Rakxon™

Ceftriaxone

Composition:
Rakxon™ 250 mg IM Injection: Each vial contains Sterile Ceftriaxone Sodium USP equivalent to Ceftriaxone 250 mg.
Rakxon™ 500 mg IM Injection: Each vial contains Sterile Ceftriaxone Sodium USP equivalent to Ceftriaxone 500 mg.
Rakxon™ 1 g IM/IV Injection: Each vial contains Sterile Ceftriaxone Sodium USP equivalent to Ceftriaxone 1 gm.
Rakxon™ 2 g IV Injection: Each vial contains Sterile Ceftriaxone Sodium USP equivalent to Ceftriaxone 2 gm.

Description:
Rakxon™ (Ceftriaxone) is a third generation, semisynthetic, broad-spectrum cephalosporin antibiotic for intravenous or intramuscular administration. It has a remarkable stability against β-lactamases, Penicillanases and Cephalosporinases of both Gram-positive and Gram-negative bacteria. **Rakxon**™ is bactericidal in action as it inhibits the synthesis of the bacterial cell wall. It eliminates bacteria that cause many kinds of infections, including lung, skin, bone, joint, stomach, blood, and urinary tract infections. This medication is sometimes prescribed for other uses. **Rakxon**™ is not absorbed after oral administration and must be given parenterally. Following IM or IV administration, **Rakxon**™ is widely distributed into body tissues and fluids. **Rakxon**™ is eliminated mainly as unchanged form, approximately 60% of the dose being excreted in the urine and the reminder via the biliary and intestine tracts. A remarkable feature of **Rakxon**™ is its relatively long plasma elimination half-life of about 6 to 9 hours, which makes single or once-daily dosage of the drug appropriate for most patients. **Rakxon**™ is interfering with the synthesis of bacterial cell wall by inhibiting transpeptidase enzyme. As a result, the bacterial cell wall is weakened and the cell swells & ruptures.

Indications:
Rakxon™ is indicated for the treatment of the following major infections when caused by susceptible organisms:
Renal and urinary tract infections
Pneumonia or other lower respiratory tract infections
Gonococcal infections
Skin and soft tissue infections
Bone and joint infections
Bacterial meningitis
ENT infections
Infections in cancer patients
Surgical prophylaxis
Typhoid fever
Other serious bacterial infections like septicemia, peritonitis, GIT or billiary tract infections etc.

Dosage & Administration:
Rakxon™ may be administered by deep intramuscular injection or slow intravenous injection. Dosage and mode of administration should be determined by severity of infection, susceptibility of causative organisms and the patient's condition. Under most circumstances once-daily dose or in the specified indications, a single dose will give satisfactory therapeutic results. ***Neonate:*** For the treatment of skin and skin structure infections, the recommended total daily dose is 50 to 75 mg/kg given once a day (or in equally divided doses twice a day). The total daily doses should not exceed 2 gm. For the treatment of acute bacterial otitis media, a single intramuscular dose of 50 mg/kg (not to exceed 1 gram) is recommended. ***Infant and child under 50 kg:*** 20-50 mg/kg daily; up to 80 mg/kg daily. In severe infections, doses of 50 mg/kg and over by intravenous infusion only; For otitis media due to ***H. influenza,*** doses are from 75 to 100 mg/kg/day administered in equally divided doses every 6 or 12 hours, but should not exceed 4 gm per day. Dosage for children should not exceed dosage recommended for adults. 50 kg and over: adult dose should be recommended. ***Adult and children (12 years and over):*** In normal infection 1gm daily; 2-4 gm daily in severe infections. The total daily dose should not exceed 4 gm. ***Elderly:*** Dosage adjustment is not required if hepatic and renal functions are satisfactory. ***Surgical prophylaxis:*** By deep intramuscular injection or by intravenous injection over at least 2-4 minutes, 1 gm at induction, Continue for ≥ 2 days after signs and symptoms of infection have disappeared. Usual duration is 4 to 14 days; in complicated infections, longer therapy may be required. Serious urinary tract infections, including prostatitis; 500 mg every 6 hours or 1 gm every 12 hours may be administered. Larger doses (up to 1 gm every 6 hours) may be given for severe or chronic infections.

