnosed* (chest pain or tightness)—15% with intravenous use \(^{(03)}\)

*Diastolic blood pressure reduction, maternal* (lightheadedness or dizziness)—80 to 100% with intravenous use \(^{(03)}(04)\)

*Hyperglycemia, maternal* (blurred vision; drowsiness; dry mouth; flushed, dry skin; fruit-like breath odor; increased frequency and volume of urination; ketones in urine; loss of appetite; somnolence; stomachache, nausea, or vomiting; tiredness; troubled breathing, rapid and deep; unconsciousness; unusual thirst)—80 to 100% with intravenous use, transient for 48 to 72 hours \(^{(03)}\)

*pulmonary edema* (shortness of breath)—15% with intravenous use

*tachycardia or other cardiac arrhythmias, maternal and fetal* (fast or irregular heartbeat)—1% with oral use and 80 to 100% with intravenous use \(^{(03)}(04)\)

**Note:** Increased cardiac output resulting from the use of beta-adrenergic agonists may result in *cardiac arrhythmias or angina* (with or without ECG changes) that has usually been associated with unrecognized cardiopulmonary disease, which may lead to myocardial ischemia, myocardial infarction, and possibly death. \(^{(03)}(07)\)

At the recommended intravenous infusion rate in one study, the *maternal and fetal heartbeat* averaged 130 (range, 60 to 180) and 164 (range, 130 to 200)
beats per minute, respectively. The maternal systolic and diastolic blood pressure measurements averaged 128 mm Hg (range, 96 to 162 mm Hg) and 48 mm Hg (range, 0 to 76 mm Hg), respectively. Only 1% of patients with persistent tachycardia or severely decreased diastolic blood pressure required withdrawal from the medication; these severe effects were managed successfully by dose reduction. Oral administration was associated with only a small increase in maternal heart rate and little or no effect on maternal blood pressure or fetal heart rate.

Maternal hyperglycemia may cause fetal or neonatal hypoglycemia. Serious maternal pulmonary edema has occurred during intravenous administration of ritodrine or other beta-adrenergic agonists for premature labor or after delivery. Although the exact cause is unknown, it appears to be related to circulatory fluid overload with subsequent pulmonary edema, and has occurred more frequently with concurrent corticosteroid administration; maternal death has been reported with or without concomitantly administered corticosteroids. Other contributing factors may include hypokalemia, twin gestations, sustained tachycardia (> 140 beats per minute), undiagnosed cardiopulmonary disease, and catecholamine-induced cardiac injury. If pulmonary edema develops during administration, ritodrine should be discontinued.

Incidence rare

Agranulocytosis or leukopenia (sore throat or fever)—with intravenous use for 2 to 3 weeks, reversible on discontinuation

hepatic function impairment or hepatitis (yellow eyes or skin)—reported in less than 1% of patients using ritodrine and other beta-adrenergic agonists

Those indicating need for medical attention only if they continue or are bothersome

Incidence more frequent

Erythema (reddened skin)—10 to 50% with intravenous use

headache —10 to 50% with intravenous use

nausea —5 to 8% with oral use and 10 to 50% with intravenous use

palpitations (pounding or racing heartbeat)—10 to 15% with oral use and 33% with intravenous use

trembling —10 to 15% with oral use and 10 to 50% with intravenous use
vomiting —5 to 8% with oral use and 10 to 50% with intravenous use

Incidence less frequent or rare

Psychological symptoms (anxiety, emotional upset, jitteriness, nervousness, restlessness)—5 to 8% with oral or intravenous use

skin rash —3 to 4% with oral use and rare with intravenous use

Those indicating possible maternal pulmonary edema and need for medical attention if they occur after medication is discontinued

Shortness of breath

Overdose
For specific information on the agents used in the management of ritodrine overdose, see:

- Beta-adrenergic Blocking Agents (Systemic) monograph; (03) (24) (25)
- Charcoal, Activated (Oral-Local) monograph; and/or (04) (24) (25)
- Furosemide (Systemic) in the Diuretics, Loop monograph. (26)

For more information on the management of overdose or unintentional ingestion, contact a Poison Control Center (see Poison Control Center Listing).

Clinical effects of overdose
The following effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate)—not necessarily inclusive:

Nausea or vomiting, severe (03)

nervousness or trembling, severe (03)

pulmonary edema (shortness of breath, severe) (03)

tachycardia (fast or irregular heartbeat, severe) (03)

Note: The dose required to produce overdose symptoms varies by individual. (03)

Treatment of overdose
Discontinuation of ritodrine is often all that is required if symptoms are not severe.

