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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 doctor about your medical condition or your treatment.

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

CellCept can cause serious side effects:

- **Increased risk of loss of a pregnancy (miscarriage) and higher risk of birth defects.** Females who take CellCept during pregnancy have a higher risk of **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 who can become pregnant

- your doctor must talk with you about acceptable birth control methods (contraceptive counseling) to use while taking CellCept.
- you should have one pregnancy test immediately before starting CellCept and another pregnancy test 8 to 10 days later. Pregnancy tests should be repeated during routine follow-up visits with your doctor. Talk to your doctor about the results of all of your pregnancy tests.
- you must use acceptable birth control during your entire CellCept therapy and for 6 weeks after stopping CellCept, unless at any time you choose to avoid sexual intercourse (abstinence) with a man completely.

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 take birth control pills while using CellCept you must also use another form of birth control. Talk to your doctor about other birth control methods that you can use while taking CellCept.

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If you plan to become pregnant, talk with your doctor. Your doctor will decide if other medicines to prevent rejection may be right for you.

If you become pregnant while taking CellCept, do not stop taking CellCept. Call your doctor right away. In certain situations, you and your doctor may decide that taking CellCept is more important to your health than the possible risks to your unborn baby.

- You and your doctor should report your pregnancy to
 - Mycophenolate Pregnancy Registry (1-800-617-8191)

The purpose of this registry is to gather information about the health of you and your baby.

- **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.** Certain viruses can live in your body and cause active infections when your immune system is weak. Viral infections that can happen with CellCept include:
 - Shingles, other herpes infections, and cytomegalovirus (CMV). CMV can cause serious tissue and blood infections.
 - BK virus. BK virus can affect how your kidney works and cause your transplanted kidney to fail.
 - **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 doctor 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

1275 blood infections (see **“What are the possible side effects of**
1276 **CellCept?”**)
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1278 **Call your doctor right away if you have any of the following signs and**
1279 **symptoms of infection:**

- 1280 • Temperature of 100.5°F or greater
- 1281 • Cold symptoms, such as a runny nose or sore throat
- 1282 • Flu symptoms, such as an upset stomach, stomach pain,
1283 vomiting or diarrhea
- 1284 • Earache or headache
- 1285 • Pain during urination
- 1286 • White patches in the mouth or throat
- 1287 • Unexpected bruising or bleeding
- 1288 • Cuts, scrapes or incisions that are red, warm and oozing pus
- 1289
- 1290 • **Increased risk of getting certain cancers.** People who take
1291 CellCept have a higher risk of getting lymphoma, and other cancers,
1292 especially skin cancer. Tell your doctor if you have:
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 - 1294 • unexplained fever, prolonged tiredness, weight loss or lymph
1295 node swelling
 - 1296 • a brown or black skin lesion with uneven borders, or one part of
1297 the lesion does not look like the other
 - 1298 • a change in the size and color of a mole
 - 1299 • a new skin lesion or bump
 - 1300 • any other changes to your health
- 1301

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

1302 **What is CellCept?**

1303 CellCept is a prescription medicine to prevent rejection (antirejection
1304 medicine) in people who have received a kidney, heart or liver transplant.
1305 Rejection is when the body’s immune system perceives the new organ as a
1306 “foreign” threat and attacks it.

1307 CellCept is used with other medicines called cyclosporine (Sandimmune®,
1308 Gengraf®, Neoral®) and corticosteroids.

1309 CellCept has been used safely and works in children who received a kidney
1310 transplant as it does in adults. It is not known if CellCept is safe and works in
1311 children who receive a heart or liver transplant.

1312 **Who should not take CellCept?**

1313 **Do not take CellCept if you are allergic to mycophenolate mofetil or**
1314 **any of the ingredients in CellCept.** See the end of this Medication Guide
1315 for a complete list of ingredients in CellCept.

