



## Bharat Parenterals Limited

Registered Office & Works:  
Vill. Haripura, Ta. Savli, Dist. Vadodara - 391520 (Guj.) India.  
Tele Fax : (02667)-251679, 251680, 251669, 99099 28332.  
E-mail: bplbrd@bplindia.in, info@bplindia.in, Web.: www.bplindia.in  
CIN NO: U24231GJ1992PLC018237

### ACTAZONE 1 g - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

#### Summary of Product Characteristics (SmPC)

##### 1. Name of the medicinal product:

**Generic Name/INN Name:** Ceftriaxone For Injection USP 1g

**Trade Name:** Actazone 1 g

##### Strength:

Each vial contains:

Ceftriaxone Sodium USP

Eq. to Anhydrous Ceftriaxone 1000 mg

##### 2. Qualitative and Quantitative composition:

Sr. No.	Ingredients.	Spec.	Std. Qty (mg/ vial)	% w/w
1.	Sterile Ceftriaxone Sodium USP eq. to Anhydrous Ceftriaxone *	USP	1000 mg	100.00 %

\* Add the calculated quantity based on the Assay (potency) and Water content of sterile Ceftriaxone Sodium USP.

##### 3. Pharmaceutical form:

**Dosage Form:** Powder For Injection

**Visual & Physical characteristics of the product:** A white crystalline powder filled in an intactly sealed clear glass vials.

##### 4. Clinical particulars:

###### 4.1. Therapeutic indications:

Ceftriaxone is indicated for the treatment of the following infections in adults and children including term neonates (from birth):

Bacterial Meningitis

Community acquired pneumonia

Hospital acquired pneumonia

Acute otitis media

Intra-abdominal infections

Complicated urinary tract infections (including pyelonephritis)





**ACTAZONE 1 g - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)**

Infections of bones and joints

Complicated skin and soft tissue infections

Gonorrhoea

Syphilis

Bacterial endocarditis

Ceftriaxone may be used:

For treatment of acute exacerbations of chronic obstructive pulmonary disease in adults

For treatment of disseminated Lyme borreliosis (early (stage II) and late (stage III)) in adults and children including neonates from 15 days of age.

For pre-operative prophylaxis of surgical site infections

In the management of neutropenic patients with fever that is suspected to be due to a bacterial infection

In the treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.

Ceftriaxone should be co-administered with other antibacterial agents whenever the possible range of causative bacteria would not fall within its spectrum.

Consideration should be given to official local guidance on the appropriate use of antibacterial agents.

**4.2. Posology and method of administration:**

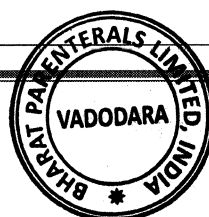
**Posology**

The dose depends on the severity, susceptibility, site and type of infection and on the age and hepato-renal function of the patient.

The doses recommended in the tables below are the generally recommended doses in these indications. In particularly severe cases, doses at the higher end of the recommended range should be considered.

Adults and children over 12 years of age ( $\geq$  50 kg)

Ceftriaxone Dosage*	Treatment frequency**	Indications
1-2 g	Once daily	Community acquired pneumonia
		Acute exacerbations of chronic obstructive pulmonary disease



**ACTAZONE 1 g - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)**

		Intra-abdominal infections
		Complicated urinary tract infections (including pyelonephritis)
2 g	Once daily	Hospital acquired pneumonia
		Complicated skin and soft tissue infections
		Infections of bones and joints
2-4 g	Once daily	Management of neutropenic patients with fever that is suspected to be due to a bacterial infection
		Bacterial endocarditis
		Bacterial meningitis

In documented bacteraemia, the higher end of the recommended dose range should be considered

Twice daily (12 hourly) administration may be considered where doses greater than 2g daily are administered.

Indications for adults and children over 12 years of age ( $\geq 50$  kg) that require specific dosage schedules:

**Acute otitis media**

A single intramuscular dose of Ceftriaxone 1-2 g can be given. Limited data suggest that in cases where the patient is severely ill or previous therapy has failed, Ceftriaxone may be effective when given as an intramuscular dose of 1-2 g daily for 3 days.

