

BELMEDPREPARATY RUE



Antibiotics

manufactured by
Belmedpreparaty RUE



Amclav

coated tablets 250 mg/125 mg

Trade name: Amclav, coated tablets 250mg/125mg.

International non-proprietary name: Amoxicillin and enzyme inhibitor.

Description: white to yellowish biconvex coated tablets.

Contents: each tablet contains:

Active substances: amoxicillin (as amoxicillin trihydrate) - 250 mg, clavulanic acid (as potassium clavulanate with microcrystalline cellulose (1:1)) - 125 mg.

Excipients: potato starch, magnesium stearate, anhydrous colloidal silicon dioxide, microcrystalline cellulose, Opadry II White (85G).

Composition of Opadry II White: partially hydrolyzed polyvinyl alcohol, titanium hydroxide E 171, talc, polyethylene glycol 3350, lecithin (soybean).

Pharmacotherapeutic group: Penicillins combinations (including those with beta-lactamase inhibitors). Amoxicillin in combination with beta-lactamase inhibitors.

ATC code: J01CR02.

Indications for use

Amclav is indicated for treatment of the following infections in adults and children:

- ▶ acute bacterial sinusitis (adequately diagnosed);
- ▶ cystitis;
- ▶ pyelonephritis;
- ▶ cellulitis;
- ▶ animal bites;
- ▶ severe dental abscess with spreading cellulitis.

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

Amoxicillin

capsules 250 mg

Trade name: Amoxicillin, capsules 250 mg.

International non-proprietary name: Amoxicillin.

Description: white capsules No. 0.

Contents: each capsule contains:

Active substance: amoxicillin (as amoxicillin trihydrate) - 250 mg.

Excipients: calcium stearate (E 470), potato starch.

Hard gelatin capsule coating composition: gelatin, glycerin, purified water, titanium dioxide, sodium lauryl sulfate.

Pharmacotherapeutic group: Broad spectrum penicillins.

ATC code: J01CA04.

Indications for use

Infectious and inflammatory diseases caused by sensitive microorganisms, including bronchitis, pneumonia, quinsy, acute otitis media, pharyngitis, sinusitis, urethritis, cystitis, pyelonephritis, endometritis, uncomplicated gonorrhea, skin and soft tissues infections, infections of gastro-intestinal tract (peritonitis, enteritis, cholecystitis, cholangitis), leptospirosis, listeriosis, borreliosis, meningitis, prevention of bacteremia, bacterial endocarditis associated with surgical manipulations (dental, in particular), in patients with risk for bacterial endocarditis; combined therapy in case of gastroduodenal ulcer associated with *Helicobacter pylori* (in combinations with metronidazole or clarithromycin and antisecretory agents), sepsis (in combination with aminoglycosides); treatment and prevention of splenic fever.



Beta-lactam antibiotics-penicillins

Cefazolin–Belmed

powder for solution for intravenous and intramuscular injection 1000 mg

Trade name: Cefazolin–Belmed, powder for solution for intravenous and intramuscular injection 1000 mg.

International non-proprietary name: Cefazolin.

Description: white or almost white powder, very hygroscopic.

Composition: each vial contains:

Active substance: cefazolin (as Cefazolin Sodium) – 1 g.

Pharmacotherapeutic group: System-use antimicrobial substances. Beta-lactam antibiotics. Generation I cephalosporins.

ATC code: J01DA04.

Indications for use

Cefazolin is used in case of infectious inflammatory diseases in adults and children older than 1 month of age, which are caused by sensitive microorganisms:

- ▶ upper and lower respiratory tract infections (bronchitis, pneumonia, pulmonary abscess and pleural empyema);
- ▶ infections of ENT organs (otitis media included);
- ▶ infections of urinary and bile-excreting tracts and pelvis minor organs (pyelitis, pyelonephritis, cystitis, urethritis, endometritis and gonorrhea);
- ▶ skin and soft tissue infections (erysipelatous inflammation and secondarily infected dermatoses);
- ▶ wound, burn and post-surgical infections;
- ▶ bone and joint infectious inflammatory diseases (including osteomyelitis);
- ▶ endocarditis, sepsis, peritonitis and mastitis;
- ▶ syphilis;
- ▶ for surgical infection prevention at pre- and post-surgical periods.