To enhance elimination—Renal dialysis for all dosage forms, if needed. Overdose of oral ritodrine may require induction of emesis, followed by administration of activated charcoal. {04}{24}

Specific treatment—Beta-adrenergic blocking agents are used to antagonize the actions of ritodrine and to treat arrhythmias. {03}{24} Loop diuretics are indicated as adjuncts to treat maternal pulmonary edema. {26}

Supportive care—Supportive measures such as establishing intravenous lines, correction of hydration or electrolyte balance, especially potassium or calcium, oxygenation, and support of ventilatory function are essential for maintaining the vital functions of the patient. {24}{25}

Patient Consultation
As an aid to patient consultation, refer to Advice for the Patient, Ritodrine (Systemic).

In providing consultation, consider emphasizing the following selected information (» = major clinical significance):

Before using this medication
» Conditions affecting use, especially:
  Sensitivity to ritodrine or sulfite preservative
  Other medications, especially beta-adrenergic agonists (other), beta-adrenergic blocking agents, or long-acting corticosteroids
  Other medical problems, especially abruptio placentae, cardiovascular disease (maternal), chorioamnionitis, diabetes mellitus, eclampsia, hemorrhage (maternal), hypertension (uncontrolled), hyperthyroidism (uncontrolled), hypovolemia, intrauterine fetal death, nonreassuring fetal status, pheochromocytoma, placenta previa, preeclampsia, or pulmonary hypertension

Proper use of this medication
» Proper dosing
  Missed dose: Taking if remembered within an hour or so; not taking if remembered later; not doubling doses

» Proper storage

Precautions while using this medication
» Checking with physician immediately if contractions begin again or in case of ruptured membranes
» Not taking other medications, especially OTC sympathomimetics, unless discussed with physician

**Side/adverse effects**
Signs of potential side effects, especially angina or cardiac disease (previously undiagnosed)(maternal), diastolic blood pressure reduction (maternal), hyperglycemia (maternal), tachycardia or other cardiac arrhythmias (maternal or fetal), agranulocytosis or leukopenia, hepatic function impairment or hepatitis, or pulmonary edema

**General Dosing Information**
Side effects, including tachycardia (maternal heart rate of greater than 120 or fetal heart rate of greater than 170 to 180), may be reduced without reducing ritodrine's effectiveness by slowing the rate of infusion or decreasing the dose. (03)

If labor persists despite administration of the maximum dose, it is recommended that ritodrine therapy be withdrawn; however, in cases of recurrence of unwanted preterm labor, ritodrine treatment may be repeated. (03)

Ritodrine should be discontinued as soon as labor is irreversible in order to allow for metabolic recovery (reversal of maternal hyperglycemia or fetal hypoglycemia or hypocalcemia) before delivery. (04) (08)

**For parenteral dosage forms only**
For better dose titration, it is recommended that ritodrine intravenous infusion be administered by means of a controlled infusion device, such as electronic volumetric controller, volumetric intravenous infusion pump, or intravenous microdrip chamber able to measure 60 drops per mL. The patient should be placed in the left lateral position to minimize hypotension. Fluids should be closely monitored to prevent circulatory fluid overload. (03)

Concurrent administration of excessive intravenous fluids or saline intravenous solutions with ritodrine therapy may cause circulatory fluid overload and maternal pulmonary edema. (03) Use of saline solutions, such as Sodium Chloride Injection USP, Ringer's Injection USP, or Hartmann's solution, should be avoided. (03)

Ambulation may be resumed gradually after 36 to 48 hours if contractions do not recur and patient is clinically stable. (25)

**Oral Dosage Forms**
RITODRINE HYDROCHLORIDE EXTENDED-RELEASE CAPSULES

Usual adult dose
Tocolytic
Initial: Oral, 40 mg thirty minutes before the intravenous infusion is discontinued, then 40 mg every eight hours for twenty-four hours.

Maintenance: Oral, 40 mg every eight to twelve hours until term (or until the 37th week of gestation) or as medical judgment dictates. (04)

Usual adult prescribing limits
Up to 120 mg a day. (04)

Strength(s) usually available
U.S.—
Not commercially available. (04)

Canada—

40 mg (Rx) [Yutopar S.R (04)]

Packaging and storage:
Store between 15 and 40 °C (59 and 104 °F), preferably below 30 °C (86 °F), unless otherwise specified by manufacturer. Store in a tight container. (04)

RITODRINE HYDROCHLORIDE TABLETS USP

Usual adult dose
Tocolytic
Initial: Oral, 10 mg thirty minutes before the intravenous infusion is discontinued, then 10 mg every two hours for twenty-four hours. (04)

Maintenance: Oral, 10 to 20 mg every four to six hours until term (or until the 37th week of gestation) or as medical judgment dictates. (04)

Usual adult prescribing limits
Up to 120 mg a day.

Strength(s) usually available
U.S.—
Not commercially available. (03)
Canada—

10 mg (Rx) [Yutopar]\textsuperscript{[04]}

Packaging and storage:
Store between 15 and 40 °C (59 and 104 °F), preferably below 30 °C (86 °F). Store in a tight container.

