SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion contains 2.10 g of Cefoxitin sodium equivalent to 2 g Cefoxitin.

3 PHARMACEUTICAL FORM

Powder for solution for injection or infusion.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion is indicated for the treatment of the following infections caused by sensitive bacteria: peritonitis and other intra-abdominal and intrapelvic infections; gonorrhoea; female genital tract infections; septicaemia; urinary tract infections; respiratory tract infections; bone and joint infections; and skin and soft-tissue infections.

'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' is a broad-spectrum, bactericidal antibiotic indicated for the treatment of infections caused by susceptible strains of Gram-positive and Gram-negative pathogens both aerobic and anaerobic.

'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' is indicated for the treatment of mixed infections caused by susceptible strains of aerobic and anaerobic bacteria. The majority of these mixed infections are associated with contamination by faecal flora as well as flora originating from the vagina, skin, and mouth. In these mixed infections, *Bacteroides fragilis* is the most commonly encountered anaerobic pathogen and is usually resistant to aminoglycosides, cephalosporins, and virtually all penicillins. However, *Bacteroides fragilis* is usually susceptible to 'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion'.

'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' is indicated for adjunctive therapy in the surgical treatment of infections, including abscesses, infection complicating hollow visceral perforations, cutaneous infections, and infections of serous surfaces, whether caused by aerobes, mixed aerobes and anaerobes, or anaerobes.

Consideration should be given to official local guidance (e.g. national recommendations) on the appropriate use of antibacterial agents.

Susceptibility of the causative organism to the treatment should be tested (if possible), although therapy may be initiated before the results are available.

Prophylaxis

'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' is indicated for the prevention of certain post- operative infections in patients undergoing contaminated or potentially contaminated surgical procedures, or where the occurrence of post-operative infection could be especially serious.

4.2 Posology and method of administration

'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' may be administered intravenously or intramuscularly. (See reconstitution directions for each route below.) Dosage and route of administration should be determined by severity of infection, susceptibility of the causative organisms, and condition of the patient.

Therapy may be started while awaiting the results of susceptibility testing.

Adults

Dosage: The usual adult dosage is 1 g or 2 g of 'Cefoxitin Powder for Solution for Injection or Infusion' every eight hours. (See chart 'Usual adult dosage'.)

Usual adult dosage

Type of infection	***Dose***	***Frequency***	***Total daily dosage***
Uncomplicated	1g	Every 8 hours (occasionally every 6 hours)	3g (4g)
Moderately severe or severe	2g	Every 8 hours (occasionally every 6 hours)	6g (8g)
Infections generally needing antibiotics in higher dosage	3g (2g)	Every 6 hours (Every 4 hours)	12g

In adults with renal insufficiency, an initial loading dose of 1 g to 2 g may be given. After a loading dose, the following recommendations for maintenance dosage may be used as a guide.

Maintenance dosage of 'Cefoxitin Powder for Solution for Injection or Infusion' *in adults with reduced renal function*

Renal function	***Creatinine clearance ml/min***	***Dose***	***Frequency***

Mild impairment	50-30	1-2 g	Every 8-12 hours
Moderate impairment	29-10	1-2 g	Every 12-24 hours
Severe impairment	9-5	0.5-1 g	Every 12-24 hours
Essentially no function	<5	0.5-1 g	Every 24-48 hours

In the patients undergoing haemodialysis, the loading dose of 1 to 2g should be given after each haemodialysis, and the maintenance dose should be given as indicated in the table above.

Uncomplicated urinary tract infections

In uncomplicated urinary tract infections due to susceptible organisms, 1 g intramuscularly twice a day for ten days has been shown to be effective.

Uncomplicated gonorrhoea

For single dose therapy of uncomplicated gonorrhoea, including that caused by penicillinase-producing strains, the recommended dose is 2 g of 'Cefoxitin Powder for Solution for Injection or Infusion' intramuscularly given with 1 g of probenecid by mouth (at the same time or up to one hour before)

Neonates, infants and children

Neonates *	
0-1week of age	20-40mg/kg every 12 hours
1-4weeks of age	20-40mg/kg every 8 hours
Infants *	20-40mg/kg every 6 hours or every 8 hours
Children	20-40mg/kg every 6 hours or every 8 hours

* Clinical data are insufficient to recommend use of the intramuscular formulation in infants less than 3 months of age.

