

PRODUCT MONOGRAPH

PrCellCept®
mycophenolate mofetil

Capsules – 250 mg
Film-Coated Tablets – 500 mg
Powder for Oral Suspension – 200 mg/mL (when reconstituted)

PrCellCept® i.v.
mycophenolate mofetil for injection (as hydrochloride) – 500 mg/vial

Manufacturer's Standard

Immunosuppressive Agent

Hoffmann-La Roche Ltd.
7070 Mississauga Road
Mississauga, Ontario
L5N 5M8

Date of Revision:
November 14, 2018

www.rochecanada.com

Submission Control No: 219236

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PART III: CONSUMER INFORMATION

PrCellCept®
mycophenolate mofetil
Capsules and Tablets
Manufacturer's Standard

This leaflet is part III of a three-part "Product Monograph" published when CellCept was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CellCept. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

- CellCept is used after kidney, heart and liver transplantation to help prevent organ rejection.
- CellCept belongs to a family of drugs known as "immunosuppressants". These drugs work to "suppress" or reduce the body's immune response.
- CellCept must be given with other drugs such as cyclosporine (Sandimmune® or Neoral®) and corticosteroids (e.g., prednisone, prednisolone, methylprednisolone, prednisolone acetate, methylprednisolone acetate) which also suppress your immune system. Together these drugs help prevent the rejection of your transplanted organ.

What it does:

Your body's immune system works to protect you from infections and other foreign material. When you receive a transplant, your immune system recognizes the new organ as foreign, and will try to reject it. CellCept, works to reduce this reaction, so that your body is more likely to accept the transplanted organ.

When it should not be used:

- CellCept should not be used in patients allergic (hypersensitive) to mycophenolate mofetil, mycophenolic acid or to any component of the drug product (see section titled "What the non-medicinal ingredients are").
- CellCept should not be used if you are pregnant or breastfeeding.
- CellCept should not be used if you can become pregnant and are not using highly effective birth control.
- CellCept should not be used unless you have a pregnancy test result showing that you are not pregnant.

What the medicinal ingredient is:

mycophenolate mofetil

What the non-medicinal ingredients are:

CellCept 250 mg capsules contain the following non-medicinal ingredients: croscarmellose sodium, magnesium stearate, povidone (K-90) and pregelatinized starch. The capsule shells contain black iron oxide, indigotine (FD&C blue #2), gelatin,

potassium hydroxide, red iron oxide, shellac, titanium dioxide, and yellow iron oxide; may also contain silicon dioxide and sodium lauryl sulfate.

CellCept 500 mg film-coated tablets contain the following non-medicinal ingredients: croscarmellose sodium, hydroxypropyl cellulose, hydroxypropyl methylcellulose, indigotine (FD&C blue #2) aluminum lake, iron oxide, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, povidone (K-90), titanium dioxide.; may also contain propylene glycol.

What dosage forms it comes in:

CellCept 250 mg capsule is available as a blue/brown two-piece hard gelatin capsule printed in black ink with "CellCept 250" on the blue cap and "Roche" on the brown body. Ten capsules are contained in each blister pack.

CellCept 500 mg tablet is available as a lavender coloured, caplet shaped film-coated tablet engraved with "CellCept 500" on one side and "Roche" on the other. Ten tablets are contained in each blister pack.

WARNINGS AND PRECAUTIONS**Warning**

- **If you use mycophenolate mofetil in combination with other medicines used to prevent organ rejection when you are pregnant; you are likely to have early pregnancy loss and infant birth defects (see Special Note for Female Patients).**
- **Because CellCept suppresses your immune system, you are more likely to get infections and have a greater chance of developing cancer. The chances of developing either are similar to the chances seen in patients taking other immunosuppressants.**

Special Note For Female Patients

- Women must not take CellCept while they are pregnant as CellCept may cause an increased risk of first trimester pregnancy loss or damage to the unborn baby (affecting development of ears, limbs, face, heart, brain for example). **For this reason it is recommended that you discuss with your doctor if you are pregnant or become pregnant or plan on becoming pregnant while taking CellCept.** You will want to discuss the possible benefits and risks of continuing with this drug.
- If you think you may be pregnant tell your doctor straight away. However, keep taking CellCept until you see him or her. Your doctor will talk to you about other medicines you can take to prevent rejection of your transplant organ.
- Women (who have the potential of becoming pregnant) should have two negative serum (blood) or urine pregnancy tests. The second test should be performed 8-10later. You can only start CellCept if the tests are negative. Repeat pregnancy tests should be performed during routine follow-up visits.
- You must always use two reliable methods of birth control:
 - Before you start taking CellCept,

- During your entire treatment with CellCept and
- For 6 weeks after stopping your treatment with CellCept.

