

Table 5. Adverse Reactions Reported in 3% to <20% of Patients Treated with CELLCEPT in Combination with Cyclosporine and Corticosteroids

Body System	Adverse Reactions
Body as a Whole	Abscess, cellulitis, chills occurring with fever, malaise, peritonitis
Hematologic and Lymphatic	coagulation disorder, ecchymosis, pancytopenia, petechia, polycythemia, prothrombin time increased, thromboplastin time increased
Urogenital	acute kidney failure, albuminuria, dysuria, , hematuria, kidney failure, kidney tubular necrosis, pain, pyelonephritis, scrotal edema
Cardiovascular	angina pectoris, arrhythmia, atrial fibrillation, atrial flutter, bradycardia, congestive heart failure, extrasystole, heart failure, hypotension, palpitation, pericardial effusion, pulmonary hypertension, supraventricular tachycardia, supraventricular extrasystoles, syncope, tachycardia, ventricular extrasystole, ventricular tachycardia,
Metabolic and Nutritional	acidosis, hypercholesteremia, hyperlipemia,
Digestive	anorexia, , esophagitis, flatulence, gastritis, gastroenteritis, gastrointestinal hemorrhage, gastrointestinal moniliasis, gingivitis, gum hyperplasia, hepatitis, ileus, jaundice, melena, mouth ulceration, nausea and vomiting, oral moniliasis, stomach ulcer, stomatitis
Respiratory	bronchitis, epistaxis, hemoptysis, lung edema, pharyngitis, pleural effusion, pneumonia, respiratory moniliasis, rhinitis, sinusitis
Skin and Appendages	acne, fungal dermatitis, hemorrhage, hirsutism ,pruritus, rash, skin benign neoplasm, skin carcinoma, vesiculobullous rash

Pediatric Study

The type and frequency of adverse events in a clinical study for prevention of kidney allograft rejection in 100 pediatric patients 3 months to 18 years of age dosed with CELLCEPT oral suspension 600 mg/m² twice daily (up to 1 g twice daily) were generally similar to those observed in adult patients dosed with CELLCEPT capsules at a dose of 1 g twice daily with the exception of abdominal pain, fever, infection, pain, sepsis, diarrhea, vomiting, pharyngitis, respiratory tract infection, hypertension, leukopenia, and anemia, which were observed in a higher proportion in pediatric patients.

Geriatrics

Elderly patients (≥65 years), particularly those who are receiving CELLCEPT as part of a combination immunosuppressive regimen, may be at increased risk of certain infections (including cytomegalovirus [CMV] tissue invasive disease) and possibly gastrointestinal hemorrhage and pulmonary edema, compared to younger individuals [*see Warnings and Precautions (5.3) and Adverse Reactions (6.1)*].

CELLCEPT Intravenous

The safety profile of CELLCEPT Intravenous was determined from a single, double-blind, controlled comparative study of the safety of 2 g/day of intravenous and oral CELLCEPT in kidney transplant patients in the immediate post-transplant period (administered for the first 5 days). The potential venous irritation of CELLCEPT Intravenous was evaluated by comparing the adverse reactions attributable to peripheral venous infusion of CELLCEPT Intravenous with those observed in the intravenous placebo group; patients in the placebo group received active medication by the oral route.

Adverse reactions attributable to peripheral venous infusion were phlebitis and thrombosis, both observed at 4% in patients treated with CELLCEPT Intravenous.

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of CELLCEPT. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure:

- **Embryo-Fetal Toxicity**: Congenital malformations and spontaneous abortions, mainly in the first trimester, have been reported following exposure to mycophenolate mofetil (MMF) in combination with other immunosuppressants during pregnancy [*see Warnings and Precautions (5.1), and Use in Specific Populations (8.1), (8.3)*]. Congenital malformations include:
 - Facial malformations: cleft lip, cleft palate, micrognathia, hypertelorism of the orbits
 - Abnormalities of the ear and eye: abnormally formed or absent external/middle ear, coloboma, microphthalmos
 - Malformations of the fingers: polydactyly, syndactyly, brachydactyly
 - Cardiac abnormalities: atrial and ventricular septal defects
 - Esophageal malformations: esophageal atresia
 - Nervous system malformations: such as spina bifida.
- **Digestive**: colitis, pancreatitis, isolated cases of intestinal villous atrophy.
- **Hematologic and Lymphatic**: Cases of pure red cell aplasia (PRCA) and hypogammaglobulinemia have been reported in patients treated with CELLCEPT in combination with other immunosuppressive agents [*see Warnings and Precautions (5.4)*].
- **Infections**: Meningitis, infectious endocarditis, tuberculosis, atypical mycobacterial infection, progressive multifocal leukoencephalopathy, BK virus infection, viral reactivation of hepatitis B and hepatitis C [*see Warnings and Precautions (5.3)*].
- **Respiratory**: Interstitial lung disorders, fatal pulmonary fibrosis, have been reported rarely and should be considered in the differential diagnosis of pulmonary symptoms ranging from dyspnea to respiratory failure in post-transplant patients receiving CELLCEPT.

