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Amikacin administration guidelines

generic name: amikacin sullfato dosage form: injection, medical reviewed solution from Drugs.com. last update on 1 December 2020. to reduce the development of drug-resistant bacteria and maintain the effectiveness of amykacin and other antibacterial drugs, amikacin should only be used to treat or prevent infections that are proven or strongly suspected of being caused by bacteria. Patients treated with parental aminoglycosides should be under close clinical observation due to the potential otosity and nephrotoxicity associated with their oo. safety for treatment periods which are longer than 14 days has not been established. neurotoxicity, manifested as bilateral and permanent hearing ototoxicity, can occur in patients with pre-existing kidney damage and in patients with normal kidney function treated at higher doses and/or for longer periods than recommended ones. the risk of otosity induced by aminoglycoside is greater in patients with kidney damage. high frequency deafness usually occurs before and can only be detected by audiometric tests. dizziness can occur and can be proof of vestibular lesions. Other manifestations of neurotoxicity may include numbness, tingling of the skin, muscle ticism and seizures. the risk of hearing loss due to aminoglycosides increases with the degree of exposure to high peak or high radius serum concentrations. patients who develop cochlear damage may not have symptoms during therapy to warn them to developtoxicity, and total or partial irreversible bilateral deafness may occur after the drug has been discontinued. Ototoxicity induced by aminoglycoside is usually irreversible. Aminoglycosides are potentially neurotoxic. The risk of nephrotoxicity is greater in patients with impaired kidney function and in those receiving high doses or prolonged therapy. The neuromuscular block and respiratory paralysis were reported as a result of parental injection, topic instillation (such as in orthopaedic and abdominal irrigation or local vacuum treatment), and after oral use of aminoglycosides. The possibility of these phenomena should be considered if aminoglycosides are administered from any path, especially in patients receiving anesthetics, neuromuscular blockers such as tubcurarine, succinylcholine, decamethonium, or in patients receiving massive blood transfusions citrate-anti-agulated. If the block occurs, calcium salts can reverse these phenomena, but mechanical respiratory assistance can be necessary. The kidney function and eighth curve should be closely monitored especially in patients with known or suspect kidney impairment at the beginning of therapy and also in those whose kidney function is initially normal but develop signs of kidney dysfunction during therapy. Amikacin serum concentrations must be monitored when possible to ensure adequate levels and to prevent potentially toxic levels and prolonged peak concentrations above 35 micrograms per mL. Urinebe examined by decrease in specific gravity, increase in protein excretion, and the presence of cells or castes. Nitrogen of the urea of blood, serum creatinine, or creatinine clearance should be measured periodically. Serial audiograms must be obtained where possible in patients old enough to be tested, especially high-risk patients. Ototoxicity test (dizziness, dizziness, dizziness, tinnitus, roaring in the ears and hearing loss) or nephrotoxicity requires suspension of regulation of the drug or dosage. It should be avoided the systemic, oral or topical use of other neurotoxic or nephrotic products, in particular bacitratin, cysplatin, amphotericin B, cephaloridine, paromomicin, viomicin, polymissin B, colistin, vancomicina or other aminoglycosides. Other factors that may increase the risk of toxicity are advanced age and dehydration. The concomitant use of Amikacin with powerful diuretics (ethcrynic acid, or furosemide) should be avoided since diuretics alone can cause otosity. In addition, when administered intravenously, diuretics can improve aminoglycoside toxicity by altering antibiotic concentrations in serum and tissue. Amikacin Description Amikacin sulphate is semisynthetic aminoglycoside antibiotic derived from kanamycin. It is C22H43N5O13•2H2SO4•O-3-amino-3-deoxy-α-D-glucopyranosyl-(1→4)-O-[6-amino-6-deoxy-α-D-glucopyranosyl-(1→6)-N3-(4-amino-L-2-hydroxybutyl)-2-deoxy-Lamine-L85. The dosing module isas a sterile solution, colourless for light straw colored for intramuscular or intravenous use. The 500 mg vial for 2 mL and 1 gram for 4 mL contains for each mL: 250 mg Amikacin (such as the Amikacin sulfate USP), 0.66% sodium metabisulfite as an antioxidant, 2.5% sodium citrate hydrohydrate as a buffer agent with pH regulated at 4.5 with sulphuric acid. Amikacin - Clinical Pharmacology Intramuscular Administration Amikacin is quickly absorbed after intramuscular