PRESCRIBING INFORMATION

Ryxon®Injection *IM/IV*

رائی زان انجکشن
آئی ایم / آئی وی

(Ceftriaxone for Injection USP)

Long-acting, broad-spectrum cephalosporin antibiotic for parenteral use

composition:
Ryxon Injection 2 g
Each vial contains:
Ceftriaxone.....2 g
(as Ceftriaxone Sodium USP)

Ryxon Injection 500mg
Each vial contains:
Ceftriaxone.....500mg
(as Ceftriaxone Sodium USP)

Ryxon Injection 1g
Each vial contains:
Ceftriaxone.....1g
(as Ceftriaxone Sodium USP)

Ryxon Injection 250 mg
Each vial contains:
Ceftriaxone.....250 mg
(as Ceftriaxone Sodium USP)

DESCRIPTION:
The bactericidal activity of Ceftriaxone results from inhibition of cell wall synthesis. Ceftriaxone exerts in-vitro activity against a wide range of gram-negative and gram-positive microorganisms. Ceftriaxone is highly stable to most β-lactamases, both penicillinases and cephalosporinases, of gram-positive and gram-negative bacteria.

PHARMACOKINETICS:
Ceftriaxone is characterized by an unusually long elimination half-life of approximately eight hours in healthy adults.
Elimination:
The elimination half-life in healthy adults is about eight hours. In infants aged less than eight days and in persons over 75 years of age, the average elimination half-life is about twice as long. In adults, 50-60% of Ceftriaxone is excreted unchanged by the kidneys, while 40-50% is excreted unchanged in the bile.

In patients with renal impairment or hepatic dysfunction, the pharmacokinetics of Ceftriaxone are only minimally altered and the elimination half-life is only slightly increased. If kidney function alone is impaired, biliary elimination of Ceftriaxone is increased; if liver function alone is impaired, renal elimination is increased.
Protein binding:
Ceftriaxone is reversibly bound to albumin, and the binding decreases with the increase in the concentration.
Penetration into the cerebrospinal fluid:
Ceftriaxone penetrates the inflamed meninges of infants and children. The average extent of diffusion in the cerebrospinal fluid in bacterial meningitis is 17% of the plasma concentration, i.e. approximately four times that in aseptic meningitis.

INDICATIONS:
Infections caused by pathogens sensitive to Ceftriaxone, e.g.:
- Sepsis;
- Meningitis;
- Abdominal infections (peritonitis, infections of the biliary and gastrointestinal tracts);
- Infections of the bones, joints, soft tissue, skin and of wounds;
- Infections in patients with impaired defence mechanisms;
- Renal and urinary tract infections;
- Respiratory tract infections, particularly pneumonia, and ear, nose and throat infections;
- Genital infections, including gonorrhea.
- Perioperative prophylaxis of infections.

DOSAGE AND ADMINISTRATION:
Adults and children over twelve years:
The usual dosage is 1-2 g of Ryxon administered once daily (every 24 hours). In severe cases or in infections caused by moderately sensitive organisms, the dosage may be raised to 4 g, administered once daily.
Neonates, infants and children up to twelve years:
The following dosage schedules are recommended for once daily administration:
Neonates (up to two weeks):
A daily dose of 20-50 mg/kg bodyweight, not to exceed 50 mg/kg,on account of the immaturity of the infant's enzyme systems. It is not necessary to differentiate between premature and infants born at term.
Infants and children (three weeks to twelve years):
A daily dose of 20-80 mg/kg. For children with body-weights of 50 kg or more, the usual adult dosage should be used. Intravenous doses of 50 mg or more per kg should be given by infusion over at least 30 minutes.

DIRECTIONS FOR USE:
Reconstituted solutions retain their physical and chemical stability for six hours at room temperature (or 24 hours at 5°C). As a general rule, however the solutions should be used immediately after preparation. The range in colour from pale yellow to amber, depending on the concentration and the length of storage. This characteristic of the active ingredient is of no significance for the efficacy or tolerance of the drug.

Intramuscular injection
For IM injection, Ryxon 250 mg & 500 mg is dissolved in 2 ml, and Ryxon 1 g in 3.5 ml, of 1% lidocaine solution and administered by deep intragluteal injection. It is recommended that not more than 1 g be injected on either side. The lidocaine solution must never be administered intravenously.

Intravenous injection:
For IV injection, Ryxon 500 mg is dissolved in 5 ml, and Ryxon 1 g in 10 ml, of sterile water for injection, and then administered by IV injection lasting two to four minutes to penicillin, the possibility of allergic cross-reactions should be borne in mind.

Although the relevent preclinical investigations revealed neither mutagenic nor teratogenic effects, Ryxon should not be used in pregnancy (particularly in the first trimester) unless absolutely indicated.