7 DRUG INTERACTIONS

7.1 Effect of Other Drugs on CELLCEPT

Table 6. Drug Interactions with CELLCEPT that Affect Mycophenolic Acid (MPA) Exposure

Antacids with Magnesium or Aluminum Hydroxide	
<i>Clinical Impact</i>	Concomitant use with an antacid containing magnesium or aluminum hydroxide decreases MPA systemic exposure [see <i>Clinical Pharmacology (12.3)</i>], which may reduce CELLCEPT efficacy.
<i>Prevention or Management</i>	Administer magnesium or aluminum hydroxide containing antacids at least 2h after CELLCEPT administration.
Proton Pump Inhibitors (PPIs)	
<i>Clinical Impact</i>	Concomitant use with PPIs decreases MPA systemic exposure [see <i>Clinical Pharmacology (12.3)</i>], which may reduce CELLCEPT efficacy.
<i>Prevention or Management</i>	Monitor patients for alterations in efficacy when PPIs are co-administered with CELLCEPT.
<i>Examples</i>	Lansoprazole, pantoprazole
Drugs that Interfere with Enterohepatic Recirculation	
<i>Clinical Impact</i>	Concomitant use with drugs that directly interfere with enterohepatic recirculation, or indirectly interfere with enterohepatic recirculation by altering the gastrointestinal flora, can decrease MPA systemic exposure [see <i>Clinical Pharmacology (12.3)</i>], which may reduce CELLCEPT efficacy.
<i>Prevention or Management</i>	Monitor patients for alterations in efficacy or CELLCEPT related adverse reactions when these drugs are co-administered with CELLCEPT.
<i>Examples</i>	Trimethoprim/sulfamethoxazole, bile acid sequestrants (cholestyramine), rifampin as well as aminoglycoside, cephalosporin, fluoroquinolone and penicillin classes of antimicrobials
Drugs Modulating Glucuronidation	
<i>Clinical Impact</i>	Concomitant use with drugs inducing glucuronidation decreases MPA systemic exposure, potentially reducing CELLCEPT efficacy, while use with drugs inhibiting glucuronidation increases MPA systemic exposure [see <i>Clinical Pharmacology (12.3)</i>], which may increase the risk of CELLCEPT related adverse reactions.
<i>Prevention or Management</i>	Monitor patients for alterations in efficacy or CELLCEPT related adverse reactions when these drugs are co-administered with

	CELLCEPT.
<i>Examples</i>	Telmisartan (induces glucuronidation); isavuconazole (inhibits glucuronidation).
Calcium Free Phosphate Binders	
<i>Clinical Impact</i>	Concomitant use with calcium free phosphate binders decrease MPA systemic exposure [see <i>Clinical Pharmacology (12.3)</i>], which may reduce CELLCEPT efficacy.
<i>Prevention or Management</i>	Administer calcium free phosphate binders at least 2 hours after CELLCEPT.
<i>Examples</i>	Sevelamer

7.2 Effect of CELLCEPT on Other Drugs

Table 7. Drug Interactions with CELLCEPT that Affect Other Drugs

Drugs that Undergo Renal Tubular Secretion	
<i>Clinical Impact</i>	When concomitantly used with CELLCEPT, its metabolite MPAG, may compete with drugs eliminated by renal tubular secretion which may increase plasma concentrations and/or adverse reactions associated with these drugs.
<i>Prevention or Management</i>	Monitor for drug-related adverse reactions in patients with renal impairment.
<i>Examples</i>	Acyclovir, ganciclovir, probenecid, valacyclovir, valganciclovir
Combination Oral Contraceptives	
<i>Clinical Impact</i>	Concomitant use with CELLCEPT decreased the systemic exposure to levonorgestrel, but did not affect the systemic exposure to ethinylestradiol [see <i>Clinical Pharmacology (12.3)</i>], which may result in reduced combination oral contraceptive effectiveness.
<i>Prevention or Management</i>	Use additional barrier contraceptive methods.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to mycophenolate during pregnancy and those becoming pregnant within 6 weeks of discontinuing CELLCEPT treatment. To report a pregnancy or obtain information about the registry, visit www.mycophenolateREMS.com or call 1-800-617-8191.