administration. In normal adult volunteers, the average peak serum concentrations of about 12, 16, and 21 mcg/mL are obtained 1 hour after intramuscular administration of 250 mg (3.7 mg/kg), 375 mg (5 mg/kg), 500 mg (7.5 mg/kg), single doses, respectively. At 10 hours, serum levels are approximately 0.3 mcg/mL, 1.2 mcg/mL and 2.1 mcg/mL, respectively. Tolerance studies in normal volunteers reveal that Amikacin is well tolerated locally following repeated intramuscular dosages, and when administered at recommended maximally doses, it was not reported ototoxicity or nephrotoxicity. There is no evidence of drug accumulation with repeated dosage for 10 days when administered according to recommended doses. With normal kidney function, about 91.9% of an intramuscular dose is excreted unchanged in the urine in the first 8 hours and 98.2% within 24 hours. Average urine concentrations for 6 hours are 563 mcg/mL as a result of a dose of 250 mg, 697 mcg/mL as a result of a dose of 375 mg and 832 mcg/mL as a result of a dose of 500 mg. Preliminary intramuscular studiesof different weights (less than 1.5 kg, from 1.5 to 2 kg, more than 2 kg) to a dose of 7.5 mg/kg revealed that, like other aminoglycosides, the values of the serum half-life were inversely correlated with the post-natal age and the kidney authorizations of Amikacin. The distribution volume indicates that Amikacin, like other aminoglycosides, remains mainly in the extracellular fluid space of the newborns. Repeated dosing every 12 hours in all the above groups has not demonstrated the accumulation after 5 days. Endovenous administrations Single doses of 500 mg (7.5 mg/kg) given to normal adults as infusion for a period of 30 minutes produced an average peak serum concentration of 38 mcg/m L at the end of infusion, and the levels of 24 mcg/mL, 18 mcg/mL, and 0.75 mcg/mL at 30 minutes, 1 hour, and 10 hours post-infusion, respectively. Eighty-four percent of the dose given was excreted in urine in 9 hours and about 94% within 24 hours. Repeated infusions of 7.5 mg/kg every 12 hours in normal adults were well tolerated and did not cause drug accumulation. Generic pharmacokinetic studies in normal adult subjects reveal the average serum half-life to be slightly higher than 2 hours with an average apparent total volume of distribution of 24 liters (28% of body weight). With ultrafiltration technique, serum protein binding ratios range from 0 to 11%. The average serum clearance rate is about 100 mL/min and the renal clearance rate is 94 mL/min in subjects with normal renal function. Amikacin is excreted mainly fromfiltration. patients with impaired kidney function or decreased glomeral filtration pressure extract the drug much slower (effectively prolonging the serum half-life.) therefore, the kidney function should be monitored carefully and the regulated dosage accordingly (see the recommended dosage program under dosages and urination) after the administration to the recommended dose, the therapeutic levels are found in bones, heart, cystilists Spinal fluid levels in normal infants are about 10-20% of serum concentrations and can reach 50% when meninges are inflamed. amikacin has been shown to cross the placental barrier and produce significant concentrations in amniotic fluid. the concentration of the peak fetal serum is about 16% of the concentration of the peak breast serum and the values of the breast and fetal serum are about 2 and 3.7 hours respectively. microbiology mechanism of amikacin action, an aminoglycoside, binds to procariotic ribosm, inhibiting protein synthesis in susceptible bacteria. is bactericidal in vitro against Gram-positive and Gram-negative bacteria. the mechanism of aminoglycosides of resistance is known to be ineffective against species of salmonella and shigella in patients. Therefore, the results of the in vitro susceptibility test should not be reported. amikacin resists degradation by some aminoglycosideenzymes known to influence gentamycin, tobramycin and kanamycin. Aminoglycosides in general have a low order of activity against Gram-positive organisms other than Staphylococcal blocks. Interaction with other antimicrobial In vitro studies they have shown that Amikacin sulphate combined with a beta-lattam antibiotics acts synergistically against many clinically significant Gram-negative organisms. The antimicrobial activity Amikacin has been demonstrated active against the following bacteria, both in vitro and in clinical infections [see Indications and use] Gram-positive Bacteria Staphylococcus species Gram-negative Bacteria Pseudomonas species Escherichia coli Proteus species (indole-bacter and indole-negative bacteria) Klebsiella species Enterobacter Citrobacter freundii Test Methods When available, the clinical microbiology laboratory should provide cumulative results of in vitro susceptibility tests for antimicrobial drugs used in local hospitals