Cefalexin

capsules 250 mg

Trade name: Cefalexin, capsules 250 mg.

International non-proprietary name: Cefalexin.

Description: yellow hard gelatin capsules No. 0.
Capsule contents – mixture of white powder and granules with a yellowish tint with a specific odor. The capsule mass thickening in form of a column or a tablet broken when being pressed by a glass stick is allowed.

Composition: each capsule contains:

Active substance: cefalexin – 250 mg.

Excipients: methyl cellulose, calcium stearate, potato starch.

Pharmacotherapeutic group: Antimicrobial preparations for systemic administration. Cephalosporins.

ATC code: J01DA01.

Indications for use

Infections of various localizations caused by cefalexin sensitive microorganisms: infections of upper and lower respiratory airways (bronchitis, acute pneumonia and chronic bronchopneumonia exacerbation); of the urogenital system (acute and chronic pyelonephritis in the exacerbation stage, cystitis, prostatitis, endometritis, gonorrhea, vulvovaginitis, etc.); of ENT organs (angina, acute otitis media, sinusitis, etc.); pyogenic infections of skin and soft tissues (furunculosis, abscesses, pyoderma, etc.); lymphadenitis, lymphangitis; acute and chronic (in the exacerbation stage) osteomyelitis for after-treatment after other parenteral antibiotics administration.



Other beta-lactam antibiotics

Cefepime

powder for solution for intravenous and intramuscular injection 1000 mg

Trade name: Cefepime, powder for solution for intravenous and intramuscular injection 1000 mg.

International non-proprietary name: Cefepime.

Description: powder, white to white with a yellowish shade in color.

Composition: each vial contains:

Active substance: cefepime hydrochloride (equivalent to Cefepime) – 1 g.

Auxiliary substance: arginine – 0.725 g.

Pharmacotherapeutic group: System-use antimicrobial substances. Beta-lactam antibiotics. Generation IV cephalosporins.

ATC code: J01DE01.

Indications for use

Cefepime is used at bacterial infections caused by sensitive microorganisms:

- ▶ respiratory tract and ENT organ infections (including pneumonia, bronchitis, pulmonary abscess and pleural empyema);
- ▶ urinary tract infections (complicated and non-complicated ones, including pyelonephritis, pyelitis, urethritis, cystitis and gonorrhea);
- ▶ bile-excreting tract infections (cholangitis, cholecystitis and gall bladder empyema);
- ▶ infections of skin, soft tissues, bones and joints;
- ▶ intra-abdominal infections (including peritonitis);
- ▶ bacterial meningitis in children;
- ▶ septicemia;
- ▶ febrile granulocytopenia and infections against the background of immunodeficiency;
- ▶ infected wounds and burns;
- ▶ surgical infection prevention at pre- and post-surgical periods.



Cefotaxime sodium

powder for solution for injection 1000 mg

Trade name: Cefotaxime sodium, powder for solution for injection 1000 mg.

International non-proprietary name: Cefotaxime.

Description: powder, white to white with a yellowish shade in color.

Composition: each vial contains:

Active substance: cefotaxime sodium (equivalent to Cefotaxime) - 1 g.

Pharmacotherapeutic group: System-use antimicrobial substances. Beta-lactam antibiotics. Generation III cephalosporins.

ATC code: J01DA10.



Indications for use

Cefotaxime is used in case of grave infectious inflammatory diseases caused by sensitive microorganisms:

- ▶ respiratory tract and ENT organ infections (except those caused by enterococci);
- ▶ infections of urinary and bile-excreting tracts, pelvis minor organs and obstetric-gynecologic infections (pyelitis, pyelonephritis, cystitis, urethritis, endometritis, chlamidiosis and gonorrhea, including that caused by penicillinase releasing microorganisms);
- ▶ skin and soft tissue infections (including wound, burn and post-surgery infections);
- ▶ bone and joint infectious inflammatory diseases (including osteomyelitis);
- ▶ bacteriemia, septicemia and endocarditis;
- ▶ intraabdominal infections and peritonitis;
- ▶ bacterial meningitis (except listeriosis one);
- ▶ infections against the background of immunodeficiency conditions;
- ▶ Lyme disease and typhoid fever;
- ▶ for pre- and post-surgery period surgical infection prevention.