Parenteral Dosage Forms

RITODRINE HYDROCHLORIDE INJECTION USP

Usual adult dose
Tocolytic
Initial: Intravenous, 50 to 100 mcg (0.05 to 0.1 mg) per minute, increased every ten minutes as necessary in increments of 50 mcg (0.05 mg) to the effective dose that balances uterine response and unwanted effects (increased maternal heart rate and decreased blood pressure and increased fetal heart rate), or until the maternal heart rate reaches 130 beats per minute. \textsuperscript{[03]}

Maintenance: Intravenous, 150 to 350 mcg (0.15 to 0.35 mg) per minute at the lowest dose that maintains a relaxed uterus; however, as soon as labor is irreversible or the maximum dose of 350 mcg (0.35 mg) per minute is reached, ritodrine should be discontinued. \textsuperscript{[03]}

Note: Injection must be diluted before use unless premixed solution is used. \textsuperscript{[03]}
Intravenous infusion should be continued for twelve to forty-eight hours after uterine contractions stop. \textsuperscript{[03]}
Ritodrine should be administered in a separate intravenous line. Other medications of any type should not be administered via the same tubing. \textsuperscript{[22]}

Usual adult prescribing limits
Intravenous, up to 350 mcg (0.35 mg) per minute.

Strength(s) usually available
U.S.—

10 mg per mL (Rx) [Yutopar]\textsuperscript{[03]}/[Generic]\textsuperscript{[23]}
15 mg per mL (Rx) [Yutopar\textsuperscript{03}][Generic]\textsuperscript{23}

Canada—

10 mg per mL (Rx) [Yutopar\textsuperscript{08}]

**Packaging and storage:**
Store between 15 and 40°C (59 and 104 °F), preferably below 30 °C (86 °F).

**Preparation of dosage form:**
Ritodrine Hydrochloride Injection USP may be prepared for intravenous infusion by dilution of 150 mg in 500 mL of 5% Dextrose Injection USP to produce a solution containing 300 mcg (0.3 mg) of ritodrine hydrochloride per mL. \textsuperscript{03} More concentrated solutions may be prepared in cases where fluid restriction is necessary. \textsuperscript{03} In general, use of saline diluents, such as Sodium Chloride Injection USP, Ringer’s Injection USP, or Hartmann’s solution as the infusion solution should be avoided because of the risk of pulmonary edema. \textsuperscript{03}

**Stability:**
Ritodrine hydrochloride is stable for up to 48 hours following preparation of intravenous infusion containing 300 mcg (0.3 mg) per mL. \textsuperscript{03} Ritodrine Hydrochloride Injection USP should not be used if the solution is discolored or contains particulate matter. \textsuperscript{03}

**RITODRINE HYDROCHLORIDE IN 5% DEXTROSE INJECTION**

**Usual adult dose**
Tocolytic—See Ritodrine Hydrochloride Injection USP.

**Note:** Intravenous infusion should be continued for twelve to forty-eight hours after uterine contractions stop. \textsuperscript{22} Ritodrine should be administered in a separate intravenous line. Other medications of any type should not be administered via the same tubing. \textsuperscript{22}

**Usual adult prescribing limits**
See Ritodrine Hydrochloride Injection USP.

**Strength(s) usually available**
U.S.—

150 mg per 500 mL of 5% Dextrose Injection USP (premix) (Rx)[Generic]\textsuperscript{22}
Canada—
Not commercially available.

**Packaging and storage:**
Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Protect from freezing.  

**Note:** If more concentrated solutions are needed when fluid restriction is necessary, ritodrine hydrochloride injection should be used to prepare the solution.  

**Stability:**
Ritodrine Hydrochloride in 5% Dextrose Injection USP should not be used if the solution is discolored or contains particulate matter.

Revised: 08/01/1996

**References**


7. Barden TP, Peter JB, Merkatz IR. Ritodrine hydrochloride: betamimetic agent for use in preterm labor. I. Pharmacology, clinical history,


27. Panel comment, 5/96.
Premature labor (prophylaxis and treatment)—Intravenous ritodrine is indicated in the treatment of preterm labor in patients with a pregnancy of 20 or more weeks' gestation. Preterm labor is defined as rhythmic uterine contractions less than 10 minutes apart accompanied by progressive cervical effacement and/or dilation before the end of the 37th week of gestation. By prolonging gestation, ritodrine may reduce the incidence of neonatal mortality and respiratory distress syndrome by allowing time for the fetus to age and the fetal lung to mature or time for corticosteroids to be administered to the mother to enhance lung maturity in the fetus. Suitable patients must have intact amniotic membranes, cervical dilation usually but not always less than 4 centimeters (cm), and cervical effacement less than 80%. Use is not recommended prior to the 20th week of pregnancy.

—For intravenous ritodrine to be most effective, it is recommended that therapy begin as soon as the diagnosis of preterm labor is confirmed. Due to the potential risks for the patient and fetus, a physician experienced in the use of intravenous ritodrine should be present to intervene in case of an emergency.

