

Dimension : 81 x 208 mm

CYCLOSPORINE

INJECTION USP

50 mg/ml

COMPOSITION

Each ml contains:

Cyclosporine USP 50 mg.

INDICATIONS

Organ rejection prophylaxis in kidney, liver, and heart allogeneic transplants, in combination with corticosteroids. Treatment of chronic rejection in patients previously treated with other immunosuppressants. IV: reserved for patients who are unable to take caps or oral solution.

DOSAGE AND ADMINISTRATION

Adult:

Observe continuously for the first 30mins after start of infusion and frequently thereafter. Give by slow IV infusion over 2–6hrs. Administer IV at ½ oral dose. Initially 5–6mg/kg/day as a single dose given 4–12hrs prior to transplantation. Adjunct corticosteroid therapy is recommended. Conversion from Neoral, blood concentration monitoring.

CONTRAINDICATIONS

IV: hypersensitivity to Cremophor EL.

WARNINGS/PRECAUTIONS

Not bioequivalent to all other forms of cyclosporine; do not interchange without physician supervision. Increased risk of infections, lymphomas and other malignancies (eg, skin). Monitor BP, renal and hepatic function. Control hypertension if develops. Malabsorption. Elderly. Pregnancy (Cat.C).

INTERACTIONS

Avoid other nephrotoxic drugs (eg, ciprofloxacin, gentamicin, tobramycin, vancomycin, SMX/TMP, melphalan, amphotericin B, ketoconazole, cimetidine, ranitidine, tacrolimus, NSAIDs, colchicine), fibric acid derivatives, methotrexate. Cyclosporine levels increased by CYP3A inhibitors (eg, calcium channel blockers, amiodarone, azithromycin, azole antifungals, erythromycin, clarithromycin, quinupristin/dalfopristin, boceprevir, telaprevir, methylprednisolone, allopurinol, colchicine, bromocriptine, danazol, metoclopramide, probably indinavir, saquinavir, nelfinavir, ritonavir, imatinib, nefazodone, oral contraceptives). Avoid alcohol, grapefruit juice.

ADVERSE REACTIONS

Renal dysfunction, tremor, hirsutism, hypertension, gum hyperplasia, cramps, convulsions, headache, diarrhea, nausea, vomiting; increased risk of infections or malignancies, progressive multifocal leukoencephalopathy, polyoma virus-associated nephropathy, hypomagnesemia, hyperkalemia, hyperuricemia, thrombotic microangiopathy, hepatotoxicity, neurotoxicity; IV: anaphylactic reactions.

STORAGE

Store between temperature 20 to 25°C. Protect from light.

KEEP OUT OF THE REACH OF CHILDREN.

PRESENTATION

10 ampoules of 1ml in a plastic tray and each try packed in a printed carton.

Manufactured by:
KWALITY PHARMACEUTICALS LTD.
Nag Kalan, Majitha Road, Amritsar - INDIA


Marketed by:
RemDcion
Healthcare International
Navi Mumbai, India.

06CLJ72

RemDcion Healthcare International

Component:
Leaflet

Code:
CYCL/LT/22

Version: 01

Colour: Black

GSM: 54 gsm Maplitho Paper

Dimension: L 81 x H 208 mm

Product: Cyclosporine Injection USP 50mg LEAFLET

Date: 18.05.22

Approved