Nelin

Netilmicin sulfate Injection USP
FOR IV/IM

PRODUCT DESCRIPTION
Clear, colorless to slightly yellow solution filled in colorless vial.

COMPOSITION
Each 2 ml contains : Netilmicin Sulfate USP equivalent to 100 mg of Netilmicin
Each 1.5 ml contains : Netilmicin Sulfate USP equivalent to 150 mg of Netilmicin
Preservative : Methylparaben 0.13 mg/ml, Propylparaben 0.02 mg/ml

PHARMACODYNAMICS
Netilmicin Sulfate is a semi-synthetic, water-soluble antibiotic of aminoglycoside group.
Netilmicin is a rapidly acting bactericidal, it probably acts by inhibiting normal protein synthesis in susceptible organisms, such as
- *Escherichia coli*
- *Klebsiella spp.*
- *Citrobacter spp.*
- *Proteus mirabilis*
- *P. vulgaris*
- *P. morganii*
- *P. rettgeri*
- *Pseudomonas aeruginosa*
- *Proteus spp.* (indole-positive and indole-negative)

Netilmicin is also active in vitro against isolates of
- *Hemophilus influenzae*
- *Shigella spp.*
- *Salmonella spp.*
- *Neisseria spp.*
- Penicillinase and non penicillinase-producing Staphylococcus including methicillin-resistant strains.
- Some strains of *Providencia spp., Acinetobacter spp.* and *Aeromonas spp.*
- Many strains of organism which are resistant to other aminoglycosides, such as kanamycin, gentamicin, tobramycin

Combination of netilmicin and penicillin G has a synergistic bactericidal effect against most strains of *Streptococcus faecalis* (enterococcus).
The combination effect of netilmicin and carbenicillin or ticarcillin is synergistic for many strains of *Pseudomonas aeruginosa.*

PHARMACOKINETICS
Absorption :
Netilmicin is poorly absorbed from the intact GI tract following oral administration.
It is rapidly and completely absorbed following IM administration.
Distribution :
Netilmicin rapidly distributes into tissues, sputum and pericardial, synovial and peritoneal fluids. The volume of distribution of netilmicin is approximately 20% of body weight. It is reported 0-30% protein bound.
Elimination :
The plasma elimination half-life of netilmicin is about 2-2.5 hours following IV or IM administration of a single dose in adults with normal renal function.

INDICATIONS
NELIN injection is indicated in the treatment of infections caused by susceptible strains of the above microorganisms. Clinical studies have shown NELIN to be effective in :
- Bacteremia, septicemia
- Serious infections of the respiratory tract
- Kidney and genitourinary tract infections
- Skin, soft tissue infections
- Bone, joint infections
- Burns, wounds, peri-operative infections
- Intra-abdominal infection (including peritonitis)
- Infections of gastrointestinal tract

NELIN injection is recommended as initial therapy in suspected or confirmed gram-negative infection. In serious infections when the causative organisms are unknown. NELIN injection may be administered as initial therapy in conjunction with a penicillin or cephalosporin type drug before, obtaining results of susceptibility testing. If anaerobic organisms are suspected suitable anti-microbial therapy in conjunction with NELIN injection should be given. Following identification of the organism and its susceptibility, NELIN injection or other appropriate antibiotic therapy should then be continued.

DOSAGE AND ADMINISTRATION
The recommended dosage for intramuscular and intravenous administration is identical as following.
Adult :
- 4.0-6.0 mg/kg/day given in three equal doses every 8 hours or two equal doses every 12 hours.
- For adults weighing 40-50 kg, a dose of 100 mg given every 12 hours.
- For adults weighing 50-90 kg, a dose of 150 mg given every 12 hours or 100 mg every 8 hours.
- For patients with life-threatening infections, dosages up to 7.5 mg/kg/day may be administered in three equal doses every 8 hours. This dosage should be reduced to 6 mg/kg/day or less as soon as clinically indicated, usually within 48 hours.

Children :
6.0-7.5 mg/kg/day (2.0 to 2.5 mg/kg administered every 8 hours)
For Intravenous Administration :
In adults, single dose may be diluted in 50 to 200 mL of one of the parenteral solutions as listed. In infants and children, the volume of diluent should be less, according to the fluid requirements of the patients. The solution must be infused over a period of $^1/_2$-2 hours.
The intravenous administration of NELIN is useful for treating patients with septicemia or shock. It may also be the preferred route of administration for some patients with congestive heart failure, hematologic disorders, severs burns, or those with reducted muscle mass.