and in practice areas to the doctor as periodic reports describing the susceptibility profile of nosocomial and community pathogens. These reports should help your doctor in choosing the most effective antimicrobial. DilutionQuantitative methods are used to determine minimum antimicrobial inhibition concentrations (MIC). These MICs provide estimates on bacteria susceptibility to antimicrobial compounds. MIC should be determined using a standardized test method.1, 3 Standardized procedures are based on a dilution method (brode or agar) or equivalent with standardized inoculo concentrations and standardized concentrations of Amikacin powder. MIC values must be interpreted according to the criteria set out in Table 1. Quantitative methods requiring measuring zone diameters also provide reproducible estimates of bacteria susceptibility to antimicrobial compounds. Such standardized procedure requires the use of standardized inoculum concentrations and impregnated paper discs with 30 mcg of Amikacin.2, 3 The disc diffusion values must be interpreted according to the criteria set out in Table 1. Table 1: Test Interpretive Criteria for Amikacin Pathogen Minimum concentrations of the inhibitory (mcg/m≤) Diffusion of the disk Zone diameter (mm) S I R I R I R Enterobacteriaceaea ≤ 16 32 ≥ 64 ≥ 17 15-16 ≤ 14 Pseudomonas aeruginosa ≤ 16 ≥ 64 ≥ 17 15-16 A "Sceptible" report indicates that antimicrobial is likely to inhibit the growth of pathogen ifthe antimicrobial compound reaches the concentration to the site of infection necessary to inhibit the growth of the pathogen. A "Intermediate" report indicates that the result should be considered equivocal, and if the microorganism is not fully susceptible to clinically feasible alternative drugs, the test should be repeated. This category implies the possible clinical applicability in the body sites where the drug is physiologically concentrated. This category also provides a buffer zone that prevents small uncontrolled technical factors from causing great discrepancies in interpretation. A report of "Resistant" indicates that antimicrobial is not likely to inhibit the growth of the pathogen if the antimicrobial compound reaches concentrations usually feasible at the site of infection; other therapy should be selected. Standardized susceptibility testing procedures require the use of laboratory controls to monitor and ensure the accuracy and accuracy of the supplies and reagents used in the analysis, and the techniques of people performing the test.1, 2, 3 standard Amikacin powder should provide the following range of MIC values provided in Table 2. For the diffusion technique using the Amikacin 30 mcg disc, the criteria set out in Table 2. Indications and use for Amikacin Amikacin Amikacin Sulfate Injection USP is indicated in the short-term treatment of serious infections due to sensitive strains of Gram-negative bacteria, including Pseudomonas species,coli, species of indole-positive and indole-negative species Proteus, species Providencia, species Klebsiella-Enterobacter-Serratia, and Acinetobacter (Mima-Herellea). Clinical studies have shown that Amikacin Sulphate Injection USP is effective in bacterial sepsis (including neonatal sepsis;) in severe respiratory, bone and joint infections, central nervous system (including meningitis) and skin and soft tissue; intra-addominal infections (including peritonitis;) and in burns and postoperative infections (including kiriche. Clinical studies have also shown Amikacin to be effective in severe complicated and recurrent urinary tract infections due to these organisms. Aminoglycosides, including Amikacin Sulfate Injection USP are not indicated in simple initial episodes of urinary tract infections unless causative organisms are susceptible to antibiotics with less potential toxicity. Bacterial studies should be performed to identify causative organisms and their susceptibility to Amikacin. Amikacin can be considered as initial therapy in suspected Gram-negative infections and therapy can be established before obtaining susceptibility test results. Clinical studies have shown that Amikacin was effective in infections caused by gentamycin and/or tobramycin-resistant strains of Gram-negative organisms, particularly Proteus rettgeri, Providencia stuartii, Serratia marcescens and Pseudomonas aeruginosa. The decisioncontinue therapy with the drug should be based on the results of susceptibility tests, the severity of the infection, the response of the patient and the important additional considerations contained in the WARNINGS box above. Amikacin has also been shown to be effective in staphylococcal infections and can be considered as an initial therapy under certain conditions in the treatment of known or suspect staphylococcal disease, such as, serious infections where the causative organism may be or a Gram-negative bacteria or a staphylococcus, infections due to sensitive strains of stacylococci in allergic patients to other tired-Glocina antibiotics. In some serious infections such as neonatal sepsis, concomitant therapy with a penicillin type drug may be indicated due to the possibility of infections due to Gram-positive organisms such as streptococci or pneumococci. