KANAMYCIN CAPSULES "MEIJI"
KANAMYCIN MONOSULFATE
CAPSULES

PROPERTIES

Kanamycin is an aminoglycoside antibiotic produced by *Streptomyces kanamyceticus*. The aminoglycosides bind to the bacterial 30 S ribosomal sub-unit in the inhibition of bacterial cell protein synthesis.
The bactericidal effect Kanamycin is to the gram — negative and gram — positive bacteria as well. Kanamycin capsules administered orally and hardly absorbed from the digestive tract. Therefore, KANAMYCIN CAPSULES "MEIJI" are only administered to treat for bowel sterilization and adjunct in the treatment of hepatic coma.

DESCRIPTION

Kanamycin capsules contain a white powder and are free of visible foreign matter and contamination.

COMPOSITION

Each capsule of KANAMYCIN CAPSULES "MEIJI" contains 250 mg (Base) of Kanamycin monosulfate.

INDICATIONS

Kanamycin capsules taken orally are hardly absorbed from the alimentary canal, so not for systemic use; it is only for sterilization of gastrointestinal tract preoperatively and adjunct in the treatment of hepatic coma.

ADMINISTRATION AND DOSAGE

For bowel sterilization:
Adult: 1 g every hour for 4 hours, and then
1 g every 6 hours for 36 — 72 hours.

Children & babies: 150 — 250 mg/kg/day in divided dosage every hour for 6 hours.

For adjunct in the treatment of hepatic coma:
Adult: 8 —12 g a day in divide dosage

PRECAUTIONS

Administered carefully to the following patients:

1. Patients with renal impairment, hearing impairment or intestinal ulcer.
2. Orally poorly nourished or parenterally nourished patients, elderly patients and patients in poor general health. (Sufficient observation should be performed because vitamin K deficiency may develop).
3. Renal function should be checked before and after therapy.
4. Eventhough this drug is hardly absorbed, but if the renal impairment the side effect may occur
5. <Pulmonary tuberculosis and other tuberculosis>
   A paradoxical drug reaction may be observed due to the treatment with antitubercular agents including this drug. If worsening of existing tuberculosis or new onset of tuberculosis symptoms is observed after initiating the treatment, whether to continue administration should be determined on the basis of drug susceptibility tests, etc.

SIDE EFFECTS

Administration of Kanamycin could induce damage of the VIII cranial nerve. If tinnitus, dizziness or vertigo occurs, administration should be discontinued. In some other patients nephrotoxic, headache, numbness, nausea, vomiting, diarrhea, and loose stool may occur.

A malabsorption syndromes after prolonged oral preparation with fatty feces, decreases carotene, and failure of xylose absorption.

Superinfection with fungi occurs during therapy particularly if the treatment is prolonged.

Acute muscular paralysis and apnea can occur following treatment with aminoglycosides antibiotics.

REPORTING OF SUSPECTED SIDE EFFECT

Reporting of suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are required to report any suspected adverse reaction via:

Pharmacovigilance Section
PT. Meiji Indonesian Pharmaceutical Industries
Jl. Prof. Dr. Soepomo No. 40, Tebet, Jakarta Selatan 12870, Indonesia
Telepon: (021) 21383388
E-mail: pv.report@meiji.co.id

CONTRAINDICATIONS

Administration of the drug should be avoided to the intestinal obstructive and hypersensitivity to aminoglycosides such as: fradiomycin, streptomycin, gentamycin, etc.

Effects on the fetus should be considered if aminoglycosides are administered during pregnancy.

Kanamycin is not effective for microorganisms which are not sensitive. This drug is not indicated in long term therapy (e.g. Tuberculosis) because of the toxic hazard associated with extended administration.

List of excipients:

Magnesium stearate, calcium carboxymethylcellulose, corn starch, gelatin capsules

Storage and shelf life

KANAMYCIN CAPSULES "MEIJI" should be stored below 30°C and should be used before the expiry date stated on the label.

Class of drug:
Prescription drug

This drug should be administered by or under the supervision of a physician.

HARUS DENGAN RESEP DOKTER

Packaging and registration number:
KANAMYCIN CAPSULES "MEIJI":
Box, 10 blisters @ 10 capsules.
Reg. No. DKL9115301101A1

Manufactured by
meiji
PT MEIJI INDONESIAN
PHARMACEUTICAL INDUSTRIES
Bangil - Pasuruan, Jawa Timur - Indonesia

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Meiji Seika Pharma Co., Ltd.
Tokyo, Japan

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