PREGNANCY AND LACTATION
Safety in pregnancy has not been established. Netilmicin is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from netilmicin, a decision should be made whether to discontinue nursing or to discontinue the drug.

CONTRAINDICATIONS
Hypersensitivity and serious toxic reaction to netilmicin or other aminoglycosides contraindicated its use.

WARNING AND PRECAUTION
Patients treated with aminoglycosides should be under close clinical observation because of the potential toxicity associated with their use. Nephrotoxicity with netilmicin has been mild. However, as with other aminoglycosides, renal function should be closely monitored during therapy. The risk of nephrotoxicity is greater in patients with impaired renal function, in those who receive high dosage or prolonged therapy and in the elderly.
Although ototoxicity with netilmicin has been infrequent and appears to be milder than with other aminoglycosides, hearing loss and vestibular dysfunction can occur, primarily in patients with preexisting renal damage and in patients with normal renal function treated with higher doses and/or for longer periods than recommended.
Warning for Metabisulfite ; Following oral ingestion, sodium metabisulfite is oxidized to sulfate and is excreted in the urine. Ingestion may result in gastric irritation to liberation of sulfurous acid while ingestion of large amounts of sodium metabisulfite can cause gastrointestinal upsets, circulatory failure and central nervous system disturbances.

ADVERSE EFFECTS
Nephrotoxicity :
Adverse renal effects, generally mild in nature have been reported infrequently after netilmicin administration.
Neurotoxicity :
NELIN injection was different from any aminoglycoside because the incidence is lower and severity appears milder than with other aminoglycosides. Some patients who have had previous ototoxic reactions to other aminoglycosides have been treated safely with NELIN injection.

DRUG INTERACTIONS
Neurotoxic, Ototoxic or Nephrotoxic Drugs :
Since neurotoxic, ototoxic or nephrotoxic effects may be additive, concurrent and/or sequential use of an aminoglycoside and other drugs (administered systemically, orally or topically) with similar toxic potentials (e.g., other aminoglycosides, acyclovir, amphotericin B, bacitracin, capreomycin, cephalosporins, colistin, cisplatin, methoxyflurane, polymyxin B, vancomycin) should be avoided, if possible.
General Anesthetics and Neuromuscular Blocking Agents :
Concurrent use of an aminoglycoside with general anesthetics or neuromuscular blocking agents (e.g., succinylcholine, tubocurarine) may potentiate neuromuscular blockade and cause respiratory paralysis.

OVERDOSAGE
In the event of overdose or toxic reaction, hemodialysis or peritoneal dialysis will aid in the removal of netilmicin sulfate from the blood. However, the rate of removal is considerably less by peritoneal dialysis. These procedures are of particular importance for patients with impaired renal function.

INCOMPATIBILITIES
NELIN injection is physically compatible with the following parenteral solution, such as
- Sterile Water For Injection
- Normal Saline
- 3% and 5% Sodium Chloride Injection
- 5% Dextrose in Water
- 5% Dextrose and 0.9% Sodium Chloride Injection
- 50% Dextrose Injection
- 10% Dextrose in water
- Ringer's Injection
- Lactated Ringer's Injection
- Lactated Ringer's Injection with 5% Dextrose

STORAGE CONDITION
Store at temperature not exceeding 30°C and protect from light.
Shelf life after opening 3 days

SUPPLY
Printing box of 1x2 ml vial (100 mg/ 2 ml)
Printing box of 1x1.5 ml vial (150 mg/ 1.5 ml)

Date of revision : October 2020

Manufactured by
BIOLAB CO., LTD.
625 Bangpoo Industrial Estate,
Samutprakarn, Thailand

EEI041/A

Code : EEI041/A	Draft Revision : 1	Final Artwork Revision : B
Name : AW_LEAFLET NELIN NEW MAL.ai		
Remark :		

Design by	Review by	Approved by
Signature Date	Signature Date	Signature Date

Note :
#0=เพิ่ม Product Description (20/10/20)
#1=เพิ่ม Date of revision (23/10/20)

◯ ลูกค้าพิจารณาอนุมัติ ◯ ทำเสนอราคา ◯ ส่งพิมพ์
☑ RA ขึ้นทะเบียน ◯ อื่น ๆ .....

Specification
Size 190 x 220 MM. (+/- 3 MM.)
Color พิมพ์ 1 สี คือ สีดำ
Material ใช้กระดาษปอนด์ น้ำหนัก 55 แกรม
Other

Color Guide
Black