Talk to your doctor about the most suitable methods of contraception for you. This will depend on your individual situation.

- If you take oral contraceptives (birth control pills) while using CellCept you must also use another form of birth control method as CellCept may adversely affect the efficacy of an oral contraceptive.
- **Do not** breastfeed your baby if you are taking CellCept as it may pass into breast milk and may harm your baby.
- Be sure to keep **all** appointments at your transplant clinic. During these visits, pregnancy tests may be administered by your doctor.

Special Note For Male Patients

- Sexually active male patients and/or their female partners are recommended to use effective birth control while taking CellCept and for at least 90 days after stopping treatment. If pregnancy occurs, talk to your doctor. (See Special Note For Female Patients, above.)
- Men should not donate semen during therapy and for 90 days after taking of CellCept.

All Patients

- Tell all health professionals you see (doctor, dentist, nurses, pharmacists) that you are taking CellCept.
- Be sure to keep **all** appointments at your transplant clinic. During these visits, complete blood counts will need to be measured weekly in the first month, twice monthly for the second and third months of treatment, and then monthly for the remainder of the first year. Your doctor may sometimes order additional blood tests.
- Patients should not donate blood during therapy and for at least 6 weeks after taking CellCept
- CellCept reduces your body's defences. As a result, there is an increased risk of skin cancer. Limit the amount of sunlight and UV light you get. Do this by:
 - wearing protective clothing which also covers your head, neck, arms and legs.
 - using a sunscreen with a high sun protection factor (SPF).
- Patients should use caution when driving or using machines.

BEFORE you use CellCept talk to your doctor or pharmacist:

- If you have had a bad, unusual or allergic reaction to CellCept, mycophenolic acid, or mycophenolate sodium;
- If you are pregnant, plan to become pregnant, are breastfeeding a baby, or plan to breastfeed;
- About all other health conditions you have now, or have had in the past, especially problems with your stomach or bowel movements;
- About all other medicines or treatments you have used or are using, including any products you buy at a pharmacy, supermarket or health food store;

INTERACTIONS WITH THIS MEDICATION

- Tell your doctor if you are taking medicines containing telmisartan, rifampicin or azathioprine.
- Do not take any other drugs without asking your doctor or pharmacist first.
- Taking antacids at the same time as CellCept may affect the way CellCept works for you and therefore should not be taken simultaneously.
- Taking proton pump inhibitors, such as lansoprazole and pantoprazole, at the same time as CellCept may affect the way CellCept works for you.
- Taking Renagel® (sevelamer), or other calcium free phosphate binders at the same time as CellCept may affect the way CellCept works for you and therefore should not be taken at the same time.
- Taking combinations of antibiotics at the same time as CellCept may affect the way CellCept works for you. Do not take any other drugs without asking your doctor or pharmacist first.
- During treatment with CellCept, vaccinations may be less effective and live vaccines should not be given. **Do** discuss this with your doctor before you get any vaccinations or immunizations.
- Do not take cholestyramine, which is used to treat high blood cholesterol.

PROPER USE OF THIS MEDICATION

- Your doctor has decided the dose you should take based on your medical condition and response to the drug.
- The initial dose of CellCept should be taken as soon as possible following transplantation. If you are not sure of your dose, or when to take it, ask your doctor, pharmacist or nurse.
- Space your two doses of CellCept as evenly as you can throughout the day leaving about 12 hours between each dose.
- If you have trouble remembering doses, or if you are uncertain about how to take them talk to your doctor, nurse or pharmacist and be sure to discuss any concerns you have about taking the drug as prescribed.
- CellCept must be taken with other immunosuppressive medicines (such as cyclosporine and corticosteroids). Discuss with your doctor if you are to stop, or to continue, the other immunosuppressant drugs you had been taking.
- Try to take your doses at the same times each day. Taking your medicine at the same time each day will also help you remember each dose.
- Vomiting or diarrhea may prevent CellCept from being taken up into your body. Always call your doctor if you have either of these episodes.
- **Do not change the dose on your own, no matter how you are feeling. Call your doctor.**
- **Do not stop taking CellCept on your own even if you have been taking it for several years.**

Usual Dose:

CellCept should be taken on an empty stomach.

Kidney Transplant Patients

Adults:

A dose of 1 g taken twice a day (daily dose of 2 g) is recommended after kidney transplantation.