Other beta-lactam antibiotics

Ceftriaxone–Belmed

powder for solution for intravenous and intramuscular injection 1000 mg

Trade name: Ceftriaxone–Belmed, powder for solution for intravenous and intramuscular injection 1000 mg.

International non-proprietary name: Ceftriaxone.

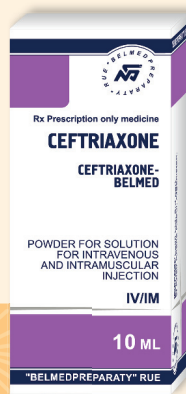
Description: powder, white to white with a yellowish shade in colour, hygroscopic.

Composition: each vial contains:

Active substance: ceftriaxone (as ceftriaxone sodium salt) – 1000 mg.

Pharmacotherapeutic group: Other beta-lactam antibiotics.

ATC code: J01DD04.



Indications for use

- ▶ infections of the upper and lower respiratory tract (including pneumonia, lung abscess, pleural empyema, infections of ENT organs);
- ▶ infections of skin, soft tissues, bones, joints;
- ▶ abdominal infections (peritonitis, inflammatory diseases of the gastrointestinal tract, biliary tract, cholangitis, gallbladder empyema);
- ▶ infectious and inflammatory diseases of the pelvic organs and the urinary tract (including pyelitis, pyelonephritis, cystitis, prostatitis, epididymitis);
- ▶ bacterial meningitis and endocarditis, sepsis, Lyme disease, shigellosis, salmonellosis, salmonella-carriage, typhoid fever;
- ▶ acute and complicated gonorrhea and other sexually-transmitted infections (including chancroid and syphilis);
- ▶ prevention and treatment of infections at surgical interventions.

Meropenem

*powder for solution for intravenous
injection 1000 mg*

Trade name: Meropenem, powder for solution for intravenous injection 1000 mg.

International non-proprietary name: Meropenem.

Description: a white to pale yellow crystalline powder.

Composition: each vial contains:

Active substance: meropenem - 500 mg.

Excipients: sodium carbonate.

Pharmacotherapeutic group: Beta-lactam antibiotic. Carbapenems.

ATC code: J01DH02.

Indications for use

Meropenem is indicated for the treatment of the following infections in adults and children over 3 months of age:

- ▶ pneumonia, including community acquired pneumonia and nosocomial pneumonia;
- ▶ broncho-pulmonary infections in cystic fibrosis;
- ▶ complicated urinary tract infections;
- ▶ complicated intra-abdominal infections;
- ▶ intra- and post-partum infections;
- ▶ complicated skin and soft tissue infections;
- ▶ acute bacterial meningitis.

Meropenem may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.

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



Other beta-lactam antibiotics

Cilapenem

powder for preparing solution for infusion

Trade name: Cilapenem, powder for preparing solution for infusion.

International non-proprietary name: Imipenem/Cilastatin.

Description: white to yellow powder.

Composition: each bottle/vial contains: imipenem (as imipenem monohydrate) - 250 mg or 500 mg and cilastatin (as cilastatin sodium salt) - 250 mg or 500 mg (as the mixture of imipenem and cilastatin sodium salt)*.

** The mixture of imipenem and cilastatin sodium salt contains sodium bicarbonate.*

Pharmacotherapeutic group: Beta-lactam antibiotics. Carbapenem + renal dehydropeptidase inhibitor.

ATC code: J01DH51.