—Intravenous ritodrine is less likely to inhibit labor when labor is advanced (cervical dilation more than 4 cm or effacement more than 80%) or when patient is close to term; its use, according to one study, may be best in pregnancies of less than 28 weeks. Risk-benefit should be cautiously assessed for those women in advanced labor or whose amniotic membranes have ruptured as safety and efficacy have not been established for these patients; use of ritodrine is not recommended. Risk of intrauterine infection when amniotic membranes are ruptured must be considered.

—Although oral ritodrine is indicated in the treatment of preterm labor in Canada, it is the opinion of the USP Obstetrics and Gynecology Advisory Panel that oral ritodrine cannot be recommended because its efficacy has not been established to be more effective than a placebo and alternative therapies may be more beneficial. Bed rest at home and early admission may be better alternatives than using oral ritodrine in treatment of preterm labor, including retreatment of recurrent preterm labor.

**Pharmacology/Pharmacokinetics**

**Physicochemical characteristics:**

**Molecular weight—**

323.82

**Mechanism of action/Effect:**

Ritodrine, a beta-2–adrenergic agonist, relaxes the uterus by stimulating the beta-2–adrenergic receptors of the uterine muscle, which causes a decrease in the intensity and frequency of uterine contractions. Specifically, ritodrine decreases uterine myometrial contractility by increasing cellular cyclic adenosine monophosphate (cAMP) and increasing cell membrane cytokines that increase and sequester intracellular calcium. Without intracellular calcium, the activation of contractile protein of smooth muscle is prevented and the uterus relaxes.

**Other actions/effects:**

In addition to stimulating the beta-2–adrenergic receptors of the uterine smooth muscle, ritodrine stimulates beta-adrenergic receptors of bronchial and vascular smooth muscles. The cardiostimulatory effects, including increased cardiac output, increased maternal and
fetal heart rates, and widening of the maternal pulse pressure, are probably due to relaxation of vascular smooth muscle. Relaxation of vascular smooth muscle stimulates the beta-1–adrenergic receptors and the reflex response to blood pressure. Also, during intravenous administration, ritodrine transiently increases maternal and fetal blood glucose and maternal plasma insulin concentrations. Other metabolic changes include increased cAMP, lactic acid, and free fatty acids, and decreased serum potassium concentration.

Distribution:
Ritodrine and its conjugates transfer via placenta into the fetal circulation; fetal and maternal concentrations may be equal.

Protein binding:
Low (almost exclusively to albumin).

Biotransformation:
Hepatic (inactive metabolites); metabolized to conjugates by both the mother and the fetus.

Half-life:
Intravenous—Nonpregnant females:
Distribution: 6 to 9 minutes.
Elimination: 1.7 to 2.6 hours.

Onset of action:
Intravenous—5 minutes (at effective dose).

Peak serum concentration
Intravenous—32 to 52 nanograms per mL after infusion of 9 mg over 60 minutes in nonpregnant females.

Elimination:
Renal (71 to 93%; conjugated metabolites; with 90% of dose eliminated within 24 hours).
In dialysis—Removable by dialysis.

Precautions to Consider
Cross-sensitivity and/or related problems
Patients sensitive to sulfites may be sensitive to intravenous ritodrine because of the sulfite preservative present.
Carcinogenicity/Tumorigenicity

Studies in rats receiving ritodrine orally found no increased risk of carcinogenicity or tumorigenicity.  

Pregnancy/Reproduction

Pregnancy—
Adequate and well-controlled studies in humans have not been done in women with a pregnancy of less than 20 weeks’ gestation. A small number of children 7 to 9 years of age who had been exposed to ritodrine prenatally were studied for up to 2 years and did not show increased risk of abnormalities. Risk-benefit to the fetus must be considered since ritodrine crosses the placenta. Neonatal hypoglycemia, tachycardia, and ileus have been reported; ketoacidosis has resulted in fetal death. Neonatal hypocalcemia and hypotension have occurred with other beta-adrenergic stimulants, although they have not been reported with ritodrine.

Studies in animals have not shown that ritodrine causes adverse effects on the fetus.

FDA Pregnancy Category B.

Drug interactions and/or related problems

The following drug interactions and/or related problems have been selected on the basis of their potential clinical significance (possible mechanism in parentheses where appropriate)—not necessarily inclusive (» = major clinical significance):

Note: Combinations containing any of the following medications, depending on the amount present, may also interact with this medication.

