LORIKACIN®

AMIKACIN

Ampule and vial 100 mg/2ml, 500 mg/2ml
I.M. / I.V. Injection

Category: Antibiotics, aminoglycoside[1]

Indications:

This medicine is prescribed to treat your current condition. So avoid using it in the similar cases, events or recommend it to others.
Treatment of serious infections (e.g.: bone infection, respiratory tract infections, endocarditis septicemia) due to gram- negative organisms, including Pseudomonas, Escherichia coli, proteus, providencia, Klebsiella, Enterobacter, serratia, and Acinetobacter.

General tips:

Take this medicine with caution in the following cases:
Continue receiving Lorikacin® for full course of therapy on regular schedule.
Use proper dose.
During pregnancy and lactation inform the physician or pharmacist before takin the medicine.
If you have a history of allergy to aminoglycosides or its derivatives, inform your doctor or pharmacist
Audiogram, renal and vestibular function determinations may be required prior to, periodically during and following treatment in patients with pre-existing renal or eighth-cranial nerve impairment. If renal, vestibular, or auditory function impairment occurs, reduction in dose or discontinuation of the Lorikacin® may require.
Urinalyses may be required prior or during treatment to detect albumin, casts and cells in the urine.
The long-term use of this drug may result in increased its side effects.[2,3]

Contraindication:

Hypersensitivity to amikacin, other aminoglycosides, or any component of the formulation.[1]

Consumption during pregnancy and lactation:

The use of this drug is in Group D during pregnancy, it may cause fatal harm if administered to a pregnant woman.[1]
In lactating women, it is not recommended due to its secretion in the milk, it should be use under the supervision of a physician.[2]

Warnings and Precautions:

Amikacin may cause neurotoxicity, nephrotoxicity, and/or neuromuscular blockade and respiratory paralysis.
Usual risk factors include preexisting renal impairment, concomitant neuro-/nephrotoxic medications, advanced age and dehydration. Dose and/or frequency of administration must be monitored and modified in patients with renal impairment. Drug should be discontinued if signs of ototoxicity, nephrotoxicity, or hypersensitivity occur. Ototoxicity is proportional to the amount of drug given and the duration of treatment. Tinnitus or vertigo may be indications of vestibular injury and impending bilateral irreversible damage. Renal damage is usually reversible. Irreversible deafness, renal failure and death due to neuromuscular blockade have been reported following use of aminoglycosides as surgical irrigation; rapid systemic absorption occurs with topical application.
Use with caution in patients with renal insufficiently, neuromuscular disorders, preexisting vertigo, hearing loss, tinnitus, or hypocalcemia.
Avoid concomitant or sequential use of other neurotoxic and/or nephrotoxic drugs and concomitant use with potent diuretics since diuretics themselves may cause ototoxicity and may enhance aminoglycoside toxicity.
Cross – sensitivity to other aminoglycoside may cause allergic-type reactions as well as life–threatening or less severe asthmatic episodes in certain individuals.

Dosing:

The amount and method of taking the drug for each patient is recommended by the physician, but the usual dose is as follows:

• Adults & Geriatric:

Individualization is critical because of the low therapeutic index
In underweight and non-obese patients, use of total body weight (TBW)
Instead of ideal body weight for determining the initial mg/kg/dose is widely accepted. Ideal body weight (IBW) also may be used to determine doses for patients who are neither underweight nor obese.
Recommended Maximum daily dose: 15 mg/kg/day
Usual dosage range:
I.M. / I.V. injection, 5 –7.5 mg/kg/dose every 8 hours.
Note: some clinician suggested a daily dose of 15 to 20 mg/kg/day for all patients with normal renal function.

Indication – specific dosing:

Meningitis:

I.V. injection, 5 mg/kg every 8 hours.

Mycobacterium fortuitum, M. chelonae, or M. abscessus:

I.V. injection, 10 – 15 mg/kg daily for at least 2 weeks with high dose cefoxitin.

• Pediatric general dosing, severe, susceptible infection:

Infants, children and adolescents: I.M, I.V. injection, 15 – 22.5 mg/kg/day or 15 – 20 mg/kg/dose every 8 hours every 24 hours.
Note: dose should be individualized based upon serum concentration monitoring, body weight (IBW, TBW).