Pediatric Patients:

- Pediatric patients with a body surface area** of 1.25 to 1.5 m² may be dosed with CellCept capsules at a dose of 750 mg twice a day (1.5 g daily dose). Pediatric patients with a body surface area** greater than 1.5 m² may be dosed with CellCept capsules or tablets at a dose of 1 g twice a day (2 g daily dose).

**Body surface area is the total surface area of the body, and is represented as square meters (m²). It is calculated from your weight and height. Body surface area is used in many measurements in medicine, such as determining the amount of drug you need to take.

Heart Transplant Patients

Adults:

A dose of 1.5 g twice a day (daily dose of 3 g) is recommended after heart transplantation in adults.

Liver Transplant Patients

Adults:

A dose of 1.5 g taken twice a day (daily dose of 3 g) is recommended after liver transplantation in adults.

How Do I Take CellCept?

Capsules and Tablets:

It is important to leave the capsules or tablets in the blister pack until you need a dose. When you are ready to take a dose, remove the number of capsules or tablets you need to make up the dose your doctor prescribed. Swallow the capsules or tablets whole with plenty of water; do not crush them. Avoid contact with any powder, including accidental inhalation, from damaged capsules or tablets. Wash any powder from your skin with soap and water; rinse eyes with plain water.

Overdose:

If you think you have taken too much CellCept, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

- Never allow your medication to run out between refills. **Plan to order your refills about one week ahead of time.** That way you will always have a supply in case the pharmacy is closed or out of the drug. Also be sure to take enough medication with you when you go on a holiday.

- If you ever do miss a dose of CellCept, do **not** catch up on your own; instead call your doctor or pharmacist right away for advice. It is also a good idea to ask your doctor ahead of time what to do about missed doses. Do not double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

- Like all medicines, along with the beneficial effects of treatment, CellCept may cause side effects in people.
- Because CellCept and the other medicines to be taken suppress your immune system, you are more likely to get infections. To help reduce complications from infections, tell your doctor about any cold or flu-like symptoms (such as fever or sore throat), any boils on your skin, or pain when you urinate (pass your water).
- The following symptoms are some possible warning signs of cancer. To help detect any cancers as soon as possible, report any of these symptoms to your doctor right away:
 - a change in your bowel or bladder habits;
 - any sore that doesn't heal;
 - unusual bleeding or discharge;
 - the appearance of a lump or thickened areas in your breast or anywhere else on your body;
 - unexplained stomach upset or any trouble with swallowing;
 - an obvious change in a wart or a mole;
 - a nagging cough or hoarseness;
 - night sweats;
 - persistent and severe headaches.
- Patients taking CellCept in combination therapy with cyclosporine and corticosteroids may experience an increase in blood pressure.
- Serious common and uncommon side-effects which have been reported with CellCept, when used in combination with cyclosporine and corticosteroids, are provided in the following table. Tell your doctor right away if you notice any of these symptoms. Do not stop taking this drug on your own.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM		
Symptom/Effect	Talk to your doctor or pharmacist	
	Only if severe	In all cases
	Stop taking the drug and call your doctor or pharmacist †	

Very Common	Abdominal pain, Blood in urine, Constipation, Increased cough, Diarrhea, Fever, Laboured breathing, Headache, Hypertension, Swelling of parts of your body, Vomiting, Weakness		✓	
Common	Chest, or back pain, Dizziness, Heart Burn, Involuntary trembling, Muscle weakness, Nausea, Nosebleed, Sleeplessness, Stomach pain		✓	
Uncommon	Blood or black tarry stools		✓	

†Do not stop your medicines unless you have discussed this with your doctor first.

This is not a complete list of side effects. For any unexpected effects you have while taking CellCept, contact your doctor or pharmacist.

HOW TO STORE IT

- **Keep CellCept out of reach and sight of children.** A child who accidentally takes the drug may be seriously harmed. A locked drawer or cupboard is best if you have small children in the house.
- CellCept capsules and tablets should be stored at room temperature (15-30°C). The tablets should be protected from light. Remember to keep each capsule or tablet in its original package until you need to take it.
- CellCept should not be used after the expiry date (EXP) shown on the package.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/consumer-side-effect-reporting-form.html>
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: **Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, ON KIA 0K9**

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/consumer-side-effect-reporting-form.html>

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: www.rochecanada.com or by contacting the sponsor, Hoffmann-La Roche Limited, at 1-888-762-4388.