Anesthetics, potent, general or
Diazoxide, parenteral or
Magnesium sulfate or
Meperidine (may potentiate cardiovascular effects of intravenous ritodrine, especially cardiac arrhythmias or hypotension)

» Beta-adrenergic agonists, other or
Parasympatholytic agents, such as atropine or
Sympathomimetics (concurrent use may cause an additive sympathomimetic effect and greatly increase the likelihood of developing side effects, including hypertension from a parasympatholytic agent or cardiac problems from another tocolytic agent. A sufficient time interval should elapse prior to administering another sympathomimetic agent [90% of an intravenous dose is eliminated within 24 hours])

» Beta-adrenergic blocking agents (these agents antagonize the effects of ritodrine, and although agents with greater beta-1—adrenergic selectivity may be less antagonistic, concurrent use is not recommended)

» Corticosteroids, long-acting (corticosteroids are often used concurrently to enhance fetal
lung maturity; however, intravenous ritodrine and, to a lesser extent, corticosteroids each expand plasma volume by causing sodium retention. Intravenous ritodrine further increases plasma volume and may cause overhydration. One possible result of overhydration is maternal pulmonary edema, which has occurred with or without corticosteroid administration. Restricting and monitoring fluids helps prevent maternal pulmonary edema; however, on occurrence, discontinuance of ritodrine should be considered. Maternal ketoacidosis has also been reported with concurrent use of high doses of corticosteroids.

**Laboratory value alterations**
The following have been selected on the basis of their potential clinical significance (possible effect in parentheses where appropriate)—not necessarily inclusive (» = major clinical significance):

**With physiology/laboratory test values**
Alanine aminotransferase (ALT [SGPT]) or Aspartate aminotransferase (AST [SGOT]) (increased serum concentrations have been reported in less than 1% of patients receiving ritodrine and other beta-adrenergic agonists)

Blood pressure, maternal and Cardiac output, maternal and Heart rate, fetal and maternal (increased maternal heart rate, increased maternal systolic blood pressure, and decreased maternal diastolic blood pressure occur in 80 to 100% of patients treated with intravenous ritodrine; oral ritodrine frequently causes small increases in maternal heart rate but usually does not affect fetal heart rate or maternal blood pressure)

Free fatty acid, serum and Glucose, blood and Insulin, serum (concentrations may be transiently increased during intravenous infusion but usually return to pretreatment concentrations within 48 to 72 hours, even with continued infusion)

Potassium (serum concentration may be decreased during intravenous infusion; related to changes in glucose and insulin; maximum effect occurs within 2 hours after infusion is started and concentrations return to normal 30 minutes to 48 hours after withdrawal)

**Medical considerations/Contraindications**
The medical considerations/contraindications included have been selected on the basis of their potential clinical significance (reasons given in parentheses where appropriate)—not necessarily inclusive (» = major clinical significance).

**Except under special circumstances, this medication should not be used when the following medical problems exist:**
» Cardiovascular diseases, maternal, especially those associated with arrhythmias or
» Hyperthyroidism, uncontrolled or
» Hypovolemia\textsuperscript{03} or
» Pheochromocytoma\textsuperscript{03} (ritodrine may precipitate arrhythmias or heart failure; occult cardiac disease may be unmasked)

» Chorioamnionitis or\textsuperscript{03}\textsuperscript{21}
» Intrauterine fetal death\textsuperscript{03}\textsuperscript{21} or
» Nonreassuring fetal status\textsuperscript{27} (premature labor should not be suppressed for these problems or conditions \textsuperscript{21})

» Eclampsia and severe preeclampsia\textsuperscript{03}\textsuperscript{21} or
» Hypertension, uncontrolled or\textsuperscript{03}\textsuperscript{21}
» Pulmonary hypertension\textsuperscript{03} (ritodrine may aggravate these conditions and, if these conditions cannot be controlled, preterm labor should not be suppressed \textsuperscript{21})

\textbf{Risk-benefit should be considered when the following medical problems exist}
» Abruptio placentae\textsuperscript{27} or
» Hemorrhage, maternal or\textsuperscript{03}\textsuperscript{15}\textsuperscript{21}
» Placenta previa\textsuperscript{27} or
» Preeclampsia, mild to moderate\textsuperscript{03}\textsuperscript{21} (ritodrine may aggravate these conditions and, if they cannot be controlled, premature labor should not be suppressed \textsuperscript{21})

Allergy or sensitivity to ritodrine or sulfites\textsuperscript{03}
» Diabetes mellitus\textsuperscript{03}\textsuperscript{21} (may be aggravated; maternal ketoacidosis has also been reported, especially in patients with poorly controlled diabetes; insulin dose may need to be increased \textsuperscript{14}; neonatal glucose should be checked after delivery)

Hypertension or\textsuperscript{03}\textsuperscript{21}
Migraine headaches, or history of\textsuperscript{10} (these conditions may be aggravated; also, transient cerebral ischemia has been reported with the use of other beta-adrenergic agonist therapy in patients who had migraines during ritodrine administration \textsuperscript{03})

\textbf{Patient monitoring}
\textit{The following may be especially important in patient monitoring (other tests may be warranted in some patients, depending on condition; » = major clinical significance):}

Assessment of gestational age and fetal maturity\textsuperscript{03} (to diagnose preterm labor)