Indication – specific dosing:

Peritonitis (CAPD):

Infants, children and adolescents: Continuous: loading doses: 25 mg per liter of dialysate; maintenance dose: 12 mg per liter.

• Renal impairment:

Some patients may require larger or more frequent doses if serum levels
Document the need

Adults:

The following adjustments have been recommended.

Note:

Renally adjusted dose recommendations are based on a 7.5 mg/kg every 12hours
GFR > 50 ml/minute: no adjustment necessary
GFR10 to 50 ml/minute: administer every 24 to 72 hours based on serum concentration
GFR< 10 ml/minute: administer every 24 to 72 hours based on serum concentration.
Intermittent hemodialysis (IHD) Dialyzable: 5 – 7.5 mg/kg every 48 to 72 hours
Note: dosing dependent on the assumption of 3 times/week, complete IHD session.
Intermittent dosing: 2 mg/kg per exchange once daily, allow to dwell ≥ 6 hours
Continuous dosing:
Loading dosing: 25 mg/l
Continuous dosing: 12 mg/l

Infants, children and adolescents:

Renally adjusted dose recommendations are based on a 5 to 7.5 mg/kg every 8 hours
GFR > 50 ml/minute/minute/1.73 m2: no adjustment necessary
GFR30 to 50 ml/minute/minute/1.73 m2: administer every 12 to 18 hours
GFR 29 to 10 ml/minute/minute/1.73 m2: administer every 18 to 24 hours
GFR < 10 ml/minute/1.73 m2: administer every 48 to 72 hours.
Intermittent hemodialysis: 5 mg/kg/dose: redoes as indication by serum concentration.
Continuous dosing: 5 mg/kg/dose: redoes as indication by serum concentration.
Continuous renal replacement therapy (CRRT): 7.5 mg/kg/dose every 12hours monitor serum concentration.
Hepatic impairment: there is no adjustment necessary
Obesity: in moderate obesity initial dosage requirement may be estimated may be estimated using a dosing weight of IBW+0.4

ADMINISTRTION:

IM: Administer IM injection in large muscle mass.
IV: Infuse over 30 to 60 minutes, adolescents (children, adolescents, and adults), or over 1 to 2 hours (infants).
The diluent volume should be sufficient for drug infusion over one to two hours in infants and over 30 to 60 minutes in older children.
Its compatible wilt solution like: dextrose, sodium chloride,

Monitoring parameter:

Urinalysis, BUN, serum creatinine, appropriately time peak and trough concentrations, vital signs, temperature, weight, I & O, hearing parameters.[1]

Adverse effects:

Each drug, along with the desired therapeutic effects, may also cause unwanted side effects.
Central nervous system: neurotoxicity
Genitourinary: nephrotoxicity
Otic: auditory ototoxicity vestibular ototoxicity
Rare but life-threatening: Dyspnea, eosinophilia, hypersensitivity reaction.[1]

Poisoning:

If you accidentally use more than recommended, go to the treatment center immediately.

Storage:

Store at the temperature below 30°C
Protect from light.
Protect from freezing.
Keep out of the reach of children.
Take the product immediately after preparation and dilution and dispose of the remainder of the drug after use.
The content is colorless to light yellow, avoid taking crystal or turbid drugs.[1]

Availability:

Each Ampoule/Vial contains amikacin (as sulfate) 100mg and 500mg produced by the Exir pharmaceutical company, supplied in 10 Ampoule/vial in 1 packages under name of lorikacin®.

References:

1. Lexi comp Drug information handbook, 2018, 26th edition , Pages 109-111
2. Drug facts and comparisons, 2015, Pages: 1347
3. AHFS Drug information 2010, Pages: 2178-2180
4. Handbook of injectable drugs 15th edition 37-39

2205131/ 1

MANUFACTURED BY
EXIR PHARMACEUTICAL CO.
IRAN

EXIR 98.09.03
W*L=140 * 200 mm
Text : 287 U
Headline : 259 U