Risk Summary

Use of mycophenolate mofetil (MMF) during pregnancy is associated with an increased risk of first trimester pregnancy loss and an increased risk of multiple congenital malformations in multiple organ systems [see *Human Data*]. Oral administration of mycophenolate to rats and

rabbits during the period of organogenesis produced congenital malformations and pregnancy loss at doses less than the recommended clinical dose (0.02 to 0.1 times the recommended clinical doses in kidney and heart transplant patients) [*see Animal Data*].

Consider alternative immunosuppressants with less potential for embryofetal toxicity. Risks and benefits of CELLCEPT should be discussed with the pregnant woman.

The estimated background risk of pregnancy loss and congenital malformations in organ transplant populations is not clear. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data

Human Data

A spectrum of congenital malformations (including multiple malformations in individual newborns) has been reported in 23 to 27% of live births in MMF exposed pregnancies, based on published data from pregnancy registries. Malformations that have been documented include external ear, eye, and other facial abnormalities including cleft lip and palate, and anomalies of the distal limbs, heart, esophagus, kidney, and nervous system.

Based on published data from pregnancy registries, the risk of first trimester pregnancy loss has been reported at 45 to 49% following MMF exposure.

Animal Data

In animal reproductive toxicology studies, there were increased rates of fetal resorptions and malformations in the absence of maternal toxicity. Oral administration of MMF to pregnant rats from Gestational Day 7 to Day 16 produced increased embryofetal lethality and fetal malformations including anophthalmia, agnathia, and hydrocephaly at doses equivalent to 0.03 and 0.02 times the recommended human doses for renal and cardiac transplant patients, respectively, when corrected for BSA. Oral administration of MMF to pregnant rabbits from Gestational Day 7 to Day 19 produced increased embryofetal lethality and fetal malformations included ectopia cordis, ectopic kidneys, diaphragmatic hernia, and umbilical hernia at dose equivalents as low as 0.1 and 0.06 times the recommended human doses for renal and cardiac transplant patients, respectively, when corrected for BSA.

8.2 Lactation

Risk Summary

There are no data on the presence of mycophenolate in human milk, or the effects on milk production. There are limited data in the National Transplantation Pregnancy Registry on the effects of mycophenolate on a breastfed child [*see Data*]. Studies in rats treated with MMF have shown mycophenolic acid (MPA) to be present in milk. Because available data are limited, it is not possible to exclude potential risks to a breastfeeding infant.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for CELLCEPT and any potential adverse effects on the breastfed infant from CELLCEPT or from the underlying maternal condition.

Data

Limited information is available from the National Transplantation Pregnancy Registry. Of seven infants reported by the National Transplantation Pregnancy Registry to have been

breastfed while the mother was taking mycophenolate, all were born at 34-40 weeks gestation, and breastfed for up to 14 months. No adverse events were reported.

8.3 Females and Males of Reproductive Potential

Females of reproductive potential must be made aware of the increased risk of first trimester pregnancy loss and congenital malformations and must be counseled regarding pregnancy prevention and planning.

Pregnancy Planning

For patients who are considering pregnancy, consider alternative immunosuppressants with less potential for embryofetal toxicity whenever possible. Risks and benefits of CELLCEPT should be discussed with the patient.

Pregnancy Testing

To prevent unplanned exposure during pregnancy, all females of reproductive potential should have a serum or urine pregnancy test with a sensitivity of at least 25 mIU/mL immediately before starting CELLCEPT. Another pregnancy test with the same sensitivity should be done 8 to 10 days later. Repeat pregnancy tests should be performed during routine follow-up visits. Results of all pregnancy tests should be discussed with the patient. In the event of a positive pregnancy test, consider alternative immunosuppressants with less potential for embryofetal toxicity whenever possible.

