Ceftriaxone for Injection, USP

**PHARMACY BULK PACKAGE**

**INDICATIONS AND USAGE**

Ceftriaxone for injection, USP is indicated for the treatment of serious infections caused by susceptible strains of the designated microorganisms in the conditions listed in INDICATIONS AND USAGE. Ceftriaxone for injection, USP is especially useful in situations where prolonged bactericidal activity is desirable, such as serious infections involving the abdomen, central nervous system (including meningitis), and bone and joint. Ceftriaxone for injection, USP is also indicated for the treatment of bone and joint infections caused by susceptible strains of Propionibacterium acnes.

**CONTRAINDICATIONS**

Ceftriaxone for injection is contraindicated in patients with a history of anaphylactic reactions to ceftriaxone or to other cephalosporins. Ceftriaxone for injection should also be used with caution in patients with a history of penicillin allergy. Because of the risk of superinfection, prolonged or repeated courses of therapy should be reserved for serious infections or infections that may be resistant to other antibiotics. Ceftriaxone for injection should not be used in patients who are known to have serum sickness, as cross-reactivity may occur with other cephalosporins.

**PRECAUTIONS**

Ceftriaxone for injection should be used with caution in the following conditions:

- **Renal Impairment:** The dosage of ceftriaxone for injection should be adjusted in patients with renal impairment. The dosage should be reduced in patients with creatinine clearance less than 50 mL/min and not administered in patients with creatinine clearance less than 30 mL/min.

- **Hepatic Impairment:** There is no information available regarding the use of ceftriaxone for injection in patients with hepatic impairment.

- **Neonates:** Ceftriaxone for injection is contraindicated in neonates due to the risk of reactive airway disease and respiratory insufficiency. Ceftriaxone for injection should be administered with caution in neonates due to the potential for allergenic reactions and anaphylactic reactions.

**ADVERSE REACTIONS**

The most common adverse reactions reported with ceftriaxone for injection include diarrhea, nausea, vomiting, and pruritus. Other adverse reactions reported include rash, urticaria, angioedema, Stevens-Johnson syndrome, and toxic epidermal necrolysis. These reactions are generally self-limiting and resolve with discontinuation of therapy. However, severe reactions such as anaphylaxis, angioedema, anaphylactic shock, and toxic epidermal necrolysis have been reported.

**DOSE AND ADMINISTRATION**

Ceftriaxone for injection should be administered intravenously or intramuscularly. The dosage and frequency of administration should be determined by the patient's clinical response and the severity of the infection. The recommended dosage and frequency of administration may vary depending on the patient's age, weight, and medical condition.

**HOW SUPPLIED**

Ceftriaxone for injection, USP is supplied in vials of 1 g and 2 g in single-dose injection, each containing 0.9 mL of sterile water for injection. The vials are available in packs of 10 and 50.

**SUPPLEMENTARY INFORMATION**

Ceftriaxone for injection, USP has been the subject of extensive research and development, and is currently approved by the United States Food and Drug Administration (FDA) for the treatment of a wide range of infections. It is a member of the third-generation cephalosporins, which are characterized by their broad spectrum of activity and excellent pharmacokinetic properties. Ceftriaxone for injection, USP is distributed by Pfizer Inc., New York, NY 10016.
A small number of cases of fetal loss in which a crystalline material was observed in the lungs and kidneys of infants who died were reported. In some of these cases, the crystalline nature of the material was confirmed by reconstituting ceftriaxone for injection in saline to form a suspension. In all cases, the same crystalline material was found in the lungs and kidneys of infants who died. These have not been similar reports in patients other than neonates.

Hypersensitivity

Before TREATMENT with CEFTRIAXONE for INJECTION is INITIATED, CAREFUL HISTORY SHOULD BE DETERMINED TO CATEGORIZE THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO BETA-LACTAM ANTIBIOTICS, INCLUDING CEPHALOSPORINS AND PENICILLINS. IF A REACTION TO CEFTRIAXONE for INJECTION is INITIATED, IMMEDIATE MEDICAL ATTENTION SHOULD BE INSTITUTED. ANY ALLERGIC REACTION TO TREATMENT with CEFTRIAXONE for INJECTION may REQUIRE THE USE OF SUBCUTANEOUS EPINEPHRINE AND OTHER EMERGENCY MEASURES. As with other cephalosporins, anaphylaxis has been reported, but there is not a known anaphylactic or previously exposed.

Interaction with Carbohydrate-containing Materials

Ceftriaxone for injection may be used with carbohydrate-containing fluids in all of the following clinical situations. Caution should be exercised when using Ceftriaxone for injection with any carbohydrate-containing fluids as the rate of infusion must be increased in order to achieve the desired serum levels. Although transient elevations of BUN and serum creatinine have been observed, at the recommended}

CEFTRIAXONE for injection has been shown to be effective in the treatment of serious infections caused by drug-resistant bacteria. These infections may be associated with patients who have had recurrent infections or have been treated with antibiotics for prolonged periods of time, leading to resistance. Ceftriaxone for injection is effective against a broad spectrum of gram-negative and gram-positive bacteria, including those commonly associated with these infections.

Hepatitis

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