Indications for use

Intravenous Cilapenem is indicated for treatment of severe infections caused by sensitive strains of the indicated microorganisms in the conditions listed below:

► lower respiratory tract infections caused by *Staphylococcus aureus* (penicillinase-producing strains), *Acinetobacter* spp., *Enterobacter* spp., *Escherichia coli*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella* spp., *Serratia marcescens*;

► urinary tract infections (complicated and uncomplicated) caused by *Enterococcus faecalis*, *Staphylococcus aureus* (penicillinase-producing strains), *Enterobacter* spp., *Escherichia coli*, *Klebsiella* spp., *Morganella morganii*, *Proteus vulgaris*, *Providencia rettgeri*, *Pseudomonas aeruginosa*;

► intraabdominal infections caused by *Enterococcus faecalis*, *Staphylococcus aureus* (penicillinase-producing strains), *Staphylococcus epidermidis*, *Citrobacter* spp., *Enterobacter* spp., *Escherichia coli*, *Klebsiella* spp., *Morganella morganii*, *Proteus* spp., *Pseudomonas aeruginosa*, *Bifidobacterium* spp., *Clostridium* spp., *Eubacterium* spp., *Peptococcus* spp., *Peptostreptococcus* spp., *Propionibacterium* spp., *Bacteroides* spp., including *B. fragilis*, *Fusobacterium* spp.;

► gynecological infections caused by *Enterococcus faecalis*; *Staphylococcus aureus* (penicillinase-producing strains), *Staphylococcus epidermidis*, *Escherichia coli*; *Streptococcus agalactiae* (Group B streptococci), *Enterobacter* spp., *Escherichia coli*, *Gardnerella vaginalis*, *Klebsiella* spp., *Proteus* spp., *Bifidobacterium* spp., *Peptococcus* spp., *Peptostreptococcus* spp., *Propionibacterium* spp., *Bacteroides* spp., including *B. fragilis*;

- ▶ bacterial sepsis caused by *Enterococcus faecalis*; *Staphylococcus aureus* (penicillinase-producing strains), *Enterobacter spp.*, *Escherichia coli*, *Klebsiella spp.*, *Serratia spp.*, *Bacteroides spp.*, including *B. fragilis*, *Pseudomonas aeruginosa*;
- ▶ bones and joints infections caused by *Enterococcus faecalis*; *Staphylococcus aureus* (penicillinase-producing strains), *Staphylococcus epidermidis*, *Enterobacter spp.*, *Pseudomonas aeruginosa*;
- ▶ skin and its structures infections caused by *Enterococcus faecalis*; *Staphylococcus aureus* (penicillinase-producing strains), *Staphylococcus epidermidis*, *Acinetobacter spp.*, *Citrobacter spp.*, *Enterobacter spp.*, *Escherichia coli*, *Klebsiella spp.*, *Morganella morganii*, *Proteus vulgaris*, *Providencia rettgeri*, *Pseudomonas aeruginosa*, *Serratia spp.*, *Peptococcus spp.*, *Peptostreptococcus spp.*, *Bacteroides spp.*, including *B. fragilis*, *Fusobacterium spp.*;
- ▶ infectious endocarditis caused by *Staphylococcus aureus* (penicillinase-producing strains);
- ▶ polymicrobial infections, including the cases when *Streptococcus pneumoniae* (pneumonia, septicemia), *Streptococcus pyogenes* (skin and its structures) or *Staphylococcus aureus*, non-penicillinase-producing strain is one of the causative agents. Nevertheless, as a rule monobacterial infections caused by these bacteria are corrected by narrow spectrum antibiotics, such as penicillin G.

Cilapenem is not indicated for patients with meningitis, since the safety and efficacy were not established.

Although a clinical improvement is observed in patients with mucoviscidosis, chronic pulmonary diseases and lower respiratory tract infections caused by *Pseudomonas aeruginosa*, eradication of the causative agent may not be always achieved. Along with other beta-lactam antibiotics, some *Pseudomonas aeruginosa* strains rather quickly can become resistant during treatment with Cilapenem. In treatment of infections caused by *Pseudomonas aeruginosa* periodical sensitivity testing should be performed.

Infections resistant to other antibiotics (for example, cephalosporins, penicillin, aminoglycosides) respond to the treatment with Cilapenem.

In order to reduce the growth of drug-resistant bacteria and to maintain the efficacy of Cilapenem and other antibacterial agents, Cilapenem should be used only for treatment or prevention of infections with proven or suspected sensitive microorganism. When the information about the culture and sensitivity is available, the conditions for selection or change of antibacterial therapy should be considered. If there is no such information, local epidemiological and sensitivity data may contribute to empiric choice of therapy.



Vancomycin

lyophilized powder for solution for infusion
1000 mg

Trade name: Vancomycin, lyophilized powder for solution for infusion 1000 mg.