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Amikacin and other antibacterial drugs, Amikacin should only be used to treat or prevent infections that are proven or strongly suspected of being caused by susceptible bacteria. When culture and susceptibility information is available, it must be considered in the selection or modification of antibacterial therapy. In the absence of such data, models of epidemiology and local susceptibility may contribute to the empirical selection of therapy. Contraindications A history of hypersensitivityAmikacin is a contraindication for its use. A history of hypersensitivity or severe toxic reactions to aminoglycosides may contraindicate the use of any other aminoglycoside due to the known cross-sensitivity of patients to drugs in this class. Warnings See WARNING box above. Aminoglycosides can cause fetal damage when administered to a pregnant woman. Aminoglycosides cross the placenta and there have been several relationships of total irreversible, congenital bilateral deafness in children whose mothers received streptomycin during pregnancy. Although severe side effects on fetus or infants have not been reported in the treatment of pregnant women with other aminoglycosides, there is potential for damage. Amikacin's reproduction studies were performed in rats and mice and revealed no evidence of fertility impairment or fetus damage due to Amikacin. There are no well-controlled studies in pregnant women, but the investigative experience does not include any positive evidence of adverse effects on the fetus. If this drug is used during pregnancy, or if the patient becomes pregnant during taking this medication, the patient must be aware of the potential danger to the fetus. It contains sodium metabisulphite, a sulphate that can cause type allergic reactions, including anaphylactic symptoms and threatening or less severe asthmatic episodes in some sensitive people. The general prevalence of sulphite sensitivity in the general population is unknown and probablySulphite sensitivity is seen more frequently in asthmatic than in non-asthmatic people. Clostridium difficult associated diarrhea (CDAD) has been reported with the use of almost all antibacterial agents, including Amikacin Sulfate Injection USP, and may vary in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon that leads to overgrowth of C. difficult. C. difficult produces A and B toxins that contribute to the development of CDAD. Hypertoxin that produces strains of C. difficult causes greater morbidity and mortality, as these infections may be refractory to antimicrobial therapy and may require cholectomy. CDAD should be considered in all patients presenting with diarrhea as a result of antibiotic use. Caution medical history is necessary since CDAD was reported to occur more than two months after administration of antibacterial agents. If the CDAD is suspected or confirmed, the continuous use of undirected antibiotics against C. difficult can be interrupted. Appropriate management of fluid and electrolyte, protein integration, antibiotic treatment of difficult C., and surgical evaluation must be established as clinically indicated. Precautions General Prescribing Amikacin in the absence of a proven or strongly suspected bacterial infection or prophylactic indication is unlikely to provide benefit to the patient and increases the risk of developing drug-resistant bacteria. Aminoglycosides are quickly and almostabsorbed when applied in a topical manner, except for urinary bladder, in association with surgical procedures. Unreversible deafness, kidney failure and death due to neuromuscular blockage were reported after irrigation of both small and large surgical fields with a preparation of Amikacin Sulfate Injection USP is potentially neurotoxic, otoxic and neurotoxic. Concurrent or serial use of other ototoxic or nephrotoxic agents should be avoided both systematically and in topology due to the potential of additive effects. The increase in nephrotoxicity was reported after concomitant parental administration of aminoglycoside and cephalosporin antibiotics. Concurrent cephalosporins can spuriously elevate the determinations of creatinine. As Amikacin is present in high concentrations in the kidney excretory system, patients must be well hydrated to minimize the chemical irritation of kidney tubules. The kidney function must be evaluated with the usual methods before starting therapy and every day during the course of treatment. If signs of kidney irritation appear (casts, white or red cells, or albumin), hydration should be