NAME OF THE MEDICINAL PRODUCT

Cefuroxim B. Braun 750 mg powder and solvent for solution for infusion
Cefuroxim B. Braun 1.5 g powder and solvent for solution for infusion

COMPOSITION

Cefuroxim B. Braun 750 mg
Each two-chamber bag contains cefuroxime sodium equivalent to 750 mg cefuroxime.
After reconstitution, the solution contains 15 mg cefuroxime per ml.
Excipients with known effect:
Contains 2.0 g glucose per dose. This should be taken into account in patients with diabetes mellitus.

Cefuroxim B. Braun 1.5 g
Each two-chamber bag contains cefuroxime sodium equivalent to 1.5 g cefuroxime.
After reconstitution, the solution contains 30 mg cefuroxime per ml.

The total quantity of sodium per two-chamber bag is as follows:

Cefuroxim B. Braun strength	Amount of sodium per two-chamber bag
750 mg	39 mg
1.5 g	78 mg

Excipients:
Solvent
Glucose anhydrous, water for injections.

THERAPEUTIC INDICATIONS

Cefuroxim B. Braun is indicated for the treatment of the infections listed below in adults and children, including neonates (from birth).
Community acquired pneumonia; acute exacerbations of chronic bronchitis; complicated urinary tract infections, including pyelonephritis; soft-tissue infections: cellulitis, erysipelas and wound infections; intra-abdominal infections; prophylaxis against infection in gastrointestinal (including oesophageal), orthopaedic, cardiovascular, and gynaecological surgery (including caesarean section).

In the treatment and prevention of infections in which it is very likely that anaerobic organisms will be encountered, cefuroxime should be administered with additional appropriate antibacterial agents.

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

CONTRAINDICATIONS

Hypersensitivity to the active substance or to any of the excipients.
Patients with known hypersensitivity to cephalosporin antibiotics.
History of severe hypersensitivity (e.g. anaphylactic reaction) to any other type of beta-lactam antibacterial agent (penicillins, monobactams and carbapenems).

UNDESIRABLE EFFECTS

The most common adverse reactions are neutropenia, eosinophilia, transient rise in liver enzymes or bilirubin, particularly in patients with pre-existing liver disease, but there is no evidence of harm to the liver.

The frequency categories assigned to the adverse reactions below are estimates, as for most reactions suitable data for calculating incidence are not available. In addition the incidence of adverse reactions associated with cefuroxime sodium may vary according to the indication.

Data from clinical trials were used to determine the frequency of very common to rare adverse reactions. The frequencies assigned to all other adverse reactions (i.e. those occurring at <1/1000) were mainly determined using post-marketing data, and refer to a reporting rate rather than a true frequency.

The adverse reactions considered at least possibly related to treatment are listed below by body system organ class, grade of severity and frequency.

Undesirable effects are listed according to their frequencies as follows:

Common: (≥ 1/100 to < 1/10)
Uncommon: (≥ 1/1 000 to < 1/100)
Not known: (cannot be estimated from the available data)

System organ class	Common	Uncommon	Not known
Infections and infestations			*Candida* overgrowth, overgrowth of *Clostridium difficile*
Blood and lymphatic system disorders	Neutropenia, eosinophilia, decreased haemoglobin concentration	Leukopenia, positive Coomb's test	Thrombocytopenia, haemolytic anaemia

Cardiac disorders			Kounis syndrome
Immune system disorders			Drug fever, interstitial nephritis, anaphylaxis, cutaneous vasculitis
Gastrointestinal disorders		Gastrointestinal disturbance	Pseudomembranous colitis
Hepatobiliary disorders	Transient rise in liver enzymes	Transient rise in bilirubin	
Skin and subcutaneous tissue disorders		Skin rash, urticaria and pruritus	Erythema multiforme, toxic epidermal necrolysis and Stevens- Johnson syndrome, angioneurotic oedema, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
Renal and urinary disorders			Elevations in serum creatinine, elevations in blood urea nitrogen and decreased creatinine clearance
General disorders and administration site conditions	Infusion site reactions which may include pain and thrombophlebitis		

Description of selected adverse reactions
Cephalosporins as a class tend to be absorbed onto the surface of red cell membranes and react with antibodies directed against the drug to produce a positive Coomb's test (which can interfere with cross matching of blood) and very rarely haemolytic anaemia.
Transient rises in serum liver enzymes or bilirubin have been observed which are usually reversible.
Pain at the intravenous infusion site is more likely at higher doses. However it is unlikely to be a cause for discontinuation of treatment.

Paediatric population
The safety profile for cefuroxime sodium in children is consistent with the profile in adults.

WARNING
Keep out of the reach and sight of children.

NOTE
Prescription only
Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

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