1316 **What should I tell my doctor before taking CellCept?**

1317 Tell your doctor about all of your medical conditions, if you:

- 1318 • **have any digestive problems**, such as ulcers.
- 1319 • **have Phenylketonuria (PKU)**. CellCept oral suspension contains
- 1320 aspartame (a source of phenylalanine).
- 1321 • **have Lesch-Nyhan or Kelley-Seegmiller syndrome or another**
- 1322 **rare inherited deficiency hypoxanthine-guanine**
- 1323 **phosphoribosyl-transferase (HGPRT)**. You should not take
- 1324 CellCept if you have one of these disorders.
- 1325 • **plan to receive any vaccines. People taking CellCept should not**
- 1326 **take live vaccines**. Some vaccines may not work as well during
- 1327 treatment with CellCept.
- 1328 • **are pregnant or are planning to become pregnant**. See **“What is**
- 1329 **the most important information I should know about CellCept?”**
- 1330 • **are breastfeeding or plan to breastfeed**. It is not known if CellCept
- 1331 passes into breast milk. You and your doctor will decide if you will take
- 1332 CellCept or breastfeed.
- 1333

1334 **Tell your healthcare provider about all of the medicines you are**

1335 **taking including prescription and nonprescription medicines,**

1336 **vitamins and herbal supplements.** Some medicines may affect the way

1337 CellCept works, and CellCept may affect how some medicines work.

1338 Especially tell your doctor if you take:

- 1339 • birth control pills (oral contraceptives). See **“What is the most**
- 1340 **important information I should know about CellCept?”**
- 1341 • sevelamer (Renagel[®], Renvela[™]). These products should be taken 2
- 1342 hours after taking CellCept
- 1343 • acyclovir (Zovirax[®]), valacyclovir (Valtrex[®]), ganciclovir (CYTOVENE[®]-
- 1344 IV, Vitrasert[®]), valganciclovir (VALCYTE[®])
- 1345 • rifampin (Rifater[®], Rifamate[®], Rimactane[®], Rifadin[®])
- 1346 • antacids that contain magnesium and aluminum (CellCept and the
- 1347 antacid should not be taken at the same time)
- 1348 • proton pump inhibitors (PPIs) (Prevacid[®], Protonix[®])
- 1349 • sulfamethoxazole/trimethoprim (BACTRIM[™], BACTRIM DS[™])
- 1350 • norfloxacin (Noroxin[®]) and metronidazole (Flagyl[®], Flagyl[®] ER, Flagyl[®]
- 1351 IV, Metro IV, Helidac[®], Pylera[™])
- 1352 • ciprofloxacin (Cipro[®], Cipro[®] XR, Ciloxan[®], Proquin[®] XR) and amoxicillin
- 1353 plus clavulanic acid (Augmentin[®], Augmentin XR[™])
- 1354 • azathioprine (Azasan[®], Imuran[®])
- 1355 • cholestyramine (Questran Light[®], Questran[®], Locholest Light,
- 1356 Locholest, Prevalite[®])

1357 Know the medicines you take. Keep a list of them to show to your doctor or

1358 nurse and pharmacist when you get a new medicine. Do not take any new

1359 medicine without talking with your doctor.

1360 **How should I take CellCept?**

- 1361 • Take CellCept exactly as prescribed.
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- 1363 • Do not stop taking CellCept or change the dose unless your doctor tells
- 1364 you to.
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- 1366 • If you miss a dose of CellCept, or are not sure when you took your last
- 1367 dose, take the regular amount of CellCept prescribed as soon as you
- 1368 remember. If it is time for your next dose, skip the missed dose and
- 1369 take your next dose at your normal scheduled time. Do not take 2
- 1370 doses at the same time. Call your doctor if you are not sure what to
- 1371 do.
- 1372
- 1373 • Take CellCept capsules, tablets and oral suspension on an empty
- 1374 stomach, either 1 hour before or 2 hours after a meal, unless your
- 1375 healthcare provider tells you otherwise. With the approval of your
- 1376 healthcare provider, in stable kidney transplant patients, CellCept can
- 1377 be taken with food if necessary.
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- 1379 • Most people take CellCept by mouth either as blue and brown capsules
- 1380 or lavender tablets. Some people may get CellCept soon after their
- 1381 transplant surgery as an infusion into a vein.
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- 1383 • Do not crush CellCept tablets. Do not open or crush CellCept capsules.
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- 1385 • If you are not able to swallow CellCept tablets or capsules, your doctor
- 1386 may prescribe CellCept Oral Suspension. This is a liquid form of
- 1387 CellCept. Your pharmacist will mix the medicine before giving it to you.
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- 1389 • Do not mix CellCept Oral Suspension with any other medicine.
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- 1391 • If you take too much CellCept, call your doctor or the poison control
- 1392 center right away.
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1394 **What should I avoid while taking CellCept?**