» Blood count determinations\textsuperscript{04} (patients using ritodrine long-term, especially intravenous use for 2 or 3 weeks, should be monitored for development of leukopenia or agranulocytosis \textsuperscript{04})

» Blood glucose, maternal and neonatal and\textsuperscript{03}
» Fluid and electrolyte status, maternal and neonatal\textsuperscript{03} (should be monitored carefully during prolonged intravenous administration, especially in diabetic patients or those receiving
corticosteroids, potassium-depleting diuretics, or digitalis glycosides; neonatal blood glucose should be determined promptly after delivery)

Cardiac function monitoring, maternal, such as electrocardiogram (ECG) and/or (03)
Pulmonary function monitoring, maternal (03) (baseline ECG should be done to rule out occult maternal cardiac disease (03); pulmonary function monitoring and an ECG should also be done immediately in patients complaining of chest pain or tightness during ritodrine therapy and ritodrine should be temporarily discontinued until ECG is assessed; a persistent high tachycardia [over 140 beats per minute] may be related to impending pulmonary edema (03)

Heart rate, fetal and (03)
Heart rate and blood pressure, maternal and (03)
Uterine activity (should be monitored frequently during intravenous administration (03))

Side/Adverse Effects

Note: Most adverse effects of ritodrine are related to its beta-adrenergic stimulating activity and are usually dose-related. (03)
Maternal ketoacidosis has been reported, especially in patients also receiving high doses of corticosteroids or in patients with poorly controlled diabetes mellitus (03).

The following side/adverse effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate)—not necessarily inclusive:

Those indicating need for medical attention
Incidence more frequent

Angina or cardiac disease, previously undiagnosed (chest pain or tightness)—15% with intravenous use (03)

Diastolic blood pressure reduction, maternal (lightheadedness or dizziness)—80 to 100% with intravenous use (03)[04]

Hyperglycemia, maternal (blurred vision; drowsiness; dry mouth; flushed, dry skin; fruit-like breath odor; increased frequency and volume of urination; ketones in urine; loss of appetite; somnolence; stomachache, nausea, or vomiting; tiredness; troubled breathing, rapid and deep; unconsciousness; unusual thirst)—80 to 100% with intravenous use, transient for 48 to 72 hours (03)

Pulmonary edema (shortness of breath)—15% with intravenous use

Tachycardia or other cardiac arrhythmias, maternal and fetal (fast or irregular heartbeat)—1% with oral use and 80 to 100% with intravenous use (03)[04]

Note: Increased cardiac output resulting from the use of beta-adrenergic agonists may result in cardiac arrhythmias or angina (with or without ECG changes) that has usually been associated with unrecognized cardiopulmonary disease, which may lead to myocardial ischemia, myocardial infarction, and possibly death. (03) (07)
At the recommended intravenous infusion rate in one study, the maternal and fetal heartbeat...
averaged 130 (range, 60 to 180) and 164 (range, 130 to 200) beats per minute, respectively. The maternal systolic and diastolic blood pressure measurements averaged 128 mm Hg (range, 96 to 162 mm Hg) and 48 mm Hg (range, 0 to 76 mm Hg), respectively. Only 1% of patients with persistent tachycardia or severely decreased diastolic blood pressure required withdrawal from the medication; these severe effects were managed successfully by dose reduction. Oral administration was associated with only a small increase in maternal heart rate and little or no effect on maternal blood pressure or fetal heart rate. Maternal hyperglycemia may cause fetal or neonatal hypoglycemia. Serious maternal pulmonary edema has occurred during intravenous administration of ritodrine or other beta-adrenergic agonists for premature labor or after delivery. Although the exact cause is unknown, it appears to be related to circulatory fluid overload with subsequent pulmonary edema, and has occurred more frequently with concurrent corticosteroid administration; maternal death has been reported with or without concomitantly administered corticosteroids. Other contributing factors may include hypokalemia, twin gestations, sustained tachycardia (> 140 beats per minute), undiagnosed cardiopulmonary disease, and catecholamine-induced cardiac injury. If pulmonary edema develops during administration, ritodrine should be discontinued.

### Incidence rare

**Agranulocytosis or leukopenia** (sore throat or fever)—with intravenous use for 2 to 3 weeks, reversible on discontinuation

**hepatic function impairment or hepatitis** (yellow eyes or skin)—reported in less than 1% of patients using ritodrine and other beta-adrenergic agonists

### Incidence more frequent

**Erythema** (redden skin)—10 to 50% with intravenous use

**headache** —10 to 50% with intravenous use

**nausea** —5 to 8% with oral use and 10 to 50% with intravenous use

**palpitations** (pounding or racing heartbeat)—10 to 15% with oral use and 33% with intravenous use

**trembling** —10 to 15% with oral use and 10 to 50% with intravenous use

**vomiting** —5 to 8% with oral use and 10 to 50% with intravenous use

### Incidence less frequent or rare

**Psychological symptoms** (anxiety, emotional upset, jitteriness, nervousness, restlessness)—5 to 8% with oral or intravenous use