Contraception

Female Patients

Females of reproductive potential taking CELLCEPT must receive contraceptive counseling and use acceptable contraception (see **Table 8** for acceptable contraception methods). Patients must use acceptable birth control during the entire CELLCEPT therapy, and for 6 weeks after stopping CELLCEPT, unless the patient chooses abstinence.

Patients should be aware that CELLCEPT reduces blood levels of the hormones from the oral contraceptive pill and could theoretically reduce its effectiveness [see *Drug Interactions (7.2)*].

Table 8. Acceptable Contraception Methods For Females Of Reproductive Potential

Pick from the following birth control options:

Option 1	
Methods to Use Alone	<ul style="list-style-type: none"> • Intrauterine devices (IUDs) • Tubal sterilization • Patient’s partner vasectomy

OR

Option 2	Hormone Methods choose 1		Barrier Methods choose 1
Choose One Hormone Method AND	Estrogen and Progesterone <ul style="list-style-type: none"> • Oral Contraceptive Pill 		<ul style="list-style-type: none"> • Diaphragm with spermicide

One Barrier Method	<ul style="list-style-type: none"> • Transdermal patch • Vaginal ring <p>Progesterone-only</p> <ul style="list-style-type: none"> • Injection • Implant 	<i>AND</i>	<ul style="list-style-type: none"> • Cervical cap with spermicide • Contraceptive sponge • Male condom • Female condom
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OR

Option 3	Barrier Methods choose 1		Barrier Methods choose 1
Choose One Barrier Method from each column <i>(must choose two methods)</i>	<ul style="list-style-type: none"> • Diaphragm with spermicide • Cervical cap with spermicide • Contraceptive sponge 	<i>AND</i>	<ul style="list-style-type: none"> • Male condom • Female condom

Male Patients

Genotoxic effects have been observed in animal studies at exposures exceeding the human therapeutic exposures by approximately 2.5 times. Thus, the risk of genotoxic effects on sperm cells cannot be excluded. Based on this potential risk, sexually active male patients and/or their female partners are recommended to use effective contraception during treatment of the male patient and for at least 90 days after cessation of treatment. Also, based on the potential risk of genotoxic effects, male patients should not donate sperm during treatment with CELLCEPT and for at least 90 days after cessation of treatment [see *Use in Special Populations (8.1)*, *Nonclinical Toxicology (13.1)*, *Patient Counseling Information (17.9)*].

8.4 Pediatric Use

Safety and effectiveness of CELLCEPT have been established in pediatric patients 3 months and older for the prophylaxis of kidney rejection after allogeneic kidney transplant. Use of CELLCEPT in this population is supported by evidence from adequate and well-controlled studies of CELLCEPT in adults with additional data from one open-label, pharmacokinetic and safety study of CELLCEPT in pediatric patients after receiving allogeneic kidney transplant [see *Dosage and Administration (2.2)*, *Adverse Reactions (6.1)*, *Clinical Pharmacology (12.3)*, *Clinical Studies (14.1)*].

Safety and effectiveness in pediatric patients receiving allogeneic heart or liver transplants have not been established.

8.5 Geriatric Use

Clinical studies of CELLCEPT did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should take into consideration the presence of decreased hepatic, renal or cardiac function and of concomitant drug therapies. [see *Adverse Reactions (6.1)*, *Drug Interactions (7)*].

- If you are not able to swallow CELLCEPT tablets or capsules, your doctor may prescribe CELLCEPT Oral Suspension. This is a liquid form of CELLCEPT. Your pharmacist will mix the medicine before you pick it up from a pharmacy.
- Do not mix CELLCEPT Oral Suspension with any other medicine. CELLCEPT Oral Suspension should not be mixed with any type of liquids before taking the dose. See the Instructions for Use at the end of this Medication Guide for detailed instructions about how to take CELLCEPT Oral Suspension the right way.
- **Do not** breathe in (inhale) or let CELLCEPT powder or oral suspension come in contact with your skin or mucous membranes.
 - If you accidentally get the powder or oral suspension on the skin, wash the area well with soap and water.
 - If you accidentally get the powder or oral suspension in your eyes or other mucous membranes, flush with plain water.
- If you take too much CELLCEPT, call your doctor or the poison control center right away.

What should I avoid while taking CELLCEPT?