OR AS DIRECTED BY THE PHYSICIAN.

Side Effects:
Ceftriaxone is generally well tolerated. A few side effects such as ***Local Reactions:*** pain, induration, tenderness, phlebitis, reaction at injection site; ***Hypersensitivity:*** rash, pruritus, fever or chills; ***Hematologic:*** eosinophilia, thrombocytopenia, leucopenia, anemia, hemolytic anemia, neutropenia, lymphopenia and prolongation of the prothrombin time; ***Gastrointestinal:*** diarrhea, nausea or vomiting and dysgeusia, the onset of pseudomembranous colitis symptoms; ***Hepatic:*** elevations of SGOT or SGPT, alkaline phosphatase and bilirubin; ***Renal:*** elevations of the blood urea nitrogen (BUN), creatinine and the presence of casts in the urine; ***Central Nervous System:*** headache or dizziness; ***Genitourinary:*** moniliasis or vaginitis; ***Miscellaneous:*** diaphoresis and flushing are reported. Other rarely observed adverse reactions include abdominal pain, allergic pneumonitis, anaphylaxis, basophilia, biliary lithiasis, bronchospasm, dyspepsia, epistaxis, flatulence, gallbladder sludge, glycosuria, hematuria, leukocytosis, lymphocytosis, monocytosis, nephrolithiasis, palpitations, renal precipitations, seizures, and serum sickness.

Precautions:
Cephalosporins can cause diarrhea. If diarrhea becomes severe, doctor should be reported. Diabetic patient may get a false-positive result for sugar in urine. The dose of diabetic medicine should not be changed without consulting the doctor. The admixture of beta-lactam antibacterials (penicillins and cephalosporins) and aminoglycosides may result in substantial mutual inactivation. If they are administered concurrently, they should be administered in separate sites. In severe renal impairment accompanied by hepatic insufficiency, dosage reduction is required.

Use in Pregnancy and Lactation:
Pregnancy: Its safety in human pregnancy has not been established. Therefore it is indicated in pregnancy only if clearly needed. ***Lactation:*** Ceftriaxone is excreted in breast milk at low concentrations. Therefore, caution should be exercised when Ceftriaxone is administered to a nursing mother.

Drug Interactions:
Ceftriaxone has an N-methylthiotriazine side-chain and may have the potential to increase the effects of anticoagulants and to cause a disulfiram-like reaction with alcohol, as many cephalosporins with the related N-methylthiotetrazole side chain. Unlike many cephalosporins, Probenecid does not affect the renal excretion of Ceftriaxone.

Contraindications:
Ceftriaxone is contraindicated in patients with known hypersensitivity to cephalosporin antibiotics.

Storage Condition:
Store in a cool & dry place, protect from light. Keep out of the reach of children.

Presentation:
Rakxon™ 250 mg IM Injection: Each box contains 1 combipack and a 5 ml sterile disposable syringe. Each combipack contains 1 vial and 1 ampoule of 2 ml Lidocaine BP 1%.
Rakxon™ 500 mg IM Injection: Each box contains 1 combipack and a 5 ml sterile disposable syringe. Each combipack contains 1 vial and 1 ampoule of 2 ml Lidocaine BP 1%.
Rakxon™ 1 g IM Injection: Each box contains 1 combipack and a 5 ml sterile disposable syringe. Each combipack contains 1 vial and 1 ampoule of 3.5 ml Lidocaine BP 1%.
Rakxon™ 1 g IV Injection: Each box contains 1 combipack and a 10 ml sterile disposable syringe. Each combipack contains 1 vial and 1 ampoule of 10 ml Water for Injection BP.
Rakxon™ 2 g IV Injection: Each box contains 1 combipack and a 20 ml sterile disposable syringe. Each combipack contains 1 vial and 2 ampoules of 10 ml Water for Injection BP.

Manufactured by:
Popular Pharmaceuticals Ltd. for
Julphar Bangladesh Ltd.
Sreepur, Gazipur, Bangladesh.