

NDA 50-722/S-019
NDA 50-723/S-017
NDA 50-758/S-017
NDA 50-759/S-022
Page 4

MEDICATION GUIDE

CellCept® [SEL-sept]
(mycophenolate mofetil capsules)
(mycophenolate mofetil tablets)

CellCept® Oral Suspension
(mycophenolate mofetil for oral suspension)

CellCept® Intravenous
(mycophenolate mofetil hydrochloride for injection)

Read the Medication Guide that comes with CellCept before you start taking it and each time you refill your prescription. There may be new information. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about CellCept?

CellCept can cause serious side effects:

- **Possible loss of a pregnancy and higher risk of birth defects.** Women who take CellCept during pregnancy have a higher risk of losing a pregnancy (miscarriage) during the first 3 months (first trimester), and a higher risk that their baby will be born with birth defects

If you are a female and are able to become pregnant

- your healthcare provider must talk with you about effective birth control methods (contraceptive counseling)
- you should have a negative pregnancy test within 1 week before you start to take CellCept
- you must use 2 different types of effective birth control at the same time, for 4 weeks before you start taking CellCept, during your entire CellCept therapy and for 6 weeks after stopping CellCept, unless you choose to avoid sexual intercourse completely (abstinence). CellCept decreases blood levels of the hormones in birth control pills that you take by mouth. Birth control pills may not work as well while you take CellCept, and you could become pregnant

If you plan to become pregnant, talk with your healthcare provider. Your healthcare provider will decide if other medicines to prevent rejection may be right for you. In certain situations, you and your healthcare provider may decide that taking CellCept is more important to your health than the possible risks to your unborn baby.

- **If you get pregnant while taking CellCept, do not stop taking CellCept. Call your healthcare provider right away.** You and your healthcare provider should report any cases of pregnancies to
 - FDA MedWatch at 1-800-FDA-1088
 - Roche Professional Drug Safety at 1-800-526-6367

NDA 50-722/S-019
NDA 50-723/S-017
NDA 50-758/S-017
NDA 50-759/S-022
Page 5

Talk to your healthcare provider about joining the National Transplantation Pregnancy Registry at 1-877-955-6877.

- **Increased risk of getting serious infections.** CellCept weakens the body's immune system and affects your ability to fight infections. Serious infections can happen with CellCept and can lead to death. Types of infections can include:
 - **Viral infections.** Viral infections, including shingles, other herpes infections, and cytomegalovirus (CMV), can happen with CellCept. CMV can cause serious tissue and blood infections
 - **A brain infection called Progressive Multifocal Leukoencephalopathy (PML).** In some patients, CellCept may cause an infection of the brain that may cause death. You are at risk for this brain infection because you have a weakened immune system. You should tell your healthcare provider right away if you have any of the following symptoms:
 - Weakness on one side of the body
 - You do not care about things that you usually care about (apathy)
 - You are confused or have problems thinking
 - You can not control your muscles
 - **Fungal infections.** Yeasts and other types of fungal infections can happen with CellCept and can cause serious tissue and blood infections (see “**What are the possible side effects of CellCept?**”)

Call your healthcare provider right away if you have any of the following signs and symptoms of infection:

- Temperature of 100.5°F or greater
 - Cold symptoms, such as a runny nose or sore throat
 - Flu symptoms, such as an upset stomach, stomach pain, vomiting or diarrhea
 - Earache or headache
 - Pain during urination
 - White patches in the mouth or throat
 - Unexpected bruising or bleeding
 - Cuts, scrapes or incisions that are red, warm and oozing pus
- **Increased risk of getting certain cancers.** People who take CellCept have a higher risk of getting lymphoma, and other cancers, especially skin cancer. Tell your healthcare provider if you have:
 - unexplained fever, prolonged tiredness, weight loss or lymph node swelling
 - a brown or black skin lesion with uneven borders, or one part of the lesion does not look like the other
 - a change in the size and color of a mole
 - a new skin lesion or bump

NDA 50-722/S-019
NDA 50-723/S-017
NDA 50-758/S-017
NDA 50-759/S-022
Page 6

- any other changes to your health

See the section “What are the possible side effects of CellCept?” for information about other serious side effects.

What is CellCept?

CellCept is a prescription medicine to prevent rejection (antirejection medicine) in people who have received a kidney, heart or liver transplant. Rejection is when the body’s immune system perceives the new organ as a “foreign” threat and attacks it.

CellCept is used with other medicines called cyclosporines (Sandimmune[®], Gengraf[®], Neoral[®]) and corticosteroids. These medicines work together to prevent rejection to your transplanted organ.

CellCept has been used safely and works in children who received a kidney transplant as it does in adults. It is not known if CellCept is safe and works in children who receive a heart or liver transplant.

Who should not take CellCept?

Do not take CellCept if you are allergic to mycophenolate mofetil or any of the ingredients in CellCept. See the end of this Medication Guide for a complete list of ingredients in CellCept.

What should I tell my healthcare provider before taking CellCept?