increased. A reduction in dosage (see DOSAGE and ADMINISTRATION) can be desirable if other evidence of kidney dysfunction occurs such as the decrease in creatinine clearance; decrease in the specific gravity of urine; increase of BUN, creatinine or oliguria. If atathemia increases or if a progressive decrease in urinary output occurs, treatment shouldHe stopped. Note: When patients are well hydrated and renal function is normal the risk of neurotoxic reactions with Amikacin is low if the dosage recommendations (see DOSAGE and ADMINISTRATION) are not exceeded. Older patients may have a reduced kidney function that cannot be evident in routine screening tests such as BUN or creatinine serum. A determination of creatinine clearance can be more useful. Monitoring the kidney function during treatment with aminoglycosides is particularly important. Aminoglycosides should be used with caution in patients with muscle disorders such as myasthenia gravis or parkinsonism, since these drugs can aggravate muscle weakness due to their potential healing effect-like on the neuromuscular intersection. In vitro the mixing of aminoglycosides with beta-lactam antibiotics (penicillin or cephalosporin) can cause a significant mutual inactivation. A reduction in the level of hemivita sierica or serum can occur when an aminoglycoside or penicillin-type drug is administered by separate paths. Inactivation of aminoglycoside is clinically significant only in patients with severely compromised kidney function. Inactivation can continue in specimens of body fluids collected for analysis, resulting in inaccurate reading of aminoglycoside. Such samples must be properly handled (engaged promptly, frozen or treated with beta-lactamasis). The allergenity between aminoglycosides has been demonstrated. As with other antibiotics, the use of Amikacin can causeof organisms not susceptible. if this happens, appropriate therapy should be established. aminoglycosides should not be given simultaneously with powerful diuretics (see check in check out.) information for patients should be recommended that antibacterial drugs including amikacin should only be used to treat bacterial infections. do not treat viral infections (for example, common cold.) when amikacin is prescribed to treat a bacterial infection, patients should be told that even if it is common to feel better early in the course of therapy, the drug should be taken exactly as indicated. jump doses or not complete the full course of therapy can (1) decrease the effectiveness of immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by amikacin or other antibacterial drugs in the future. diarrhea is a common problem caused by antibiotics that usually ends when the antibiotic is stopped. Sometimes after starting treatment with antibiotics, patients may develop aqueous and bloody feces (with or without stomach cramps and fever) even up to two or more months after taking the last dose of the antibiotic. If this happens, patients should contact their doctor as soon as possible. carcinogenesis, mutagenesis, impairment of fertility long-term studies in animals to assess the carcinogenic potential have not been performed, and mutagenicity has not been studied. amikacin administeredto rats at doses up to 4 times the human daily dose did not alter male or female fertility. Pregnancy Teratogenic Effects; Pregnancy Category D (See ATTENTION section.) Nursing Mothers It is not known whether Amikacin is excreted in human milk. Since many drugs are excreted in human milk and due to the potential for severe adverse reactions in infants from Amikacin, you should make a decision if you stop breastfeeding or stop the drug, taking into account the importance of the drug to the mother. Pediatrics Using aminoglycosides should be used with caution in premature and neonatal infants due to the kidney immaturity of these patients and the consequent prolongation of the sieric half-life of these drugs. Adverse reactions All aminoglycosides have the potential to induce hearing, vestibular and renal toxicity and neuromuscular blockade (see ATTENTION box). They occur more frequently in patients with present or past history of kidney alteration, treatment with other otoxic or nephrotoxic drugs, and in patients treated for longer periods and/or with higher doses than recommended. Neurotoxicity-Otoxicity The toxic effects on the eighth cranial nerve can cause hearing loss, loss of balance, or both. Amikacin mainly affects the auditory function. Cochlear damages include high frequency deafness and usually occurs before the loss of clinical hearing can be detected. Neurotoxicity-Neuromuscular Muscle paralysis and acute apnea blocked may occur afterwith aminoglycoside drugs. nephrotoxicity have been reported the elevation of sierica creatinine, albuminuria, presence of red and white cells, cast, azotemia and oliguria. kidney function changes are generally