Co-amoxiclav (Natravox) IV is less stable in infusions containing glucose, dextran or bicarbonate. Reconstituted solution should, therefore, not be added to such infusions but may be injected into the drip tubing over a period of three to four minutes.

NOTE: Co-amoxiclav (Natravox) IV vials are not suitable for intramuscular or subcutaneous administration.

Co-amoxiclav (Natravox) IV vials should be given by slow intravenous injection over a period of three to four minutes. It may be injected directly into a vein or via a drip tube.

USE RECONSTITUTED SOLUTION WITHIN 20 MINUTES. DISCARD ANY UNUSED SOLUTION.

Duration of therapy should be appropriate to the indication and should not exceed 14 days without review

Dosages for the treatment of infection

Adults and children over 12 years: Usually 1.2 g every eight hours. By intravenous injection (3–4 minutes) or intravenous infusion (30 minutes). In more serious infections, increase frequency to six-hours intervals.

Adult dosage for surgical prophylaxis

The usual dose is 1.2 g Co-amoxiclav (Natravox) IV given at the induction of anaesthesia. Operations where there is a high risk of infection, e.g. colorectal surgery, may require three, and up to four, doses of 1.2 g Co-amoxiclav (Natravox) IV in a 24-hour period. These doses are usually given at 0, 8, 16 (and 24) hours. This regimen can be continued for several days if the procedure has a significantly increased risk of infection.
Clear clinical signs of infection at operation will require a normal course of intravenous or oral Co-amoxiclav (Natravox) therapy post-operatively.

Dosage in renal impairment

Adults

Mild impairment (creatinine clearance > 30 ml/min)	Moderate impairment (creatinine clearance 10-30 ml/min)	Severe impairment (creatinine clearance <10 ml/min)
No change in dosage.	1.2 g IV stat., followed by 600 mg IV 12 hourly.	1.2 g IV stat., followed by 600 mg IV 24 hourly. Dialysis decreases serum concentrations of Natravox and an additional 600 mg IV dose may need to be given during dialysis and at the end of dialysis.

Dosage in hepatic impairment

Dose with caution; monitor hepatic function at regular intervals.
There are, as yet, insufficient data on which to base a dosage recommendation.
Each 1.2 g vial of Co-amoxiclav (Natravox) IV contains 1.0 mmol of potassium and 2.7 mmol of sodium (approx).

Natravox 600 mg (IV): DR-XY31388
Natravox 1.2 g (IV): DR-XY31387
Date of First Authorization: January 2006
Revision Date: March 2019

STORE THE DRY POWDER IN COOL DRY PLACE
STORE BELOW 25° C

Manufactured by
Samjin Pharm. Co., Ltd.
52, Jeyakgongdan 1-gil, Hyangnam-eup,
Hwaseong-si, Gyeonggi-do,
Republic of Korea
Imported, Repacked and Distributed by
Natrapharm, Inc.
The Patriot Building,
Km. 18, West Service Road,
SLEX, Parañaque City

NTNXIALL000IN2001

Natrapharm

Co-amoxiclav

Natravox®

Antibacterial

FORMULATION:
600 mg Powder for IV Injection - Each vial contains:
Amoxicillin (as sodium) ..... 500 mg
Clavulanic Acid (as Potassium clavulanate) ..... 100 mg

1.2 g Powder for IV Injection - Each vial contains:
Amoxicillin (as sodium) ..... 1000 mg
Clavulanic Acid (as Potassium clavulanate) ..... 200 mg

These powder vials are for reconstitution as an intravenous injection or infusion

INDICATIONS:
-*Upper Respiratory Tract infections (including ENT)* - sinusitis, otitis media, recurrent tonsillitis. These infections are often caused by *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis* and *Streptococcus pyogenes.*

-*Lower Respiratory Tract Infections* acute exacerbations of chronic bronchitis, bronchopneumonia, urinary-tract infections often caused *Streptococcus pneumoniae*, *Haemophilus influenzae* and Moraxella catarrhalis,

-*Genito-urinary Tract* and *Abdominal Infections* in particular cystitis (especially when recurrent or complicated, but not prostatitis) septic abortion, pelvic or puerperal sepsis, and intra-abdominal sepsis. These infections are often caused by *Enterobacteriaceae* (mainly *Escherichia coli*), *Staphylococcus saprophyticus*, *Enterococcus* species.

-*Skin* and *Soft Tissues Infections* in particular cellulites, animal bites and severe dental abscess with spreading cellulites caused by *Staphylococcus aureus*, *Streptococcus pyogenes* and *Bacteriodes* species

ANTIMICROBIAL ACTIONS:
Co-amoxiclav is antibacterial combination consisting of amoxicillin (as sodium) and the beta-lactamase inhibitor, clavulanic acid (as potassium clavulanate)

Amoxicillin is the 4-hydroxy analogue of ampicillin. Amoxicillin hinders the cell wall synthesis of sensitive bacteria and is bactericidal against many Gram-positive and Gram-negative bacteria. It is active against all penicillin-sensitive bacteria: streptococci and most strains of pneumococci, gonococci and meningococci are sensitive. Bacteria that produce beta-lactamase (e.g. most of the staphylococci) are resistant. Amoxicillin is also active against strains of haemophilus influenza that do not produce beta-lactamase.

Clavulanic acid has a beta-lactam structure resembling that of penicillin nucleus, except that the fused thiazolidine ring of the penicillins is replaced by an oxazolidine ring. In general, clavulanic acid has only weak antibacterial activity. It is potent progressive inhibitor of plasmid-mediated and some chromosomal beta-lactamases produced by Gram-negative bacteria including *Haemophilus ducreyi*, *H. influenzae*, *Neisseria gonorrhoeae*, *Moraxella catarrhalis* (*Branhamella catarrhhalis*), *Bacteroides fragilis* and some *Enterobacteriacese.* It is also an inhibitor of the beta-lactamases produced by *Staphylococcus aureus.* Clavulanic acid can permeate bacterial cell walls and can therefore inactivate both extracellular enzymes and those that are bound to the cell. Its mode of action depends on the particular enzyme inhibited, but it generally acts as a competitive, and often irreversible, inhibitor. Clavulanic acid consequently enhances the activity of penicillin and cephalosporin antibacterials against many resistant strains of bacteria. However, it is generally less effective against chromosomally medicated type 1 beta-lactamases: therefore, many *Citrobacter, Enterobacter, Morganells* and *Serratia spp.* And *Pseudomonas aeruginosa* remain resistant. Some plasmid-mediated extended-spectrum beta lactamases in *Klebsiella pneumoniae*, some other *Enterobactriaceae*, and *Ps. aeruginosa* are also not inhibited by beta-lactamases inhibitors.

Co-amoxiclav is bactericidal to a wide range of organisms including:

Gram-positive:
Aerobes: *Enterococcus faecalis, Enterococcus faecium, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus viridans, Staphylococcus aureus,* Coagulase negative staphylococci