- Avoid becoming pregnant. See “**What is the most important information I should know about CELLCEPT?**”
- Limit the amount of time you spend in sunlight. Avoid using tanning beds or sunlamps. People who take CELLCEPT have a higher risk of getting skin cancer (See “**What is the most important information I should know about CELLCEPT?**”). Wear protective clothing when you are in the sun and use a sunscreen with a high protection factor. This is especially important if your skin is very fair or if you have a family history of skin cancer.
- You should not donate blood while taking CELLCEPT and for at least 6 weeks after stopping CELLCEPT.
- You should not donate sperm while taking CELLCEPT and for 90 days after stopping CELLCEPT.
- CELLCEPT may influence your ability to drive and use machines (See “**What are the possible side effects of CELLCEPT?**”). If you experience drowsiness, confusion, dizziness, tremor, or low blood pressure during treatment with CELLCEPT, you should be cautious about driving or using heavy machines.

What are the possible side effects of CELLCEPT?

CELLCEPT can cause serious side effects, including:

- See “**What is the most important information I should know about CELLCEPT?**”
- **Low blood cell counts.** People taking high doses of CELLCEPT each day may have a decrease in blood counts, including:
 - **white blood cells, especially neutrophils.** Neutrophils fight against bacterial infections. You have a higher chance of getting an infection when your white blood cell count is low. This is most common from 1 month to 6 months after your transplant.
 - **red blood cells.** Red blood cells carry oxygen to your body tissues. You have a higher chance of getting severe anemia when your red blood cell count is low.
 - **platelets.** Platelets help with blood clotting.
 Your doctor will do blood tests before you start taking CELLCEPT and during treatment with CELLCEPT to check your blood cell counts. Tell your doctor right away if you have any signs of infection (See “**What is the most important information I should know about CELLCEPT?**”), including any unexpected bruising or bleeding. Also, tell your doctor if you have unusual tiredness, lack of energy, dizziness or fainting.
- **Stomach problems.** Stomach problems including intestinal bleeding, a tear in your intestinal wall (perforation) or stomach ulcers can happen in people who take CELLCEPT. Bleeding can be severe and you may have to be hospitalized for treatment. Call your doctor right away if you have sudden or severe stomach-area pain or stomach-area pain that does not go away, or if you have diarrhea.

The most common side effects of CELLCEPT include:

- | | |
|---|--|
| <ul style="list-style-type: none"> • diarrhea • blood problems including low white and red blood cell counts • infections • blood pressure problems • fast heart beat • swelling of the lower legs, ankles and feet | <ul style="list-style-type: none"> • changes in laboratory blood levels, including high levels of blood sugar (hyperglycemia) • stomach problems including diarrhea, constipation, nausea and vomiting • rash • nervous system problems such as headache, dizziness and tremor |
|---|--|

Side effects that can happen more often in children than in adults taking CELLCEPT include:

- | | |
|---|--|
| <ul style="list-style-type: none"> • stomach area pain • fever • infection • pain • blood infection (sepsis) • diarrhea | <ul style="list-style-type: none"> • vomiting • sore throat • colds (respiratory tract infections) • high blood pressure • low white blood cell count • low red blood cell count |
|---|--|

These are not all of the possible side effects of CELLCEPT. Tell your doctor about any side effect that bothers you or that

does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Genentech at 1-888-835-2555.

How should I store CELLCEPT?

- Store CELLCEPT capsules and tablets at room temperature between 59°F to 86°F (15°C to 30°C).
- Keep CELLCEPT tablets in the light resistant container that it comes in.
- Store CELLCEPT Oral Suspension at room temperature between 59°F to 86°F (15°C to 30°C), for up to 60 days. You can also store CELLCEPT Oral Suspension in the refrigerator between 36°F to 46°F (2°C to 8°C). **Do not freeze.**

Keep CELLCEPT and all medicines out of the reach of children.

General Information about the safe and effective use of CELLCEPT.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use CELLCEPT for a condition for which it was not prescribed. Do not give CELLCEPT to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about CELLCEPT. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about CELLCEPT that is written for health professionals.

What are the ingredients in CELLCEPT?

Active Ingredient: mycophenolate mofetil

Inactive Ingredients:

CELLCEPT 250 mg capsules: croscarmellose sodium, magnesium stearate, povidone (K-90) and pregelatinized starch. The capsule shells contain black iron oxide, FD&C blue #2, gelatin, red iron oxide, silicon dioxide, sodium lauryl sulfate, titanium dioxide, and yellow iron oxide.