International non-proprietary name: Vancomycin.

Description: white to off-white or pinkish-white powder or porous mass.

Composition: each vial contains:

Active substance: vancomycin (as vancomycin hydrochloride) - 1000 mg.

Pharmacotherapeutic group: Glycopeptide antibacterial agents.

ATC code: J01XA01.

Pharmacological properties

Antibacterial agent having a bactericidal effect on the majority of microorganisms (acts bacteriostatically on enterococci).



Therapeutic indications

Vancomycin is indicated for the treatment of serious infections caused by susceptible strains of methicillin-resistant

staphylococci. It is indicated in the following cases:

- ▶ for patients with allergic reactions to anti-bacterial agents from the group of penicillins;
- ▶ for patients who cannot be prescribed or who have not got a positive result after administration of other antibacterial agents, including penicillins or cephalosporins;
- ▶ for infections caused by vancomycin-susceptible organisms that are resistant to other antimicrobial agents.

Vancomycin is indicated for initial therapy of infections caused with high probability by methicillin-resistant staphylococci, but after receiving the results of studies of sensitivity to antibacterial agents the therapy should be adjusted accordingly.

Vancomycin is indicated for treatment of staphylococcal endocarditis. Its efficacy has been confirmed in treatment of infections caused by staphylococci, including septicaemia, bone infections, infections of the lower respiratory tract infections, infections of the skin and skin structure. If staphylococcal infection is purulent and localized, antibacterial agents are used as an adjunctive therapy to the appropriate surgical treatment.

There is an evidence that vancomycin is effective as monotherapy or in combination with aminoglycosides for treatment of endocarditis caused by *Streptococcus viridans* or *S. bovis*. For endocarditis caused by enterococci (e.g. *E. faecalis*), vancomycin can be effective in combination with aminoglycosides only.

There is an evidence that vancomycin is effective for the treatment of diphtheroid endocarditis. Vancomycin is used in combination either with rifampicin or with aminoglycosides or rifampicin and aminoglycosides (e.g. in treatment of endocarditis emerged in the early period after valve replacement, caused by *S. epidermidis* or diphtheroids).

Vancomycin for oral administration is used for treatment of pseudomembranous colitis caused by *Clostridium difficile*, and enterocolitis caused by *Staphylococcus aureus*. Samples for bacteriological cultures should be obtained for the isolation and identification of pathogens, as well as for determination of their sensitivity to vancomycin.

In order to reduce the development of resistance and maintain the efficacy of vancomycin and other antibacterial agents, vancomycin should be used for treatment or prevention of infections caused by microorganisms with proven sensitivity to this agent. After receiving the results of studies of sensitivity to antibacterial agents the therapy should be adjusted accordingly. In the absence of the results of bacteriological studies, the data of local epidemiological studies are taken into account.



Linezolid

granules for oral suspension

Trade name: Linezolid, granules for oral suspension.

International non-proprietary name: Linezolid.

Description: mixture of granules and powder of white to almost white or light yellow colour with vanilla flavour.

Composition: each bottle contains:

Active substance: linezolid – 2 g.

Excipients: microcrystalline cellulose of type 101 (E 460), sodium citrate (E 331), citric acid monohydrate (E 330), methyl cellulose (E 461), mannitol (E 421), xanthan gum (E 415), sodium benzoate (E 211), anhydrous colloidal silicon dioxide of type 300 (E 551), sodium chloride, ammonium glycyrrizinate, aspartame (E 951), “Vanilla AN 1361” flavouring, “Refreshing GX 1422” flavouring, sucrose.

Pharmacotherapeutic group: Antibacterial drugs for systemic use, linezolid.

ATC code: J01XX08.

Indications for use

Treatment of infections caused by sensitive anaerobic or aerobic gram-positive strains, including the infections accompanied by bacteremia, in case of the conditions listed below. Linezolid is not indicated for treatment of gram-negative infections. It is very important to immediately initiate specific gram-negative therapy, if an infection with gram-negative bacteria is suspected or documentally confirmed.

► Pneumonia

Hospital-acquired pneumonia caused by *Staphylococcus aureus* (methicillin-sensitive and resistant isolates) or *Streptococcus pneumoniae*.

