

Genentech takes the health and safety of our patients, customers, employees, and local communities very seriously, and we are actively responding to the global COVID-19 pandemic. For more, please visit our [COVID-19 response page](#) or call [1-877-436-3683](tel:1-877-436-3683).

**CellCept®** (mycophenolate mofetil) CellCept has been helping appropriate transplant patients for over 22 years



## Prescribing Information

### Why CellCept

CellCept® (mycophenolate mofetil) is a prescription medicine for people who have had a kidney, heart, or liver transplant. CellCept can help prevent rejection of the transplanted organ. After the transplant, you may take several of these anti-rejection medicines to keep your immune system from rejecting the transplant.

CellCept has been approved by the Food and Drug Administration (FDA) for use in children and adults who have had a kidney transplant. It is not known if CellCept works or is safe in children who have had a heart or liver transplant.

**CellCept is available in multiple forms for adults and children who have had a transplant.**



Capsules



Tablets



Oral Suspension

*Not actual size and may not represent exact color. CellCept is also available in an intravenous form for use in hospitals.*

### IMPORTANT SAFETY INFORMATION & INDICATION

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### INDICATION

### WHAT IS CELLCEPT?

- CellCept® (mycophenolate mofetil) 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 containing cyclosporine and corticosteroids.

## WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT CELLCEPT?

### CELLCEPT CAN CAUSE SERIOUS SIDE EFFECTS, INCLUDING:

**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 1 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 treatment 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.
- **If you are a sexually active male whose female partner can become pregnant while you are taking CellCept**, use effective contraception during treatment and for at least 90 days after stopping CellCept.
- **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.

### IMPORTANT SAFETY INFORMATION & INDICATION

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- **If you become pregnant while taking CellCept, do not stop taking CellCept. Call your doctor right away.** You and your doctor may decide that other medicines to prevent rejection may be right for you. You and your doctor should report your pregnancy to the Mycophenolate Pregnancy Registry either:

### WHAT IS CELLCEPT?

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- CellCept® (mycophenolate mofetil) 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.

The purpose of this registry is to gather information about the health of you and your baby. CellCept is used with other medicines containing cyclosporine and corticosteroids.

**WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT CELLCEPT?**

**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 doctor 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

**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 1 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 treatment 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

**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 hospitalizations and death. These serious infections can include:

- **Viral infections.** Certain viruses can live in your body and cause active infections 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.
- **If you are a sexually active male whose female partner can become pregnant while you are taking CellCept,** use effective contraception during treatment and for at least 90 days after stopping CellCept.
- **If you plan to become pregnant,** talk with your doctor. Your doctor will decide if you should become pregnant or not. Talk to your doctor about how hepatitis viruses may affect you

**IMPORTANT SAFETY INFORMATION & INDICATION**

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- **A brain infection called Progressive Multifocal Leukoencephalopathy (PML).** If you become pregnant while taking CellCept, do not stop taking CellCept. INDICATION: 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. Call your doctor right away if you have any of the following symptoms:

**WHAT IS CELLCEPT?**

Call your doctor right away if you have any of the following symptoms: pregnancy to the Mycophenolate Pregnancy Registry either.

- CellCept® (mycophenolate mofetil) is a prescription medicine to prevent rejection (antirejection medication) in patients who have received a kidney (healthy or liver transplant). Rejection is what the body's thinking system perceives the new organ as a "foreign" that attacks itself.

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

**WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT CELLCEPT?**

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 doctor if you have any of the following signs and symptoms:

- 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.

- unexplained fever or 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
- 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 1 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.
- See "What are the possible side effects of CellCept?" for information about other serious side effects.
- unexpected bruising or bleeding

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 hospitalizations and death. These serious infections can include:

- viral infections

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.

**WHO SHOULD NOT TAKE CELLCEPT**

Do not take CellCept if you are allergic to mycophenolate mofetil or any of the ingredients in CellCept.

**WHAT SHOULD I TELL MY DOCTOR BEFORE TAKING CELLCEPT?**

• If you are a sexually active male whose female partner can become pregnant, tell your doctor about all of your medical conditions, including if you:

- have had a sexually transmitted infection, such as herpes, syphilis, or cytomegalovirus (CMV). CMV can cause serious tissue and blood infections.

• If you plan to become pregnant, talk with your doctor. Your doctor will decide if you should take CellCept.

**IMPORTANT SAFETY INFORMATION & INDICATION**

• If you have any digestive problems, such as ulcers, you may be at a higher risk of getting a serious infection while taking CellCept. Tell your doctor about all of your medical conditions, including if you:

- have had a brain infection (meningitis) or a seizure.
- have had hepatitis B and C viruses. Hepatitis viruses can affect how your liver works.
- have had a kidney infection (pyelonephritis) or kidney failure.

