

Only for the use of Medical Professionals

Ritopar[®]

Ritodrine hydrochloride

Description

Ritopar[®] is a preparation of Ritodrine hydrochloride. It is a β_2 -adrenergic agonist. It relaxes the uterus by stimulating the β_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.

Indications

Ritopar[®] is indicated for the treatment of uncomplicated premature labour.

Dosage and Administration

By intravenous infusion

Initially 50 micrograms/minute, increased gradually according to response by 50 micrograms/minute every 10 minutes until contractions stop or maternal heart rate reaches 140 beats/minute; continue for 12–48 hours after contractions cease (usual rate 150–350 micrograms/minute); maximum rate 350 micrograms/minute.

Intramuscular injection

10 mg in every 3–8 hours continued for 12–48 hours after contractions have ceased; then by mouth.

Oral maintenance treatment

One tablet (10 mg) may be given approximately 30 minutes before termination of intravenous therapy, repeated every 2 hours for 24 hours, followed by 10–20 mg every 4–6 hours, maximum oral dose 120 mg daily.

Use in pregnancy & lactation

Ritodrine is a drug of pregnancy category B. There are no adequate and well controlled studies of effects in pregnant women before 20 weeks gestation; therefore, this drug should not be used before the 20th week of pregnancy. Studies in pregnant women from the 20th week of gestation onwards have not shown increased risk of fetal abnormalities. Nonetheless, although clinical studies did not indicate a risk of permanent adverse fetal effects from ritodrine, the possibility cannot be excluded; therefore, it should be used only when clearly indicated. In frequently reported neonatal symptoms include hypoglycemia and ileus. In addition, hypocalcemia and hypotension have been reported in neonates whose mothers were treated with other beta mimetic agents. Caution should be exercised unless the potential benefit of treatment to the mother outweighs any possible risk of the infants.

Side-effects

The common side-effects of ritodrine hydrochloride are nausea, vomiting, flushing, sweating, tremor, hypokalaemia, tachycardia, palpitations, hypotension (left lateral position throughout infusion to minimize risk), uterine bleeding, pulmonary oedema; chest pain or tightness, arrhythmias and salivary gland enlargement. On prolonged administration for several weeks may cause leucopenia and agranulocytosis; liver function abnormalities including increased transaminases and hepatitis.

Precautions

It should be used cautiously in patient with suspected cardiac diseases, hypertension, hyperthyroidism, hypokalaemia, diabetes mellitus, mild to moderate preeclampsia, monitor blood pressure and pulse rate and avoid over-hydration during taking ritodrine hydrochloride.

Contra-indications

It is contraindicated in patients with known hypersensitivity to the active ingredient or any of the excipients of this component. β_2 -agonists are contra-indicated in cardiac disease and in patients with significant risk factors for myocardial ischaemia; they should also be avoided in antepartum haemorrhage, intra-uterine infection, intra-uterine fetal death, placenta praevia, abruptio placenta, threatened miscarriage, cord compression, and eclampsia or severe pre-eclampsia.

Overdosage

Symptoms of overdosage are tachycardia (maternal and fetal), palpitation, cardiac arrhythmia, hypotension, nervousness, tremor, nausea and vomiting. If an excess of ritodrine tablets is ingested, gastric lavage or induction of emesis should be carried out followed by administration of activated charcoal. When symptoms of overdose occur as a result of parenteral administration, ritodrine should be discontinued; an appropriate β -blocking agent may be used as an antidote.

Drug interactions

Increased risk of hypokalaemia if high doses of corticosteroids, diuretics (acetazolamide, loop diuretics and thiazides) or theophylline given with high doses of ritodrine. A sufficient time interval should elapse prior to administration of another sympathomimetic drug. β -adrenergic blocking drugs inhibit its action; coadministration of these drugs should, therefore, be avoided. With anesthetics used in surgery, the possibility that hypotensive effects may be potentiated should be considered.

Pharmaceutical precautions

Keep away from the reach of the children. Store in cool & dry place protected from light.

Package Quantities

Ritopar® 10 mg tablet: Each tablet contains Ritodrine hydrochloride USP 10 mg. Each commercial box contains 3 blister strips. Each strip contains 10 tablets.

Ritopar® 50 mg/5 ml injection: Each ampoule contains Ritodrine Hydrochloride USP 50 mg/5 ml. Ampoules are available in pack of 5 ampoules.

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