Community-acquired pneumonia caused by *Streptococcus pneumoniae*, including the cases with concomitant bacteremia, or *Staphylococcus aureus* (only methicillin-sensitive isolates).

► Skin and its structures infections

Complicated skin and its structures infections, including diabetic foot infections, without concomitant osteomyelitis, caused by *Staphylococcus aureus* (methicillin-sensitive and resistant isolates), *Streptococcus pyogenes* or *Staphylococcus agalactiae*. Linezolid is not studied with respect to bedsores treatment.

Uncomplicated skin and its structures infections caused by *Staphylococcus aureus* (only methicillin-sensitive isolates) or *Streptococcus pyogenes*.

► Vancomycin-resistant *Enterococcus Faecium* infections

Vancomycin-resistant *Enterococcus Faecium* infections, including the cases of concomitant bacteremia.

► Administration

To reduce the growth of drug-resistant bacteria and to maintain the efficacy of linezolid and other antibacterial agents, linezolid should be used only for treatment or prevention of infections with proven or suspected sensitive microorganism. When the information about the culture and sensitivity is available, the conditions for selection or change of antibacterial therapy should be considered. If there is no such information, local epidemiological and sensitivity data may contribute to empiric choice of therapy.

Safety and efficacy of Linezolid course for more than 28 days were not evaluated in controlled clinical trials.



Linezolid

solution for infusion 2 mg/ml

Trade name: Linezolid, solution for infusion 2 mg/ml.

International non-proprietary name: Linezolid.

Description: transparent colourless or slightly yellowish solution.

Composition:

each bottle of contains	100 ml	200 ml	300 ml
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Active substance: linezolid, g	0.2	0.4	0.6
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Excipients: anhydrous			
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glucose, g	4.57	9.14	13.71
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sodium citrate,			
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anhydrous citric acid, water			
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for injections, ml	up to 100	up to 200	up to 300
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Pharmacotherapeutic group: Antibacterial drugs for systemic use.

ATC code: J01XX08.

Indications for use

Treatment of infections caused by sensitive anaerobic or aerobic gram-positive strains, including the following infections accompanied by bacteremia:

- ▶ hospital-acquired pneumonia;
- ▶ community-acquired pneumonia;
- ▶ skin and soft tissues infections;
- ▶ enterococcal infections, including those caused by vancomycin-resistant strains *Enterococcus faecium* and *faecalis*.

If the causative agents include gram-negative bacteria, combined therapy is clinically indicated.

Linezolid

tablets

Trade name: Linezolid, tablets.

International non-proprietary name: Linezolid.

Description: white to off-white round biconvex film-coated tablets. Inequality of the film coating surface is acceptable.



Composition: each tablet contains:

Active substance: linezolid - 300 mg or 600 mg.

Excipient: corn starch, sodium starch glycolate of type A, hydroxypropyl cellulose (E463), magnesium stearate (E572), microcrystalline cellulose (type 101) (E460), Opadry II White (85F48105).

Composition of Opadry II White (85F48105) per one tablet: partially hydrolyzed polyvinyl alcohol, macrogol/polyethylene glycol, talc (E553b), titanium hydroxide (E171).

Pharmacotherapeutic group: Antibacterial drugs for systemic use, linezolid.

ATC code: J01XX08.

Indications for use

Treatment of infections caused by sensitive anaerobic or aerobic gram-positive strains, including the infections accompanied by bacteremia, in case of the conditions listed below. Linezolid is not indicated for treatment of gram-negative infections. It is very important to immediately initiate specific gram-negative therapy, if an infection with gram-negative bacteria is suspected or documentally confirmed.

► Pneumonia

Hospital-acquired pneumonia caused by *Staphylococcus aureus* (methicillin-sensitive and resistant isolates) or *Streptococcus pneumoniae*.

Community-acquired pneumonia caused by *Streptococcus*

pneumonia, including the cases with concomitant bacteremia, or *Staphylococcus aureus* (only methicillin-sensitive isolates).

► Skin and its structures infections

Complicated skin and its structures infections, including diabetic foot infections, without concomitant osteomyelitis, caused by *Staphylococcus aureus* (methicillin-sensitive and resistant isolates), *Streptococcus pyogenes* or *Staphylococcus agalactiae*.