**WHAT IS CELLCEPT?**

CellCept may be right for you. You and your doctor should report your pregnancy to the Mycophenolate Pregnancy Registry either:

- before you start taking CellCept.
- if you become pregnant while taking CellCept, do not stop taking CellCept.



- You should not take CellCept if you have one of these disorders.
- CellCept is a prescription medicine used by your doctor to prevent rejection of an organ transplant and to help suppress your body's immune system.
- You should not take CellCept if you are pregnant, planning to become pregnant, or breastfeeding. See “What is the most important information I should know about CellCept?” for more information.

### HOW SHOULD I TAKE CELLCEPT?

The most important information you should know about CellCept is that it may cause serious side effects, including an increased risk of getting certain cancers. People who take CellCept have a higher risk of getting certain cancers, including lymphoma and leukemia. It is not known if CellCept causes cancer. Tell your doctor right away if you have any of the following signs and symptoms:

### WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT CELLCEPT?

- **Increased risk of getting certain cancers.** People who take CellCept have a higher risk of getting certain cancers, including lymphoma and leukemia. It is not known if CellCept causes cancer. Tell your doctor right away if you have any of the following signs and symptoms:
- **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 and birth defects. Do not become pregnant while taking CellCept. See “What is the most important information I should know about CellCept?” for more information.

• **Unexplained fever, prolonged tiredness, weight loss or lymph node swelling.** Tell your doctor right away if you have any of the following signs and symptoms:

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- **Dark spots or blisters on your skin.** Tell your doctor right away if you have any of the following signs and symptoms:
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### WHO SHOULD NOT TAKE CELLCEPT?

- **Do not breathe in (inhale) or let CellCept powder or oral suspension come in contact with your skin or mucous membranes.** Tell your doctor right away if you have any of the following signs and symptoms:
- **Do not breathe in (inhale) or let CellCept powder or oral suspension come in contact with your skin or mucous membranes.** Tell your doctor right away if you have any of the following signs and symptoms:

• **Do not take CellCept if you are pregnant, planning to become pregnant, or breastfeeding.** See “What is the most important information I should know about CellCept?” for more information.

### WHAT SHOULD I TELL MY DOCTOR BEFORE TAKING CELLCEPT?

- **Do not take CellCept if you are pregnant, planning to become pregnant, or breastfeeding.** See “What is the most important information I should know about CellCept?” for more information.
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### WHAT IS CELLCEPT?

CellCept is a prescription medicine used by your doctor to prevent rejection of an organ transplant and to help suppress your body's immune system. It is not known if CellCept causes cancer. Tell your doctor right away if you have any of the following signs and symptoms:

- You should not take CellCept if you have any of these disorders:
- You should not take CellCept if you are pregnant or you are planning to become pregnant. See “What is the most important information I should know about CellCept?”
- You should not take CellCept if you are breastfeeding or you are planning to breastfeed. It is not known if CellCept passes into breast milk or if it could harm your baby or affect the way your baby develops.

**HOW SHOULD I TAKE CELLCEPT?**

The most important information I should know about CellCept is that it can harm your unborn child if you become pregnant while taking CellCept. Tell your doctor if you are pregnant or planning to become pregnant. See “What is the most important information I should know about CellCept?”

**WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT CELLCEPT?**

CellCept can cause serious side effects, including:

- increased risk of getting certain cancers. People who take CellCept have a higher risk of getting certain cancers, including:
- 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.

**WHAT ARE THE POSSIBLE SIDE EFFECTS OF CELLCEPT?**

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- You should not take CellCept if you have any of these disorders.
- The most common side effects of CellCept include:
- **HOW SHOULD I TAKE CELLCEPT?** and Mitigation Strategy (REMS) website at [www.mycophenolateREMS.com](http://www.mycophenolateREMS.com)
- **WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT CELLCEPT?**
- **CELLCEPT CAN CAUSE SERIOUS SIDE EFFECTS, INCLUDING:**

The pregnancy should be closely monitored. Tell your doctor if you are pregnant or planning to get pregnant. See "What is the most important information I should know about CellCept?"

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Side effects of CellCept include: See "What is the most important information I should know about CellCept?"

Increased risk of getting certain infections. See "What is the most important information I should know about CellCept?"

Do not take CellCept if you are pregnant or planning to get pregnant. See "What is the most important information I should know about CellCept?"

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