CELLCEPT 500 mg tablets: black iron oxide, croscarmellose sodium, FD&C blue #2 aluminum lake, hydroxypropyl cellulose, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, povidone (K-90), red iron oxide, talc, and titanium dioxide; may also contain ammonium hydroxide, ethyl alcohol, methyl alcohol, n-butyl alcohol, propylene glycol, and shellac.

CELLCEPT Oral Suspension: aspartame, citric acid anhydrous, colloidal silicon dioxide, methylparaben, mixed fruit flavor, sodium citrate dihydrate, sorbitol, soybean lecithin, and xanthan gum.

CELLCEPT Intravenous: polysorbate 80, and citric acid. Sodium hydroxide may have been used in the manufacture of CELLCEPT Intravenous to adjust the pH.

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For more information, call 1-888-835-2555 or visit www.gene.com/gene/prodcuts/information/CELLCEPT.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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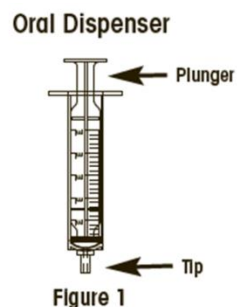
INSTRUCTIONS FOR USE
CELLCEPT®[SEL-sept]
(mycophenolate mofetil for oral suspension)

Be sure that you read, understand and follow these instructions carefully to ensure proper dosing of CELLCEPT Oral Suspension.

Important:

- Always use the oral dispenser provided with CELLCEPT Oral Suspension to make sure you measure the right amount of medicine.
- Call your pharmacist if your oral dispenser is lost or damaged.
- Your pharmacist will write the expiration date on your CELLCEPT Oral Suspension bottle label. Do not use after the expiration date.
- Ask your doctor or pharmacist if you have any questions or are unsure about how to take your dose of medicine.

To take a dose of CELLCEPT Oral Suspension, you will need the bottle of medicine and an oral dispenser provided with the medicine (**See Figure 1**). Your pharmacist will insert the bottle adapter in the CELLCEPT Oral Suspension bottle.



- Step 1:** With the child-resistant cap on the bottle, shake the bottle well for about 5 seconds before each use.
- Step 2:** Open the bottle by pressing down on the child-resistant bottle cap and turning it counter-clockwise (to the left). **Do not** throw away the child-resistant bottle cap.
- Step 3:** Before inserting the tip of the oral dispenser into the bottle adapter, push the plunger completely down toward the tip of the oral dispenser. Insert the tip firmly into the opening of the bottle adapter.

Step 4: Carefully turn the bottle upside down with the oral dispenser in place. Slowly pull the plunger down to withdraw your prescribed dose. **Do not** pull the plunger out of the oral dispenser (See **Figure 2**).

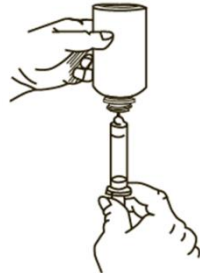


Figure 2

Step 5: Leave the oral dispenser in the bottle and turn the bottle to an upright position. Slowly remove the oral dispenser from the bottle.

Step 6: Place the tip of the oral dispenser in the patient's mouth and slowly push the plunger down until the oral dispenser is empty. The CELLCEPT oral suspension that is in the oral dispenser should not be mixed with any type of liquids before taking the dose.

Step 7: Put the child-resistant bottle cap back on the bottle after each use.

Step 8: Rinse the oral dispenser under running tap water after each use:

- Remove the plunger from the oral dispenser.
- Rinse the oral dispenser and plunger with water and let them air dry.
- When the oral dispenser and plunger are dry, put the plunger back in the oral dispenser for the next use.

Important:

- **Do not** let CELLCEPT Oral Suspension come in contact with the skin. If this happens, wash the skin well with soap and water.
- If you spill any oral suspension, wipe it up using paper towels wet with water. Put the child-resistant bottle cap back on the bottle and wipe the outside of the bottle with wet paper towels.

How should I store CELLCEPT Oral Suspension?

- Store the CELLCEPT Oral Suspension at room temperature between 59°F to 86°F (15°C to 30°C), for up to 60 days. You can also store CELLCEPT Oral Suspension in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not** freeze.

Keep CELLCEPT Oral Suspension and all medicines out of the reach of children.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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