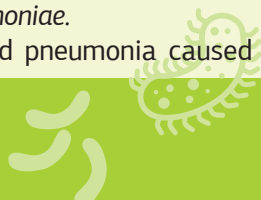
Linezolid is not studied with respect to bedsores treatment. Uncomplicated skin and its structures infections caused by *Staphylococcus aureus* (only methicillin-sensitive isolates) or *Streptococcus pyogenes*.

► Vancomycin-resistant *Enterococcus faecium* infections

Vancomycin-resistant *Enterococcus faecium* infections, including the cases of concomitant bacteremia.

► Administration

To reduce the growth of drug-resistant bacteria and to maintain the efficacy of linezolid and other antibacterial agents, linezolid should be used only for treatment or prevention of infections with proven or suspected sensitive microorganism. When the information about the culture and sensitivity is available, the conditions for selection or change of antibacterial therapy should be considered. If there is no such information, local epidemiological and sensitivity data may contribute to empiric choice of therapy.



Metronidazole

solution for infusion 5 mg/ml 100 ml

Trade name: Metronidazole, solution for infusion 5 mg/ml 100 ml.

International non-proprietary name: Metronidazole.

Description: clear colorless or with a pale greenish-yellow tint liquid.

Composition: 1 ml of the solution contains:

Active substance: metronidazole – 5 mg.

Adjuvant components: sodium chloride and water for injection.

Pharmacotherapeutic group: Synthetic antibacterial agents. Imidazole derivatives.

ATC code: J01XD01.

Indications for use

► Protozoal infections

Extraintestinal amebiasis, amebic liver abscess included, intestinal amebiasis (amebic dysentery), trichomoniasis, balantidiasis, lambliasis (giardiasis), dermal leishmaniasis, trichomonal vaginitis and trichomonal urethritis.

Infections caused by *Bacteroides* spp. (including *Bacteroides fragilis*, *Bacteroides distasonis*, *Bacteroides*



ovatus, *Bacteroides thetaiotaomicron* and *Bacteroides vulgatus*): bone and joint infections, central nervous system infections, including meningitis, cerebral abscess, bacterial endocarditis, pneumonia, pulmonary empyema and abscess and sepsis.

► Infections caused by species *Clostridium* spp., *Peptococcus* and

Peptostreptococcus: abdominal cavity infections (peritonitis and hepatic abscess) and pelvis minor organ infections (endometritis, Fallopian tube and ovary abscess and vaginal vault infections).

- Pseudomembranous colitis (antibiotics administration related). Gastritis or duodenal ulcer related to *Helicobacter pylori*.
- Post-surgery complication prevention (particularly operative interventions in colon and pararectal area, appendectomy and gynecological surgeries).
- Radiotherapy of tumor patients – as a radiation sensitizing medicinal agent in cases the tumor resistance is due to the tumor cell hypoxia.

Ornidazole

tablets 500 mg

Trade name: Ornidazole, tablets 500 mg.

International non-proprietary name: Ornidazole.

Description: white or white yellowish round biconvex tablets.

Composition: each tablet contains:

Active substance: ornidazole – 500 mg.

Excipients: potato starch, sodium lauryl sulphate, povidone, sodium starch glycolate (of type A), anhydrous colloidal silicon dioxide, talc, magnesium stearate, microcrystalline cellulose, Opadry II coating (85 G18490).

Composition of the Opadry II coating (85 G18490): polyvinyl alcohol, titanium hydroxide, talc, macrogol/polyethylene glycol 3350, lecithin (soybean).

Pharmacotherapeutic group: Other antibacterial drugs. Antiprotozoal drugs.

ATC code: J01XD03.

Indications for use

- ▶ trichomoniasis in women and men (urogenital infections in women and men caused by *Trichomonas vaginalis*);
- ▶ amebiasis (all intestinal infections caused by *Entamoeba histolytica*, including amoebic dysentery, all abentric amebiasis types, especially hepatic amoebiasis);
- ▶ giardiasis;
- ▶ prevention of anaerobic infections during large bowel surgeries and gynecological manipulations.



Other antibiotics