In severe infections, the total daily dosage may be increased to 200 mg/kg, but not to exceed 12 g per day.

'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' is not recommended for the therapy of meningitis. If meningitis is suspected an appropriate antibiotic should be used.

In children with renal insufficiency, the dosage frequency should be reduced as indicated for adults.

Prophylactic Administration to Adults

2 g administered intramuscularly or intravenously just prior to surgery ½ to 1 hour before initial incision); then 2g every six hours.
Prophylactic therapy should not usually be given for more than 24 hours.

Prophylactic administration for neonates, infants, and children

In infants and children, 30-40 mg/kg doses may be given at same times as designated for adults. However, in neonates, 30-40 mg/kg doses may be given ½ to 1 hour before initial incision and the second and third dose may be given every 8-12 hours.

Clinical data are insufficient to recommend use of the intramuscular formulation in infants less than 3 months of age.

Obstetric and Gynaecological Surgery

For patients undergoing caesarean section, a single 2 g dose is administered intravenously as soon as the cord is clamped. If necessary, a second and third dose of 2 g may be administered intravenously 4 hours and 8 hours after the first dose.

In gynaecological surgical procedures, a single prophylactic dose of 2 g intravenously or intramuscularly has been effective given ½ to 1 hour before surgery.

In prolonged or heavily contaminated cases, additional 2g doses may be given at 6-hour intervals. Prophylactic therapy does not ordinarily extend beyond 24 hours.

Intravenous administration only

For direct intravenous injection, 'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' may be slowly injected into the vein over a period of 3 to 5 minutes or may be given through the tubing when the patient is receiving parenteral solutions.

An intermittent intravenous infusion of 'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' may be employed when large amounts of fluid are to be given. However, during infusion of the solution containing 'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion', it may be advisable temporarily to discontinue administration of any other infusion solution at the same site (by using an appropriate IV infusion set).

A solution of 'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' may also be given by continuous intravenous infusion (see 6.6 'Instructions for use and handling').

Intramuscular Administration Only

'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' is given by deep injection into a large muscle mass. Avoid injection into a blood vessel.
Note: Some patients may be hypersensitive to lignocaine.

Use in the elderly

The dosage should be determined by the severity of the infection, the susceptibility of the causative organisms, the patient's clinical condition and renal function.

4.3 Contraindications

‘Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion’ is contra-indicated in persons who have shown hypersensitivity to Cefoxitin. In the absence of clinical experience, ‘Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion’ should not be administered to patients who have shown hypersensitivity to cephalosporins.

4.4 Special warnings and precautions for use

There is some clinical and laboratory evidence of partial cross-allergenicity between cephamycins and other beta-lactam antibiotics, penicillins, and cephalosporins. Severe reactions (including anaphylaxis) have been reported with most beta-lactam antibiotics.

Before therapy with ‘Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion’, careful inquiry should be made concerning previous hypersensitivity reactions to beta-lactam antibiotics. ‘Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion’ should be given cautiously to penicillin-allergic patients.

Any patient who has demonstrated some form of allergy, particularly to drugs, should be given antibiotics cautiously. If an allergic reaction to ‘Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion’ occurs, the drug should be discontinued.

Pseudomembranous colitis, reported with virtually all antibiotics, can range from mild to life threatening in severity. Antibiotics should be prescribed with caution in patients with a history of gastro-intestinal disease, particularly colitis. Treatment-related diarrhoea should always be considered as a pointer to this diagnosis. While studies indicate that a toxin of *Clostridium difficile* is one of the primary causes of antibiotic-related colitis, other causes should be considered.

The total daily dosage should be reduced when ‘Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion’ is administered to patients with transient or persistent reduction of urinary output due to renal insufficiency (see 4.2 ‘Posology and method of administration’) because high and prolonged serum antibiotic concentrations can occur from usual doses.

Interference with laboratory tests
A false-positive reaction to glucose in the urine may occur with reducing substances but not with the use of specific glucose oxidase methods.

Using the Jaffe Technique, falsely high creatinine values in serum may occur if ‘Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion’ serum concentrations exceed 100 micrograms per ml. Serum samples from patients treated with ‘Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion’ should not be analysed for creatinine if withdrawn within two hours of drug administration.