Tell your healthcare provider about all of your medical conditions, if you:

- **have any digestive problems**, such as ulcers
- **have Phenylketonuria (PKU)**. CellCept contains aspartame (a source of phenylalanine)
- **have Lesch-Nyhan or Kelley-Seegmiller syndrome or another rare inherited deficiency hypoxanthine-guanine phosphoribosyl-transferase (HGPRT)**. You should not take CellCept if you have one of these disorders
- **plan to receive any vaccines. People taking CellCept should not take live vaccines.** Some vaccines may not work as well during treatment with CellCept
- **are pregnant or are planning to become pregnant.** See “What is the most important information I should know about CellCept?”
- **are breastfeeding.** It is not known if CellCept passes into breast milk. You and your healthcare provider will decide if you will take CellCept or breastfeed. You should not do both without first talking with your healthcare provider

Tell your healthcare provider about all of the medicines you are taking including prescription and nonprescription medicines, vitamins and herbal supplements. Some medicines may affect the way CellCept works, and CellCept may affect how some medicines work. Especially tell your healthcare provider if you take:

- birth control pills (oral contraceptives). See “What is the most important information I should know about CellCept?”
- sevelamer (Renagel[®], Renvela[™]). These products should be taken 2 hours after taking CellCept
- acyclovir (Zovirax[®]), valacyclovir (Valtrex[®]), ganciclovir (Cytovene[®]-IV, Valcyte[®])
- rifampin (Rifater[®], Rifamate[®], Rimactane[®], Rifadin[®])

NDA 50-722/S-019

NDA 50-723/S-017

NDA 50-758/S-017

NDA 50-759/S-022

Page 7

- antacids that contain magnesium and aluminum (CellCept and the antacid should not be taken at the same time)
- sulfamethoxazole/trimethoprim (Bactrim™, Bactrim DS™)
- norfloxacin (Noroxin®) and metronidazole (Flagyl®, Flagyl® ER, Flagyl® IV, Metro IV, Helidac®, Pylera™)
- azathioprine (Azasan®, Imuran®)
- cholestyramine (Questran Light®, Questran®, Locholest Light, Locholest, Prevalite®)

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine. Do not take any new medicine without talking with your healthcare provider.

How should I take CellCept?

- Take CellCept exactly as prescribed
- Do not stop taking CellCept or change the dose unless your healthcare provider tells you to
- If you miss a dose of CellCept, or are not sure when you took your last dose, take the regular amount of CellCept prescribed as soon as you remember. If it is time for your next dose, skip the missed dose. Do not take 2 doses at the same time. Call your healthcare provider if you are not sure what to do
- Take CellCept capsules, tablets and oral suspension on an empty stomach, either 1 hour before or 2 hours after a meal, unless your healthcare provider tells you otherwise. With the approval of your healthcare provider, in stable kidney transplant patients, CellCept can be taken with food if necessary
- Most people take CellCept by mouth either as blue and orange capsules or lavender tablets. Some people may get CellCept soon after their transplant surgery as an infusion into a vein
- Do not crush CellCept tablets. Do not open or crush CellCept capsules
- If you are not able to swallow CellCept tablets or capsules, your healthcare provider may prescribe CellCept Oral Suspension. This is a liquid form of CellCept. Your pharmacist will mix the medicine before giving it to you
- Do not mix CellCept Oral Suspension with any other medicine
- If you take too much CellCept, call your healthcare provider or the poison control center right away

What should I avoid while taking CellCept?

- **Avoid pregnancy.** See “What is the most important information I should know about CellCept?”

NDA 50-722/S-019
NDA 50-723/S-017
NDA 50-758/S-017
NDA 50-759/S-022
Page 8

- **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 (SPF 30 and above). This is especially important if your skin is very fair or if you have a family history of skin cancer

What are the possible side effects of CellCept?

CellCept can cause serious side effects:

- 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 3 months to 6 months after your transplant
 - **red blood cells.** Red blood cells carry oxygen to your body tissues
 - **platelets.** Platelets help with blood clotting

Your healthcare provider will do blood tests before you start taking CellCept and during treatment with CellCept to check your blood cell counts.

Tell your healthcare provider right away if you have any signs of infection (see “**What is the most important information I should know about CellCept?**”). Also, tell your healthcare provider about any unexpected bruising or bleeding.

- **Stomach problems.** Stomach and intestinal bleeding can happen in people who take high doses of CellCept. Bleeding can be severe and you may have to be hospitalized for treatment

Common side effects include:

- diarrhea. Call your healthcare provider right away if you have diarrhea. Do not stop taking CellCept without first talking with your healthcare provider
- vomiting
- pain
- stomach area pain
- swelling of the lower legs, ankles and feet
- high blood pressure

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

- stomach area pain
- fever
- infection
- pain
- blood infection (sepsis)
- diarrhea
- sore throat
- colds (respiratory tract infections)
- high blood pressure
- low white blood cell count
- low red blood cell count

NDA 50-722/S-019
NDA 50-723/S-017
NDA 50-758/S-017
NDA 50-759/S-022
Page 9

- vomiting

These are not all of the possible side effects of CellCept. Tell your healthcare provider 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 the FDA at 1-800-FDA-1088.

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 the container closed tightly
- Store the prepared 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 at 36°F to 46°F (2°C to 8°C). **Do not freeze CellCept Oral Suspension**
- **Keep CellCept and all medicines out of the reach of children**

General Information about 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 healthcare professionals. For more information, go to www.rocheusa.com/products/CellCept or call 1-800-526-6367.

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.

NDA 50-722/S-019
NDA 50-723/S-017
NDA 50-758/S-017
NDA 50-759/S-022
Page 10

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

CellCept, Cytovene-IV, and Valcyte are registered trademarks of Hoffmann-La Roche Inc.
Bactrim and Bactrim DS are trademarks of Hoffmann-La Roche Inc.
Any other trademarks in this document are the property of their respective owners.

Distributed by:
 **Roche Laboratories Inc.**
340 Kingsland Street
Nutley, New Jersey 07110-1199

XXXXXXXX

Issued: Month Year

Copyright © 2008 by Roche Laboratories Inc. All rights reserved.

For additional copies of this Medication Guide, please call 1-800-526-6367 or visit www.rocheusa.com/products/CellCept.