CODAL-SYNTO

For treatment of severe infection

AMIKA-SYNTO®

Amikacin

Amika-Synto® 250mg/2ml ampoules • Amika-Synto® 500mg/2ml ampoules

Summary of SPC for Amika-Synto®

Trade Name of the Medicinal Product:	Amika-Synto®
Qualitative and Quantitative Composition:	Each Amika-Synto ampoule contains: Amikacin Sulphate equivalent to 250mg/2ml amikacin or Amikacin Sulphate equivalent to 500mg/2ml amikacin.
Therapeutic Indications:	Amikacin is indicated in the short-term treatment of serious infections due to susceptible strains of G (-) bacteria including Pseudomonas species. At times it may also be indicated for the treatment of known or suspected Staphylococcal disease although it is not the drug of choice for infections due to Staphylococci. These situations include severe infections when the organisms suspected are either G (-) or Staphylococci, patients allergic to other antibiotics and mixed Staphylococcal/ G (-) infections. Amikacin sulphate is also active against some G (+) organisms like Staphylococcus aureus, including methicillin-resistant strains. Amikacin has some activity against other G (+) organisms including certain strains of Streptococcus pyogenes, Enterococci and Diplococcus pneumoniae.
Posology and Method of Administration:	Adults and children: The recommended dose is 15mg/kg in two equally divided doses (equivalent to 500mg bid in adults) daily. In life-threatening infections and/or in infections caused by Pseudomonas the adult dose may be increased to 500mg every eight hours. It should neither exceed 1.5g/day nor be administered for a period longer than 10 days. A maximum total adult dose of 15g should not be exceeded. Neonates and premature infants: The suggested initial leading dose is 10mg/kg followed by 15mg/kg daily, in two equally divided doses. Urinary tract infections (other than Pseudomonal infections): The suggested dose is 7.5mg/kg/day in two equally divided doses (equivalent to 250mg bid in adults). As the activity of amikacin is enhanced by increasing the pH, a urinary alkalizing agent may be administered concurrently. In patients with impaired renal function, the daily dose should be reduced and /or the intervals between doses increase to avoid accumulation of the drug. Intraperitoneal use: In concentrations of 0.25% (2.5mg/ml) as an irrigant after recovery from anaesthesia. If instillation is desired in adults, a single dose of 500mg is diluted in 20ml of sterile distilled water and may be instilled through a polyethylene catheter sutured into the wound at closure.
Contra-indications:	Patients with known hypersensitivity to amikacin or any of the other ingredients of Amika-Synto; Patients with myasthenia gravis.
Special Warnings and Precautions for Use:	Patients should be well hydrated during amikacin therapy. Impaired renal function or diminished glomerular filtration. Ototoxicity and/or nephrotoxicity can result from the use of amikacin, as with other aminoglycosides; Elderly patients; If signs of renal irritations appear hydration should be increased and a reduction in dosage may be desirable. However, if azotaemia or a progressive decrease in urine output occurs, treatment should be stopped; Patients with a history of allergy to aminoglycosides or in patients who may have subclinical renal or eighth nerve damage induced by prior administration of nephrotoxic and / or ototoxic should be considered with caution, as toxicity may be additive; Large doses given during surgery have been responsible for a transient Myasthenic syndrome; Sulphites can cause allergic-type reactions.
Interactions with Other Medicinal Products and Other Forms of Interaction:	Other potentially nephrotoxic or ototoxic drug substances (frusemide and ethacrynic acid); In patients under the influence of anaesthetics or muscle-relaxing drugs (including ether, halothane, d-tubocurarine, succinylcholine and decamethonium) intraperitoneal use of amikacin is not recommended as neuromuscular blockade and consequent respiratory depression may occur; Indomethacin.
Pregnancy and Lactation:	The safety of amikacin in pregnancy has not been established. Amikacin rapidly crosses the placenta into the foetal circulation and amniotic fluid and there is a potential risk of ototoxicity in the foetus.
Undesirable Effects:	Tinnitus, vertigo, partial reversible deafness, skin rash, drug fever, headache, paraesthesia, nausea, vomiting, renal irritation, azotaemia, oliguria and retinal toxicity.
	MAH: Codal Synto Ltd.