

# yutopar®

## Ritodrine Hydrochloride

YUTOPAR® (beta<sub>2</sub>-agonist) is an uterine relaxant that is active after oral, intramuscular and intravenous administration. It inhibits uterine contractions in frequency and intensity.

### INDICATIONS

Uncomplicated premature labour.

### DOSE

#### 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 per minute; continue for 12-48 hours after contractions cease (usual rate 150-350 micrograms/minute); maximum rate 350 micrograms/minute.

#### Intramuscular injections

10 mg every 3-8 hours continue for 12-48 hours after contractions have ceased; then by mouth (see notes above).

#### 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.

### CONTRA-INDICATIONS

Cardiac disease, eclampsia and severe pre-eclampsia, intra-uterine infection, intra-uterine fetal death, antepartum haemorrhage (requires immediate delivery), placenta praevia and cord compression pregnancy before 20th week.

### SIDE EFFECTS

Nausea, vomiting, flushing, sweating, tremor, hypokalaemia, tachycardia, palpitations, and hypotension (left lateral position throughout infusion to minimize risk), uterine bleeding (may be reversed with a non-selective beta-blocker), pulmonary oedema (see under cautions); chest pain or tightness (with or without ECG changes) and arrhythmias reported; salivary gland enlargement also reported; on prolonged administration (several weeks) leucopenia and agranulocytosis reported; liver function abnormalities (including increased transaminases and hepatitis) reported.

### CAUTIONS

Suspected cardiac disease (physician experienced in cardiology to assess), hypertension, hyperthyroidism, hypokalaemia (special risk with potassium-depleting diuretics), diabetes mellitus (closely monitor blood glucose during intravenous treatment), mild to moderate preeclampsia, monitor blood pressure and pulse rate (should not exceed 140 beats per minute) and avoid over-hydration.

**Important Remarks:** Although fatal pulmonary oedema associated with ritodrine infusion is almost certainly multifactorial in origin evidence suggests that fluid overload may be the most important single factor. To

avoid pulmonary oedema oral therapy following initial parental therapy is not recommended. Less effect can be expected if the membranes are ruptured or the dilation of the cervix exceeds 4 cm.

### INTERACTIONS

Increased risk of hypokalaemia if high doses of corticosteroids, diuretics (acetazolamide, loop diuretics and thiazides) or theophylline given with high doses of ritodrine.

### PRESENTATIONS

- Tablets: each tablet contains 10 mg Ritodrine Hydrochloride. Tablets are available in pack of 20 tablets.

- Ampoules of 5 ml: each ampoule contains 50 mg/5 ml Ritodrine Hydrochloride.

Ampoules are available in pack of 2 ampoules.

### DOSAGE SCHEDULE FOR YUTOPAR INFUSION

In the table below you will find several desired ritodrine dosage: (1) The number of ampoules used, (2) The infusion rate. The infusion rate can be regulated with an infusion pump or by the rate of drip. The recommended infusion liquids in isotonic glucose solution.

| Desired ritodrine dosages in mg/ml | Number of 5 ml ampoules* needed per 500 ml infusion liquid | Infusion rate in drops per minute |
|------------------------------------|--|-----------------------------------|
| 0.15                               |  | 15                                |
| 0.25                               |  | 25                                |
| 0.35                               | 2  | 35                                |
| 0.40                               |  | 40                                |

\* one 5 ml ampoule = 50 mg ritodrine

Storage: Ampoule: Store at temperature not below 0°C and not to exceed 25°C.

Tablets: Store below 30°C.

#### Ampoules

Manufactured by SPIMACO, Al-Qassim Pharmaceutical Plant, Saudi Arabia for SAJA Pharmaceuticals Jeddah, Saudi Arabia

#### Tablets

Saudi Arabian Japanese Pharmaceutical Company  
P.O.Box 42600, Jeddah 21551 - Saudi Arabia

### THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The Doctor and the Pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your Doctor.

### Keep medicament out of reach of children

Council of Arab Health Ministers  
Union of Arab Pharmacists