High concentration of Cefoxitin in the urine may interfere with the measurement of 17- hydroxy-corticosteroids by the Porter-Silber reaction to give slight, falsely increased results.

Sodium:

This medicinal product contains approximately 51.17 mg and 102.35 sodium content for 1g and 2g respectively.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Fertility, pregnancy and lactation

Use of the drug in women of childbearing potential requires that the anticipated benefits be weighed against possible hazards. Reproductive and teratogenic studies have been performed in mice and rats and have revealed no evidence of impaired fertility or harm to the foetus due to 'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion'. There are no controlled studies with 'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' in pregnant women.

'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' is excreted in human milk. Caution should be exercised if use is indicated.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Side Effects

'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' is generally well tolerated. Side effects have usually been mild and transient and treatment rarely needs to be stopped. The most common side effects have been local reactions following intravenous or intramuscular injection.

Local reactions

Thrombophlebitis has occurred with intravenous administration. Pain, induration and tenderness after intramuscular injections have been reported.

Allergic

Rash (including exfoliative dermatitis and toxic epidermal necrolysis), urticaria, flushing, pruritus, eosinophilia, fever and other allergic reactions (including anaphylaxis, interstitial nephritis and angioedema) have been reported.

Cardiovascular

Hypotension.

Gastro-intestinal

Diarrhoea, including pseudomembranous colitis can appear during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Blood

Eosinophilia, leucopenia including granulocytopenia, neutropenia, anaemia including haemolytic anaemia, thrombocytopenia and bone-marrow depression have been reported. Some individuals, particularly those with azotaemia, may develop positive direct Coombs tests during therapy with 'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion'.

Musculoskeletal

Worsening myasthenia gravis (single case)

Liver function

Transient elevations in AST (SGOT), ALT (SGPT), serum LDH, serum alkaline phosphatase and jaundice have been reported.

Kidney function

Elevations in serum creatinine and/or blood urea levels have been observed. Acute renal failure has been reported rarely. The role of 'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' in changes in renal function tests is difficult to assess, since factors predisposing to pre-renal azotaemia or to impaired renal function usually have been present.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

No specific information is available on the treatment of overdose with 'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion'

After injection, Cefoxitin has a half-life between 45 and 60 minutes with a 70% binding to plasma proteins. The parenteral dose of 'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' is carefully controlled by the physician and no case of overdosage has been recorded. No antidote is available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Cephalosporins and related substances.
ATC code: J01DC01.

The bactericidal action of Cefoxitin results from inhibition of cell wall synthesis. Cefoxitin has *in vitro* activity against a wide range of gram positive and gram-negative organisms. The methoxy group in the 7 position provides 'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' with a high degree of stability in the presence of beta-lactamases, both penicillinases and cephalosporinases, of Gram-negative bacteria. Many gram-negative pathogens are resistant to penicillins and cephalosporins through the action of beta-lactamases which are produced by these pathogens. 'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' is remarkably stable in the presence of these bacterial beta lactamases, both penicillinases and cephalosporinases. Hence, the clinical efficacy of 'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' extends to many infections caused by such pathogens. However, 'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' is not stable to extended spectrum beta-lactamases. Break points (NCCLS)

The general MIC susceptibility test breakpoints to separate susceptible (S) pathogens from resistant (R) pathogens are:

S ≤ 8 mcg/ml, R ≥ 32 mcg/ml except for:

Neisseria gonorrhoeae: S ≤ 2 mcg/ml, R ≥ 8 mcg/ml.

Anaerobes: S ≤ 16 mcg/ml, R ≥ 64 mcg/ml

Susceptibility

The prevalence of resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when treating severe infections. The information below gives only approximate guidance on the probability as to whether the micro-organism will be susceptible to 'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' or not.

