

**CellCept® (mycophenolate mofetil)**

No data are available for cardiac or hepatic transplant patients with severe chronic renal impairment. CellCept may be used for cardiac or hepatic transplant patients with severe chronic renal impairment if the potential benefits outweigh the potential risks.

If neutropenia develops ( $ANC < 1.3 \times 10^3/\mu L$ ), dosing with CellCept should be interrupted or the dose reduced, appropriate diagnostic tests performed, and the patient managed appropriately (see WARNINGS, ADVERSE REACTIONS, and PRECAUTIONS: *Laboratory Tests*).

**HANDLING AND DISPOSAL:** Mycophenolate mofetil has demonstrated teratogenic effects in rats and rabbits (see PRECAUTIONS: Pregnancy). CellCept tablets should not be crushed and CellCept capsules should not be opened or crushed. Avoid inhalation or direct contact with skin or mucous membranes of the powder contained in CellCept capsules and CellCept Oral Suspension (before or after constitution). If such contact occurs, wash thoroughly with soap and water; rinse eyes with plain water. Should a spill occur, wipe up using paper towels wetted with water to remove spilled powder or suspension. Caution should be exercised in the handling and preparation of solutions of CellCept Intravenous. Avoid direct contact of the prepared solution of CellCept Intravenous with skin or mucous membranes. If such contact occurs, wash thoroughly with soap and water; rinse eyes with plain water.

**HOW SUPPLIED:****CellCept (mycophenolate mofetil capsules)****250 mg**

Blue-brown, two-piece hard gelatin capsules, printed in black with "CellCept 250" on the blue cap and "Roche" on the brown body. Supplied in the following presentations:

<u>NDC Number</u>	<u>Size</u>
NDC 0004-0259-01	Bottle of 100
NDC 0004-0259-05	Package containing 12 bottles of 120
NDC 0004-0259-43	Bottle of 500

**Storage:** Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).

**CellCept (mycophenolate mofetil tablets)****500 mg**

Lavender-colored, caplet-shaped, film-coated tablets printed in black with "CellCept 500" on one side and "Roche" on the other. Supplied in the following presentations:

<u>NDC Number</u>	<u>Size</u>
NDC 0004-0260-01	Bottle of 100
NDC 0004-0260-43	Bottle of 500

**CellCept® (mycophenolate mofetil)**

**Storage and Dispensing Information:** Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). Dispense in light-resistant containers, such as the manufacturer's original containers.

**CellCept Oral Suspension (mycophenolate mofetil for oral suspension)**

Supplied as a white to off-white powder blend for constitution to a white to off-white mixed-fruit flavor suspension. Supplied in the following presentation:

<u>NDC Number</u>	<u>Size</u>
NDC 0004-0261-29	225 mL bottle with bottle adapter and 2 oral dispensers

**Storage:** Store dry powder at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). Store constituted suspension at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) for up to 60 days. Storage in a refrigerator at 2° to 8°C (36° to 46°F) is acceptable. Do not freeze.

**CellCept Intravenous (mycophenolate mofetil hydrochloride for injection)**

Supplied in a 20 mL, sterile vial containing the equivalent of 500 mg mycophenolate mofetil as the hydrochloride salt in cartons of 4 vials:

<u>NDC Number</u>
NDC 0004-0298-09

**Storage:** Store powder and reconstituted/infusion solutions at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).

R<sub>x</sub> only

**CellCept® (mycophenolate mofetil)**

Distributed by:



**Pharmaceuticals**

Roche Laboratories Inc.  
340 Kingsland Street  
Nutley, New Jersey 07110-1199

XXXXXXXX-XXXX

Revised: Month/Year  
Printed in USA

Copyright © 1998-2001 by Roche Laboratories Inc. All rights reserved.