Last revised: November 14, 2018

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Hoffmann-La Roche Limited
Mississauga, Ontario L5N 5M8

PART III: CONSUMER INFORMATION

PrCellCept®
 mycophenolate mofetil
 Powder for Oral Suspension
 Manufacturer's Standard

This leaflet is part III of a three-part "Product Monograph" published when CellCept was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CellCept. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- CellCept is used after kidney, heart and liver transplantation to help prevent organ rejection.
- CellCept belongs to a family of drugs known as "immunosuppressants". These drugs work to "suppress" or reduce the body's immune response.
- CellCept must be given with other drugs such as cyclosporine (Sandimmune® or Neoral®) and corticosteroids (e.g., prednisone, prednisolone, methylprednisolone, prednisolone acetate, methylprednisolone acetate) which also suppress your immune system. Together these drugs help prevent the rejection of your transplanted organ.

What it does:

Your body's immune system works to protect you from infections and other foreign material. When you receive a transplant, your immune system recognizes the new organ as foreign, and will try to reject it. CellCept, works to reduce this reaction, so that your body is more likely to accept the transplanted organ.

When it should not be used:

- CellCept should not be used in patients allergic (hypersensitive) to mycophenolate mofetil, mycophenolic acid or to any component of the drug product (see section titled "What the non-medicinal ingredients are").
- CellCept should not be used if you are pregnant or breastfeeding.
- CellCept should not be used if you can become pregnant and are not using highly effective birth control.
- CellCept should not be used unless you have a pregnancy test result showing that you are not pregnant.

What the medicinal ingredient is:

mycophenolate mofetil

What the non-medicinal ingredients are:

CellCept 200 mg/mL powder for oral suspension contains the following non-medicinal ingredients: aspartame, citric acid, colloidal silicon dioxide, fruit flavour, methylparaben, sodium citrate, sorbitol, soybean lecithin, and xanthan gum.

What dosage forms it comes in:

CellCept 200 mg/mL powder for oral suspension is available as a white to off-white fruit flavour suspension. Each bottle of suspension is supplied with a bottle adapter and 2 oral dispensers*.

WARNINGS AND PRECAUTIONS

Warning

- If you use mycophenolate mofetil in combination with other medicines used to prevent organ rejection when you are pregnant; you are likely to have early pregnancy loss and infant birth defects (see Special Note for Female Patients).
- Because CellCept suppresses your immune system, you are more likely to get infections and have a greater chance of developing cancer. The chances of developing either are similar to the chances seen in patients taking other immunosuppressants.

Special Note For Female Patients

- Women must not take CellCept while they are pregnant as CellCept may cause an increased risk of first trimester pregnancy loss or damage to the unborn baby (affecting development of ears, limbs, face, heart, brain for example). **For this reason it is recommended that you discuss with your doctor if you are pregnant or become pregnant or plan on becoming pregnant while taking CellCept.** You will want to discuss the possible benefits and risks of continuing with this drug.
- If you think you may be pregnant tell your doctor straight away. However, keep taking CellCept until you see him or her. Your doctor will talk to you about other medicines you can take to prevent rejection of your transplant organ.
- Women (who have the potential of becoming pregnant) should have two negative serum (blood) or urine pregnancy tests. The second test should be performed 8-10 later. You can only start CellCept if the tests are negative. Repeat pregnancy tests should be performed during routine follow-up visits.
- You must always use two reliable methods of birth control:
 - Before you start taking CellCept,
 - During your entire treatment with CellCept and
 - For 6 weeks after stopping your treatment with CellCept.
 Talk to your doctor about the most suitable methods of contraception for you. This will depend on your individual situation.
- If you take oral contraceptives (birth control pills) while using CellCept you must also use another form of birth control method as CellCept may adversely affect the efficacy of an oral contraceptive.
- **Do not** breastfeed your baby if you are taking CellCept as it may pass into breast milk and may harm your baby.

- Be sure to keep **all** appointments at your transplant clinic. During these visits, pregnancy tests may be administered by your doctor.

Special Note For Male Patients

- Sexually active male patients and/or their female partners are recommended to use effective birth control while taking CellCept and for at least 90 days after stopping treatment. If pregnancy occurs, talk to your doctor. (See Special Note For Female Patients, above.)
- Men should not donate semen during therapy and for 90 days after taking of CellCept

All Patients

- If you have a restriction to dietary phenylalanine, talk to your doctor or pharmacist before you use CellCept Oral Suspension, as this product contains aspartame, a source of phenylalanine.
- Tell all health professionals you see (doctor, dentist, nurses, pharmacists) that you are taking CellCept.
- Be sure to keep **all** appointments at your transplant clinic. During these visits, complete blood counts will need to be measured weekly in the first month, twice monthly for the second and third months of treatment, and then monthly for the remainder of the first year. Your doctor may sometimes order additional blood tests.
- Patients should not donate blood during therapy and for at least 6 weeks after taking CellCept
- CellCept reduces your body's defences. As a result, there is an increased risk of skin cancer. Limit the amount of sunlight and UV light you get. Do this by:
 - wearing protective clothing which also covers your head, neck, arms and legs.
 - using a sunscreen with a high sun protection factor (SPF).
- Patients should use caution when driving or using machines.