reversible when the drug is stopped. as you would expect with any aminoglycoside, reports of toxic nephropathy and acute kidney failure were received during post-marketing surveillance. in addition to those described above, other adverse reactions that have been reported on rare occasions are rash, drug fever, headache, paresthesia, tremor, nausea and vomiting, eosinophilia, arthlargy, anemia, hypotension and hypomagnesimia. Macular heart attack sometimes leads to permanent loss of vision was reported after the amikacin intravitrea administration (injection in the eye). overdose in case of overdose or toxic reaction, peritoneal dialysis or hemodialysis will help in removing amikacin from the blood. in the newborn, the transfusion of exchange can also be considered. amikacin dosage and administration the body weight of pretreatment of the patient must be obtained for the calculation of the correct dosage. amikacin sulphate injection op can be administered by endomuscular or intravenous. the state of the kidney function should be estimated by measuring the concentration of serum creatinine or the calculation of the clearance rate of endogenous creatinine. Nitrogen of urea of blood (bun) is much less reliable for this purpose. reassessment of renal functionbe done periodically during therapy. When possible, concentrations of amikacin in serum must be measured to ensure adequate but not excessive levels. It is desirable to measure both peak serum and cough concentrations intermittently during therapy. peak concentrations (from 30 to 90 minutes after injection) above 35 micrograms per ml and cough concentrations (only before next dose) should be avoided above 10 micrograms per ml. the dosage must be adjusted as indicated. since the vials are only for monodose, any unused portion remaining in the vial must be discarded. intramuscular administration for patients with normal kidney function the recommended dose for adults, children and older children (see attention box) with the normal kidney function is 15 mg/kg/day divided into 2 or 3 equal doses administered at fairly divided intervals, i.e. 7,5 mg/kg q12h or 5 mg/kg q8h. Treatment of patients in the heavier weight classes should not exceed 1.5 grams per day. when amikacin is indicated in infants (see attention box,) it is recommended that a load dose of 10 mg/kg is initially administered to be followed with 7.5 mg/kg every 12 hours. the usual duration of treatment is from 7 to 10 days. It is desirable to limit the duration of the short-term treatment when possible. the total daily dose from all routes of administration should not exceed 15 mg/kg/day. in difficult and complicated infections where treatment over 10 days is considered, the amikacin oo should be re-evaluated. If you're notAmikacin serum levels and kidney, auditory and vestibule functions must be monitored. At the recommended dosage level, simple infections due to Amikacin sensitive organisms should respond in 24 to 48 hours. If the defined clinical response does not occur within 3-5 days, the therapy must be stopped and the antibiotic susceptibility model of the intrusive organism should be checked again. The failure of the responding infection may be due to the resistance of the body or the presence of septic septic septic septics requiring surgical drainage. When Amikacin is indicated in simple urinary tract infections, a dose of 250 mg twice a day can be used. DOSAGE GUIDELINS ADULTS AND CHILDREN WITH NORMAL RENAL FUNCTION 5 mg/kg of 5 mg/kg q12h or q8h 99 457.5 mg 225 mg 110 50 375 mg 250 mg 121 55 412.5 mg 132 60 mg 300 mg 143 65 487.5 mg 325 mg 154 70 525 mg 350 mg 165 75 562.5 mg 375 mg Both methods are based on patient creatinine clearance or serum creatinine values since these have beencorrelate with half-life aminoglycoside in patients with decreased kidney function. These dosing programs should be used in conjunction with patient's clinical and laboratory observations and should be modified if necessary. Nor should the method be used when dialysis is performed. Normal dose at prolonged intervals If the clearance rate of creatinine is not available and the patient's condition is stable, a dose interval in hours for the normal dose can be calculated by multiplying the patient's serum creatinine of 9, for example, if the creatinine serum concentration is 2 mg/100 mL, the recommended single dose (7.5 mg/kg) must be administered every 18 hours. Reduced dose at fixed time intervals When renal function is compromised and it is desirable to administer Amikacin to a fixed time interval, the dosage must be reduced. In these patients, Amikacin serum concentrations must be measured to ensure the accurate administration of Amikacin and to avoid concentrations of more than 35 mcg/mL. If the serum test determinations are not available and the patient's condition is stable, the creatinine serum and creatinine clearance values are the