Organism	**Prevalence of Resistance (Range)**
SUSCEPTIBLE:	
Gram-positive aerobes:	
*Staphylococcus aureus (*including penicillinase-producing strains)	0 to 13%
Staphylococcus, coagulase negative	0 to 29%
Staphylococcus saprophyticus	0 to 20%
Staphylococcus epidermidis	0%
Group A β-hemolytic streptococci *(Streptococcus pyogenes)*	0%
Group B β-hemolytic streptococci (*Streptococcus agalactiae)*	0 to 8%
Streptococcus pneumoniae (*Diplococcus pneumoniae)*	0 to 25%
Streptococcus pneumoniae (PRSP)	0 to 100%

Streptococcus spp.	0%
Gram-negative aerobes:	
Escherichia coli	0 to 27%
*Haemophilus influenzae**	
Klebsiella oxytoca	0 to 20%
Klebsiella pneumoniae	0 to 20%
Neisseria gonorrhoeae (including penicillinase-producing strains)	0%
Neisseria meningitidis	
Proteus (indole-positive)	
*Morganella morganii (*formerly *Proteus morganii)*	0 to 25%
Proteus vulgaris	0 to 17%
Proteus mirabilis	0 to 31%
Providencia spp.	0%
Providencia rettgeri (formerly Proteus rettgeri)	0 to 33%
Providencia stuartii	0 to 29%
Salmonella spp.	0 to 17%
Serratia marcescens	0 to 67%
Shigella spp.	0 to 17%
Anaerobes:	
Bacteroides fragilis	0 to 20%
Bacteroides spp.	13%
Bacteroides thetaiotaomicron	0 to 80%
Clostridium spp.	0 to 20%
Clostridium perfringens	
Eubacterium spp.	
Fusobacterium spp.	
Microaerophilic streptococcus	
Peptostreptococcus spp.	0%
Peptococcus spp.	
*Prevotella melaninogenica (*formerly *Bacteroides melaninogenicus)*	
Propionibacterium acnes	
Veillonella spp.	
INTERMEDIATE:	
Gram-negative aerobes:	

*Acinetobacter baumannii (*formerly *A. calcoaceticus* var. *anitratum;* formerly *Herellea vaginicola*)	13 to 100%
Acinetobacter calcoaceticus var. *Lwoffi (*formerly *Mima polymorpha)*	
Alcaligenes faecalis	
Citrobacter koseri (formerly *Citrobacter diversus*)	0%
Citrobacter freundii	20 to 100%
Enterobacter spp.	
Flavobacterium spp.	
RESISTANT:	
Gram-positive aerobes:	
Enterococci	
Enterococcus faecalis	
Methicillin-resistant staphylococci	
Listeria monocytogenes	
Gram-negative aerobes:	
Enterobacter cloacae	
Enterobacter aerogenes	
Pseudomonas aeruginosa	

*MIC breakpoint not defined.

Mechanisms of Resistance

The major mechanisms of resistance to the beta-lactam class of antibiotics, including Cefoxitin, is through the production of beta-lactamase enzymes by infecting microorganisms. Additional minor mechanisms of resistance to Cefoxitin include alterations of penicillin-binding proteins (PBPs) and alterations to outer membrane proteins.

5.2 Pharmacokinetic properties

Human Pharmacology

'Cefoxitin 2 g Powder for Solution for Injection or Infusion' administered parenterally, produces high serum and urine concentrations. It is excreted virtually unchanged as active 'Cefoxitin 2 g Powder for Solution for Injection or Infusion' by the kidneys, and has a mean terminal serum half-life of approximately one hour. 'Cefoxitin 2 g Powder for Solution for Injection or Infusion' passes rapidly into body fluids such as pleural, bile, and ascitic fluids. Probenecid slows tubular excretion and increases and prolongs blood levels.

Intravenous administration

Peak serum concentrations of ‘Cefoxitin 2 g Powder for Solution for Injection or Infusion’ following 2 g infused intravenously over 3 minutes was 125 micrograms/ml, infused over 30 minutes was 72 micrograms/ml, and infused over 120 minutes was 25 micrograms/ml. Following 2 g infused intravenously over 3 minutes, peak serum concentration was 221 micrograms/ml. In a number of studies using 0.5 g, 1 g, or 2 g intravenous doses of ‘Cefoxitin Edgepharma Powder for Solution for Injection or Infusion’ mean total urinary recovery ranged from 77% to 99% of the Cefoxitin dose.

Intramuscular administration

When ‘Cefoxitin 2 g Powder for Solution for Injection or Infusion’ was reconstituted for intramuscular injection with 0.5% or 1% lignocaine hydrochloride, the lignocaine had no effect on the absorption or elimination of ‘Cefoxitin 2 g Powder for Solution for Injection or Infusion’. Intramuscular injections of 1 g of ‘Cefoxitin Powder for Solution for Injection or Infusion’ in 0.5% lignocaine hydrochloride solution produced a peak serum concentration of 30 micrograms/ml at 20 minutes. Approximately 85% of an intramuscular dose is excreted by the kidneys in the first six hours; this results in high urine levels (e.g. >3,000 micrograms/ml between one and two hours after a 1 g dose).