UNDESIRABLE EFFECTS:
Ryxon is generally well tolerated. During the use of Ryxon the following side effects, which were reversible either spontaneously or after withdrawal of the drug, have been observed:

SYSTEMIC SIDE EFFECTS:
Gastrointestinal complaints (about 2% of cases): loose stools or diarrhea, nausea, vomiting, stomatitis and glossitis. Hematological changes (about 2%): eosinophilia, leukopenia, granulocytopenia, hemolytic anemia, thrombocytopenia. Skin reactions (about 1%): exanthema, allergic dermatitis, pruritus, urticaria, edema, erythema multiforme.

STORAGE:
Store at temperature 15 to 30 °C away from light and moisture.

PRESENTATION:
Each pack of Ryxon IM 250 mg contains :
1 vial with 250 mg ceftriaxone + 1 Amp. with 2 ml lidocaine 1%.

Each pack of Ryxon IM 500 mg contains:
1 vial with 500 mg ceftriaxone + 1 Amp. with 2 ml lidocaine 1%.

Each pack of Ryxon IM 1 g contains:
1 vial with 1 g ceftriaxone + 1 Amp. with 3.5 ml lidocaine 1%.

Each pack of Ryxon IV 500 mg contains:
1 vial with 500 mg ceftriaxone + 1 Amp. with 5 ml of sterile water for injection.

Each pack of Ryxon IV 1 g contains:
1 vial with 1g ceftriaxone + 1 Amp. with 10 ml of sterile water for injection.

Each pack of Ryxon IV 2 g contains:
1 vial with 2g ceftriaxone + 2 Amp. with 10 ml of sterile water for injection.

خوراک اور طریقہ استعمال
بالغ اور 12 سال سے زائد عمر کے بچے:
عمومی خوراک 1 سے 2 گرام روزانہ انجکشن بوسیہ کے حساب سے دیں، حالت زیادہ خراب ہونے کی
صورت میں روزانہ زان انجکشن 4 گرام تک دن میں دیا جا سکتا ہے۔
نوزائیدہ بچے 12 سال تک کے بچے:
دن میں ایک دفعہ کا تجویز کردہ طریقہ استعمال درج ذیل ہے:
نوزائیدہ (2 ہفتے تک) 20 سے 50 ملی گرام/کلوگرام جسمانی وزن
کے مطابق روزانہ دیا جا سکتا ہے۔ 50 ملی گرام/کلوگرام سے تجاوز نہ کریں۔
3 ماہ سے 12 سال تک کے بچے:
20 سے 80 ملی گرام/کلوگرام جسمانی وزن کے مطابق روزانہ دیا جا سکتا ہے۔
50 کلوگرام یا اس سے زائد وزن کے بچوں کو بالغوں کی عمومی مقدار خوراک دی جا سکتی ہے۔
انتظامیہ شدہ خوراک 80 ملی گرام یا اس سے زائد ملی کلوگرام کم از کم 30 منٹ تک بذریعہ انفیوژن دی جائے۔
ہدایات برائے استعمال
تیار شدہ محلول کمرے کے درجہ حرارت پر 4 گھنٹے یا 5 ڈگری سینٹی گریڈ پر 24 گھنٹوں تک قابل استعمال ہے۔
تاہم تیار شدہ محلول فوری طور پر استعمال کر لینا چاہیے تیار شدہ محلول کی رنگت کا ہلکے پیلے رنگ سے گہرے پیلے رنگ کی ہوتی ہے جو کارآمد ادویہ کی مقدار اور
اس کی مدت دستیاب پر ہے۔ محلول کی اس تبدیلی رنگت کا دوا کی افادیت پر کوئی اثر نہیں پڑتا۔
انتراعضلی انجکشن:
آئی۔ایم انجکشن کے لیے 250 سے 500 ملی گرام زان 2 ملی لیٹر میں اور 1 گرام زان 3.5 ملی لیٹر 1% لیڈوکین محلول میں حل کر کے کولہوں
کے پٹھوں میں لگائیں۔ لیڈوکین محلول کسی بھی صورت میں بذریعہ آئی وی نہ دیا جائے۔
انتراوریدی انجکشن
آئی وی انجکشن کے لیے 500 ملی گرام زان 5 ملی لیٹر میں اور ایک گرام زان 10 ملی لیٹر اور 2 گرام زان 20 ملی لیٹر
اسٹرائل واٹر (sterile water) میں حل کر کے دو سے چار منٹ میں آئی وی لگائیں۔
نوٹ:
حاملہ خواتین (بالخصوص ابتدائی 3 ماہ کی حاملہ) بلا ضرورت زان کا استعمال منع ہے۔
اسٹوریج:
15 سے 30 ڈگری سینٹی گریڈ درجہ حرارت پر روشنی اور نمی سے بچا کر رکھیے

brookes

Manufactured by:
Brookes Pharma Private Limited
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ISO 9001
ISO14001
OHSAS 18001
BUREAU VERITAS
Certification