**skin rash** —3 to 4% with oral use and rare with intravenous use
Those indicating possible maternal pulmonary edema and need for medical attention if they occur after medication is discontinued

*Shortness of breath*

**Overdose**
For specific information on the agents used in the management of ritodrine overdose, see:
- *Beta-adrenergic Blocking Agents (Systemic)* monograph; (03) (24) (25)
- *Charcoal, Activated (Oral-Local)* monograph; and/or (04) (24) (25)
- *Furosemide (Systemic)* in the *Diuretics, Loop* monograph. (26)

For more information on the management of overdose or unintentional ingestion, contact a Poison Control Center (see Poison Control Center Listing).

**Clinical effects of overdose**
The following effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate)—not necessarily inclusive:

*Nausea or vomiting, severe* (03)

*nervousness or trembling, severe* (03)

*pulmonary edema* (shortness of breath, severe) (03)

*tachycardia* (fast or irregular heartbeat, severe)

**Note:** The dose required to produce overdose symptoms varies by individual. (03)

**Treatment of overdose**
Discontinuation of ritodrine is often all that is required if symptoms are not severe.

To enhance elimination—Renal dialysis for all dosage forms, if needed. Overdose of oral ritodrine may require induction of emesis, followed by administration of activated charcoal. (04) (24)

Specific treatment—Beta-adrenergic blocking agents are used to antagonize the actions of ritodrine and to treat arrhythmias. (03) (24) Loop diuretics are indicated as adjuncts to treat maternal pulmonary edema. (26)

Supportive care—Supportive measures such as establishing intravenous lines, correction of hydration or electrolyte balance, especially potassium or calcium, oxygenation, and support of ventilatory function are essential for maintaining the vital functions of the patient. (24) (25)

**Patient Consultation**
As an aid to patient consultation, refer to *Advice for the Patient, Ritodrine (Systemic).*

In providing consultation, consider emphasizing the following selected information (* = major clinical significance):
Before using this medication
» Conditions affecting use, especially:
  Sensitivity to ritodrine or sulfite preservative
  Other medications, especially beta-adrenergic agonists (other), beta-adrenergic blocking agents, or long-acting corticosteroids
  Other medical problems, especially abruptio placentae, cardiovascular disease (maternal), chorioamnionitis, diabetes mellitus, eclampsia, hemorrhage (maternal), hypertension (uncontrolled), hyperthyroidism (uncontrolled), hypovolemia, intrauterine fetal death, nonreassuring fetal status, pheochromocytoma, placenta previa, preeclampsia, or pulmonary hypertension

Proper use of this medication
» Proper dosing
  Missed dose: Taking if remembered within an hour or so; not taking if remembered later; not doubling doses

» Proper storage

Precautions while using this medication
» Checking with physician immediately if contractions begin again or in case of ruptured membranes

» Not taking other medications, especially OTC sympathomimetics, unless discussed with physician

Side/adverse effects
Signs of potential side effects, especially angina or cardiac disease (previously undiagnosed)(maternal), diastolic blood pressure reduction (maternal), hyperglycemia (maternal), tachycardia or other cardiac arrhythmias (maternal or fetal), agranulocytosis or leukopenia, hepatic function impairment or hepatitis, or pulmonary edema

General Dosing Information
Side effects, including tachycardia (maternal heart rate of greater than 120 or fetal heart rate of greater than 170 to 180), may be reduced without reducing ritodrine's effectiveness by slowing the rate of infusion or decreasing the dose.  

If labor persists despite administration of the maximum dose, it is recommended that ritodrine therapy be withdrawn; however, in cases of recurrence of unwanted preterm labor, ritodrine treatment may be repeated.

Ritodrine should be discontinued as soon as labor is irreversible in order to allow for metabolic recovery (reversal of maternal hyperglycemia or fetal hypoglycemia or hypocalcemia) before delivery.

For parenteral dosage forms only
For better dose titration, it is recommended that ritodrine intravenous infusion be administered by means of a controlled infusion device, such as electronic volumetric controller, volumetric intravenous infusion pump, or intravenous microdrip chamber able to measure 60 drops per mL. The patient should be placed in the left lateral position to
minimize hypotension. Fluids should be closely monitored to prevent circulatory fluid overload. (03)

Concurrent administration of excessive intravenous fluids or saline intravenous solutions with ritodrine therapy may cause circulatory fluid overload and maternal pulmonary edema. (03) Use of saline solutions, such as Sodium Chloride Injection USP, Ringer's Injection USP, or Hartmann's solution, should be avoided. (03)

Ambulation may be resumed gradually after 36 to 48 hours if contractions do not recur and patient is clinically stable (25).