5.3 Preclinical safety data

No relevant data

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

When reconstituting ‘Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion’ for neonates, water for injections must be preservative-free.

6.3 Shelf life

2 years.

After reconstitution:

‘Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion’, as reconstituted in section 6.6 “Special precaution for disposal”, maintains satisfactory potency:

- for 8 hours at room temperature or under refrigeration for 0.5% Lidocaine Hydrochloride Injection, Water for Injection and 0.9% Sodium Chloride Injection.

- for 8 hours at room temperature for 5% or 10% Dextrose Injection BP, Dextrose and Sodium Chloride Injection BP (5%/0.9%, 5%/0.45%, or 5%/0.2%), Lactated Ringer's Injection USP, 5% dextrose injection in 0.02% sodium bicarbonate solution, 5% Dextrose in Lactated Ringer's Injection, M/6 Sodium Lactate Injection BP, 5% Fructose Injection.

In keeping with good clinical and pharmaceutical practice, 'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' should be administered as a freshly prepared solution

Although chemical and physical in-use stability has been demonstrated for above listed storage time for the reconstitution solutions and diluents, from a microbiological point of view, the product should be used immediately. If not used immediately, in use storage times and conditions prior to use are the responsibility of the user.

Therefore, it's recommended that the proposed product shall be used immediately after reconstituted.

6.4 Special precautions for storage

'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' in the dry state should be stored below 25□, in an airtight container protected from light.

For storage conditions after reconstitution of this product, see section 6.3.

6.5 Nature and contents of container

'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' is supplied in 20 ml Neutral borosilicate clear glass tubular injection vial (Ph.Eur. Type I) stopped with Chlorinated butyl rubber stopper partly coated with PTFE film and sealed with aluminium plastic cap prior to storage and transport. Each pack contains 10 vials.

6.6 Special precautions for disposal

Intravenous injection administration

Reconstitute 'Cefoxitin Powder for Solution for Injection or Infusion' with Water for Injections Ph.Eur.: 1 g is soluble in 2 ml. Although 'Cefoxitin Powder for Solution for Injection or Infusion' is very soluble, for intravenous use it is preferable to add 10 ml of Water for Injections Ph.Eur. to the 1g vial or to the 2g vial. Shake to dissolve and then withdraw entire contents of vial into syringe.

Solutions of 'Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion' range from clear to light amber in colour. The pH of freshly reconstituted solutions usually ranges from 4.2 to 7.0.

Intramuscular administration only

Reconstitute ‘Cefoxitin Powder for Solution for Injection or Infusion’ 1g with 2ml of Water for Injections BP, or 0.5% lignocaine hydrochloride Injection.

Intravenous infusion administration

Reconstitute ‘Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion’ with 10 ml of Water for Injection and then dilute it with 40 ml of Solutions for Infusion.

Preparation of solution

The following Table is provided for convenience in reconstituting ‘Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion’ for both intravenous and intramuscular administration.

Strength	*Amount of diluent to be added (ml*)*	*Approximate volume (ml)*	*final Approximate average concentration (mg/ml)*
1 gram vial	2 (intramuscular)	2.5	400
1 gram vial	l0(IV)	10.5	95
2 gram vial	l0 or 20(IV)	11 or 21	180 or 95

* Shake to dissolve and let stand until clear

Compatibility and stability

A solution of ‘Cefoxitin Edgepharma 2 g Powder for Solution for Injection or Infusion’ in Water for Injections Ph.Eur. may be added to the following solutions:

0.9% Sodium Chloride Injection BP

5% or 10% Dextrose Injection BP

Dextrose and Sodium Chloride Injection BP (5%/0.9%, 5%/0.45%, or 5%/0.2%)

Lactated Ringer’s Injection USP

5% dextrose injection in 0.02% sodium bicarbonate solution

5% Dextrose in Lactated Ringer’s Injection

Sodium Lactate Solution at M/6

0.5% Lidocaine Hydrochloride Injection

Water for Injection

5% Fructose Injection

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 57328/0002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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