**Pre-operative prophylaxis of surgical site infections**

2 g as a single pre-operative dose.

**Gonorrhoea**

500 mg as a single intramuscular dose.

**Syphilis**

The generally recommended doses are 500 mg-1 g once daily increased to 2 g once daily for neurosyphilis for 10-14 days. The dose recommendations in syphilis, including neurosyphilis, are based on limited data. National or local guidance should be taken into consideration.

Disseminated Lyme borreliosis (early [Stage II] and late [Stage III]) 2 g once daily for 14-21 days. The recommended treatment durations vary and national or local guidelines should be taken into consideration.

**Paediatric population**

**ACTAZONE 1 g - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)**

Neonates, infants and children 15 days to 12 years of age (< 50 kg)

For children with bodyweight of 50 kg or more, the usual adult dosage should be given.

Ceftriaxon	Treatment	Indications
50-80 mg/kg	Once daily	Intra-abdominal infections
		Complicated urinary tract infections (including pyelonephritis)
		Community acquired pneumonia
		Hospital acquired pneumonia
50-100 mg/kg (Max 4 g)	Once daily	Complicated skin and soft tissue infections
		Infections of bones and joints
		Management of neutropenic patients with fever that is suspected to be due to a bacterial
80-100 mg/kg (max 4 g)	Once daily	Bacterial meningitis
100 mg/kg (max 4 g)	Once daily	Bacterial endocarditis

In documented bacteraemia, the higher end of the recommended dose range should be considered.

Twice daily (12 hourly) administration may be considered where doses greater than 2 g daily are administered.

Indications for neonates, infants and children 15 days to 12 years (< 50 kg) that require specific dosage schedules:

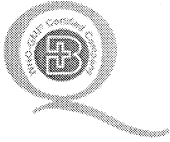
**Acute otitis media**

For initial treatment of acute otitis media, a single intramuscular dose of Ceftriaxone 50 mg/kg can be given. Limited data suggest that in cases where the child is severely ill or initial therapy has failed, Ceftriaxone may be effective when given as an intramuscular dose of 50 mg/kg daily for 3 days.

**Pre-operative prophylaxis of surgical site infections**

50-80 mg/kg as a single pre-operative dose.

**Syphilis**



## Bharat Parenterals Limited

Registered Office & Works:  
Vill. Haripura, Ta. Savli, Dist. Vadodara - 391520 (Guj.) India.  
Tele Fax : (02667)-251679, 251680, 251669, 99099 28332.  
E-mail: bplbrd@bplindia.in, info@bplindia.in, Web.: www.bplindia.in  
CIN NO: U24231GJ1992PLC018237

### ACTAZONE 1 g - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The generally recommended doses are 75-100 mg/kg (max 4 g) once daily for 10-14 days. The dose recommendations in syphilis, including neurosyphilis, are based on very limited data. National or local guidance should be taken into consideration.

Disseminated Lyme borreliosis (early [Stage II] and late [Stage III])

50-80 mg/kg once daily for 14-21 days. The recommended treatment durations vary and national or local guidelines should be taken into consideration.

Neonates 0-14 days

Ceftriaxone is contraindicated in premature neonates up to a postmenstrual age of 41 weeks (gestational age + chronological age).

Ceftriaxone dosage*	Treatment	Indications
20-50 mg/kg	Once daily	Intra-abdominal infections
		Complicated skin and soft tissue infections
		Complicated urinary tract infections (including pyelonephritis)
		Community acquired pneumonia
		Hospital acquired pneumonia
		Infections of bones and joints
		Management of neutropenic patients with fever that is suspected to be due to a bacterial infection
50 mg/kg	Once daily	Bacterial meningitis
		Bacterial endocarditis

In documented bacteraemia, the higher end of the recommended dose range should be considered.

A maximum daily dose of 50 mg/kg should not be exceeded.

Indications for neonates 0-14 days that require specific dosage schedules:

Acute otitis media

For initial treatment of acute otitis media, a single intramuscular dose of Ceftriaxone 50 mg/kg can be given.

Pre-operative prophylaxis of surgical site infections

20-50 mg/kg as a single pre-operative dose.

Syphilis