**Oral Dosage Forms**

**RITODRINE HYDROCHLORIDE EXTENDED-RELEASE CAPSULES**

**Usual adult dose**

Tocolytic

Initial: Oral, 40 mg thirty minutes before the intravenous infusion is discontinued, then 40 mg every eight hours for twenty-four hours.

Maintenance: Oral, 40 mg every eight to twelve hours until term (or until the 37th week of gestation) or as medical judgment dictates. (04)

**Usual adult prescribing limits**

Up to 120 mg a day. (04)

**Strength(s) usually available**

U.S.—

Not commercially available. (04)

Canada—

40 mg (Rx) [Yutopar S.R](04]

**Packaging and storage:**

Store between 15 and 40 °C (59 and 104 °F), preferably below 30 °C (86 °F), unless otherwise specified by manufacturer. Store in a tight container. (04)

**RITODRINE HYDROCHLORIDE TABLETS USP**

**Usual adult dose**

Tocolytic

Initial: Oral, 10 mg thirty minutes before the intravenous infusion is discontinued, then 10 mg every two hours for twenty-four hours. (04)

Maintenance: Oral, 10 to 20 mg every four to six hours until term (or until the 37th week of gestation) or as medical judgment dictates. (04)
Usual adult prescribing limits
Up to 120 mg a day.

Strength(s) usually available
U.S.—
Not commercially available. (03)

Canada—

10 mg (Rx) [Yutopar\textsuperscript{04}]

Packaging and storage:
Store between 15 and 40 °C (59 and 104 °F), preferably below 30 °C (86 °F). Store in a tight container.

Parenteral Dosage Forms

RITODRINE HYDROCHLORIDE INJECTION USP

Usual adult dose
Tocolytic
Initial: Intravenous, 50 to 100 mcg (0.05 to 0.1 mg) per minute, increased every ten minutes as necessary in increments of 50 mcg (0.05 mg) to the effective dose that balances uterine response and unwanted effects (increased maternal heart rate and decreased blood pressure and increased fetal heart rate), or until the maternal heart rate reaches 130 beats per minute. (03)

Maintenance: Intravenous, 150 to 350 mcg (0.15 to 0.35 mg) per minute at the lowest dose that maintains a relaxed uterus; however, as soon as labor is irreversible or the maximum dose of 350 mcg (0.35 mg) per minute is reached, ritodrine should be discontinued. (03)

Note: Injection must be diluted before use unless premixed solution is used. (03) Intravenous infusion should be continued for twelve to forty-eight hours after uterine contractions stop. (03) Ritodrine should be administered in a separate intravenous line. Other medications of any type should not be administered via the same tubing. (22)

Usual adult prescribing limits
Intravenous, up to 350 mcg (0.35 mg) per minute.

Strength(s) usually available
U.S.—

10 mg per mL (Rx) [Yutopar\textsuperscript{03}][Generic\textsuperscript{23}]

15 mg per mL (Rx) [Yutopar\textsuperscript{03}][Generic\textsuperscript{23}]
10 mg per mL (Rx) [Yutopar] 

Packaging and storage:
Store between 15 and 40°C (59 and 104 °F), preferably below 30 °C (86 °F).

Preparation of dosage form:
Ritodrine Hydrochloride Injection USP may be prepared for intravenous infusion by dilution of 150 mg in 500 mL of 5% Dextrose Injection USP to produce a solution containing 300 mcg (0.3 mg) of ritodrine hydrochloride per mL. More concentrated solutions may be prepared in cases where fluid restriction is necessary. In general, use of saline diluents, such as Sodium Chloride Injection USP, Ringer’s Injection USP, or Hartmann’s solution as the infusion solution should be avoided because of the risk of pulmonary edema.

Stability:
Ritodrine hydrochloride is stable for up to 48 hours following preparation of intravenous infusion containing 300 mcg (0.3 mg) per mL. Ritodrine Hydrochloride Injection USP should not be used if the solution is discolored or contains particulate matter.

RITODRINE HYDROCHLORIDE IN 5% DEXTROSE INJECTION

Usual adult dose
Tocolytic—See Ritodrine Hydrochloride Injection USP.

Note: Intravenous infusion should be continued for twelve to forty-eight hours after uterine contractions stop. Ritodrine should be administered in a separate intravenous line. Other medications of any type should not be administered via the same tubing.

Usual adult prescribing limits
See Ritodrine Hydrochloride Injection USP.

Strength(s) usually available
U.S.—

150 mg per 500 mL of 5% Dextrose Injection USP (premix) (Rx)[Generic]

Canada—
Not commercially available.

Packaging and storage:
Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Protect from freezing.

Note: If more concentrated solutions are needed when fluid restriction is necessary, ritodrine hydrochloride injection should be used to prepare the solution.

Stability:
Ritodrine Hydrochloride in 5% Dextrose Injection USP should not be used if the solution is discolored or contains particulate matter.\(^{[22]}\)

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References


27. Panel comment, 5/96.