most readily available indicators of the renal alteration degree to be used as a guide to the dosage. First, start therapy by administering a normal dose, 7.5 mg/kg, as a load dose. This load dose is the same as the normally recommended dose which would be calculated for a patient with a normal kidney function as described above. Athe size of the maintenance doses administered every 12 hours, the load dose should be reduced in proportion to the reduction of the patient's creatinine clearance rate: An alternative rough guide to determine the reduced dosage at 12 hours intervals (for patients whose values of creatinine serum constant state are known) is to divide the dose normally recommended by the creatinine serum of the patient. The above dosage programs are not intended to be strict recommendations, but are provided as dosing guides when measuring Amikacin serum levels is not feasible. Endovenous administration The individual dose, the total daily dose and the total cumulative dose of Amikacin sulphate are identical to the recommended dose for intramuscular administration. The solution for intravenous use is prepared by adding the content of a 500 mg vial to 100 or 200 mL of sterile diluent such as injection of sodium chloride of 0.9% or injection of 5% dextrose or any of the compatible solutions listed below. The solution is given to adults for a period of 30-60 minutes. The total daily dose should not exceed 15 mg/kg/day and can be divided into two or three doses equally divided at fair intervals. In pediatric patients the amount of fluid used will depend on the amount of Amikacin ordered for the patient. It should be enough to instill Amikacin Sulfate Injection USP in a period of 30-60 minutes. Children should receive an infusion from 1 to 2 hours. Amikacin should not beprovided with other drugs, but must be administered separately according to the recommended dose and path. The stability in IV Amikacin sulphate fluids is stable for 24 hours at ambient temperature at concentrations of 0.25 and 5 mg/mL in the following solutions: Ringer Normosol® Injection Sodium Chloride Injection 5% Dextrose and Injection 0.2% Sodium Chloride Injection 0,45% M in 5% of dextrose injection (or plasma-L6L water) In the above solutions with the concentrations of Amikacin Sulfate Injection USP of 0.25 and 5 mg/mL, age solutions of 60 days at 4°C and then stored at 25° C had 24 hour utility times. At the same concentrations, frozen and aged solutions for 30 days at - 15°C, disconnected and stored at 25° C had 24 hour utility times. Parenteral pharmaceutical products should be visually inspected for particulate matter and discoloration before administration whenever the solution and container permit. Aminoglycosides administered by any of the above mentioned paths should not be physically preset with other drugs, but should be administered separately. Due to the potential toxicity of aminoglycosides, "fixed doses" recommendations that are not based on body weight are not recommended. Rather, it is essential to calculate the dosage to meet the needs of each patient. How is Amikacin Provided AmikacinUSP injection is provided as a transparent colorless solution for the colored light straw that does not require refrigeration. Sometimes the solution can become a very pale yellow; This does not indicate a decrease in power. Amikacin Sulphate Injection, USP Strength NDC Packing Configuration 500 mg for 2 mL 23155-785-41 10 Vials mono-dose (NDC 23155-785-31) in a 1 gram box for 4 mL 23155-786-41 10 Vials mono-Dose (NDC 23155-786-31) in a 20° to 25°C carton Store; [See the temperature of the controlled room USP]. To report DIVERSE SUSPECTED EVENTS, contact Avet Pharmaceuticals Inc. at 1-866-901-DRUG (3784) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. REFERENCES 1. Institute of clinical and laboratory standards (CLSI). Methods for dilution Antimicrobial susceptibility test for aerobic growing bacteria; Standard approved - tenth edition. CLSI document M07-A10, Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087, USA, 2015. 2. Institute of clinical and laboratory standards (CLSI). Performance standard for antimicrobial disk susceptibility test; Standard approved – Twelfth edition. CLSI document M02-A12, Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087, USA, 2015. 3. Institute of clinical and laboratory standards (CLSI). Performance standard for antimicrobial sensitivity tests; Twenty-fiveSupplement. CLSI documents M100-S25. Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087, USA, 2015. Manufactured by: Emcure Pharmaceuticals Ltd., Sanand, Ahmedabad – 382110, India. Product for: Avet Pharmaceuticals Inc. East Brunswick, NJ 08816 1.866.901.DRUG (3784) Novaplus is a registered trademark of Vizient, Inc. Main display panel - 500 mg/2 mL - label NDC 23155-785-31 Amikacin SULFATE INJECTION, USP *Equivalent to Amikacin FOR IM O IV 500 mg /2 m RT RT RT