- 1395 • **Avoid pregnancy.** 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 (SPF 30 and above). This is especially important if your skin is very fair or if you have a family history of skin cancer.

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1397 **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?**”

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- **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. You have a higher chance of getting severe anemia when your red blood cell count is low.
 - **platelets.** Platelets help with blood clotting.

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

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

- **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.

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Common side effects include:

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

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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

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- 1432 • vomiting

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1434 These are not all of the possible side effects of CellCept. Tell your doctor
1435 about any side effect that bothers you or that does not go away.

1436 Call your doctor for medical advice about side effects. You may report side
1437 effects to the FDA at 1-800-FDA-1088 or to Genentech at 1-888-835-2555.

1438 **How should I store CellCept?**

1439 • Store CellCept capsules and tablets at room temperature, between 59°F
1440 to 86°F (15°C to 30°C). Keep the container closed tightly.

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1442 • Store the prepared CellCept Oral Suspension at room temperature,
1443 between 59°F to 86°F (15°C to 30°C), for up to 60 days. You can also
1444 store CellCept Oral Suspension in the refrigerator at 36°F to 46°F (2°C to
1445 8°C). **Do not freeze CellCept Oral Suspension.**

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1447 • **Keep CellCept and all medicines out of the reach of children**

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1449 **General Information about CellCept**

1450 Medicines are sometimes prescribed for purposes other than those listed in a
1451 Medication Guide. Do not use CellCept for a condition for which it was not
1452 prescribed. Do not give CellCept to other people, even if they have the same
1453 symptoms that you have. It may harm them.

1454 This Medication Guide summarizes the most important information about
1455 CellCept. If you would like more information, talk with your doctor. You can
1456 ask your doctor or pharmacist for information about CellCept that is written
1457 for healthcare professionals. For more information, call 1-888-835-2555 or
1458 visit www.gene.com/gene/products/information/cellcept.

1459 **What are the ingredients in CellCept?**

1460 **Active Ingredient:** mycophenolate mofetil

1461 **Inactive Ingredients:**

1462 CellCept 250 mg capsules: croscarmellose sodium, magnesium stearate,
1463 povidone (K-90) and pregelatinized starch. The capsule shells contain black
1464 iron oxide, FD&C blue #2, gelatin, red iron oxide, silicon dioxide, sodium
1465 lauryl sulfate, titanium dioxide, and yellow iron oxide.

1466 CellCept 500 mg tablets: black iron oxide, croscarmellose sodium, FD&C blue
1467 #2 aluminum lake, hydroxypropyl cellulose, hydroxypropyl methylcellulose,
1468 magnesium stearate, microcrystalline cellulose, polyethylene glycol 400,
1469 povidone (K-90), red iron oxide, talc, and titanium dioxide; may also contain
1470 ammonium hydroxide, ethyl alcohol, methyl alcohol, n-butyl alcohol,
1471 propylene glycol, and shellac.

1472 CellCept Oral Suspension: aspartame, citric acid anhydrous, colloidal silicon
1473 dioxide, methylparaben, mixed fruit flavor, sodium citrate dihydrate, sorbitol,
1474 soybean lecithin, and xanthan gum.

1475 CellCept Intravenous: polysorbate 80, and citric acid. Sodium hydroxide may
1476 have been used in the manufacture of CellCept Intravenous to adjust the pH.

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1478 This Medication Guide has been approved by the US Food and Drug
1479 Administration.

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