B BRAUN
SHARING EXPERTISE

Cefuroxim B. Braun

INJECTABLE DRUGS

Cefuroxim B. Braun belongs to the antibiotic class of Cephalosporins.

Cefuroxim B. Braun is indicated for the treatment of the infections listed below in adults and children[1]*:

- 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).

* Note: Dosing in neonates, infants and toddlers depends on the age and bodyweight, please check the SmPC for further information.

Safety benefits

- Improves medication efficacy – cannot deliver diluent without drug
- Reduces medication errors – no vial mixing required
- Helps to protect patients and healthcare workers from exposure to airborne cephalosporins
- Barcoding references final admixture, lot number and expiration date
- Not manufactured with PVC, DEHP, or Latex
- Closed system – reduces medication errors and contamination risks

FIG. 1 | Duplex® – Cefuroxim B. Braun, 750 mg/50 ml

FIG. 2 | Duplex® – Cefuroxim B. Braun, 1.500 g/50 ml

USER BENEFITS WITH CEFUROXIM

- Duplex® dual-chamber container system is an almost ready-to-use formulation
  - Reduces admixture steps versus powder vials
  - Is safer for your patients as it can help to reduce the risk of medication errors, such as wrong drug, dose, diluent, and microbiological contamination[2]
- Simply fold and squeeze container to mix – no vials to attach or activate
- Saves time and labor for pharmacy and nursing
- Needle-free admixture port (universal set port)
- Convenient storage at room temperature
- Economical – drug formulation in almost ready-to-use Duplex® dual-chamber IV bag reduces drug lost to waste and requires less device material
- B. Braun Injectable Drugs do not contain sodium bisulphite as excipient which can cause hypersensitivity reactions and bronchospasm[3]

Product	Container Type	Concentration	Total Volume	Sales Unit
Cefuroxim B. Braun 750 mg	Duplex®	15 mg/ml	750 mg/50 ml	24
Cefuroxim B. Braun 1.5 g	Duplex®	30 mg/ml	1.5 g/50 ml	24

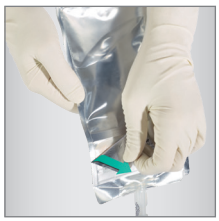
LITERATURE

1. SmPC Cefuroxim, B. Braun | 2. Cousins DH et al. Medication errors in intravenous drug preparation and administration: a multicentre audit in the UK, Germany and France. Qual Saf Health Care. 2005 Jun; 14(3):190–195. | 3. Vally H, Misso NLA. Adverse reactions to the sulphite additives. Gastroenterol Hepatol Bed Bench 2012; 5(1):16-23.

Product Information

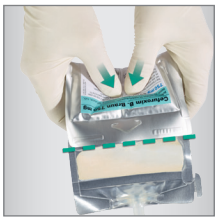
How to apply B. Braun Duplex®

1 PEEL



Peel foil strip from drug chamber

2 SNAP



Squeeze bag to open the first seal between diluent and drug powder

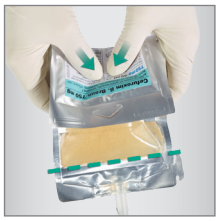
3 SHAKE

Shake thoroughly to mix

4 SPIKE

Remove the foil tab from set port and spike the bag

5 SNAP



Squeeze bag to open the second seal releasing solution to set port

6 GO

Ready to use

EASY TO LEARN AND EASY TO USE

- Easy bedside activation: Simply break the quick release seal and squeeze to mix drug and diluent just prior to administration
- Simply label and dispense

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 injection.

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

Infections and infestations
Not known: Candida overgrowth, overgrowth of Clostridium difficile

Blood and lymphatic system disorders
Common: Neutropenia, eosinophilia, decreased haemoglobin concentration
Uncommon: Leukopenia, positive Coomb's test
Not known: Thrombocytopenia, haemolytic anaemia

Immune system disorders
Not known: Drug fever, interstitial nephritis, anaphylaxis, cutaneous vasculitis

Gastrointestinal disorders
Uncommon: Gastrointestinal disturbance
Not known: Pseudomembranous colitis

Hepatobiliary disorders
Common: Transient rise in liver enzymes
Uncommon: Transient rise in bilirubin

Skin and subcutaneous tissue disorders
Uncommon: Skin rash, urticaria and pruritus
Not known: Erythema multiforme, toxic epidermal necrolysis and Stevens- Johnson syndrome, angioneurotic oedema

Renal and urinary disorders
Not known: Elevations in serum creatinine, elevations in blood urea nitrogen and decreased creatinine clearance

General disorders and administration site conditions
Common: 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.

MARKETING AUTHORIZATION HOLDER
B. Braun Melsungen AG, 34209 Melsungen, Germany

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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.

B. Braun Melsungen AG | Hospital Care | 34209 Melsungen | Germany
Tel. +49 5661 71-0 | www.bbraun.com

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