BEFORE you use CellCept talk to your doctor or pharmacist:

- If you have had a bad, unusual or allergic reaction to CellCept, mycophenolic acid, or mycophenolate sodium;
- If you are pregnant, plan to become pregnant, are breastfeeding a baby, or plan to breastfeed;
- About all other health conditions you have now, or have had in the past, especially problems with your stomach or bowel movements;
- About all other medicines or treatments you have used or are using, including any products you buy at a pharmacy, supermarket or health food store.

INTERACTIONS WITH THIS MEDICATION

- Tell your doctor if you are taking medicines containing telmisartan, rifampicin or azathioprine.
- Do not take any other drugs without asking your doctor or pharmacist first.
- Taking antacids at the same time as CellCept may affect the

way CellCept works for you and therefore should not be taken simultaneously.

- Taking proton pump inhibitors, such as lansoprazole and pantoprazole, at the same time as CellCept may affect the way CellCept works for you.
- Taking Renagel® (sevelamer), or other calcium free phosphate binders at the same time as CellCept may affect the way CellCept works for you and therefore should not be taken at the same time.
- Taking combinations of antibiotics at the same time as CellCept may affect the way CellCept works for you. Do not take any other drugs without asking your doctor or pharmacist first.
- During treatment with CellCept, vaccinations may be less effective and live vaccines should not be given. **Do** discuss this with your doctor before you get any vaccinations or immunizations.
Do not take cholestyramine, which is used to treat high blood cholesterol.

PROPER USE OF THIS MEDICATION

- Your doctor has decided the dose you should take based on your medical condition and response to the drug.
- The initial dose of CellCept should be taken as soon as possible following transplantation. If you are not sure of your dose, or when to take it, ask your doctor, pharmacist or nurse.
- Space your two doses of CellCept as evenly as you can throughout the day leaving about 12 hours between each dose.
- If you have trouble remembering doses, or if you are uncertain about how to take them talk to your doctor, nurse or pharmacist and be sure to discuss any concerns you have about taking the drug as prescribed.
- CellCept must be taken with other immunosuppressive medicines (such as cyclosporine and corticosteroids). Discuss with your doctor if you are to stop, or to continue, the other immunosuppressant drugs you had been taking.
- Try to take your doses at the same times each day. Taking your medicine at the same time each day will also help you remember each dose.
- Vomiting or diarrhea may prevent CellCept from being taken up into your body. Always call your doctor if you have either of these episodes.
- **Do not change the dose on your own, no matter how you are feeling. Call your doctor.**
- **Do not stop taking CellCept on your own even if you have been taking it for several years.**

Usual Dose:

CellCept should be taken on an empty stomach.

Kidney Transplant Patients

Adults:

A dose of 1 g taken twice a day (daily dose of 2 g) is recommended after kidney transplantation.

Pediatric Patients:

- In pediatrics (2 years and older), the recommended dose of CellCept oral suspension following kidney transplantation is 600 mg/m² body surface area** twice a day (up to a maximum daily dose of 2 g).

**Body surface area is the total surface area of the body, and is represented as square meters (m²). It is calculated from your weight and height. Body surface area is used in many measurements in medicine, such as determining the amount of drug you need to take.

Heart Transplant Patients

Adults:

A dose of 1.5 g twice a day (daily dose of 3 g) is recommended after heart transplantation in adults.

Liver Transplant Patients

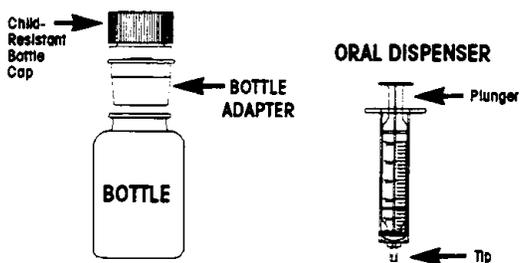
Adults:

A dose of 1.5 g taken twice a day (daily dose of 3 g) is recommended after liver transplantation in adults.

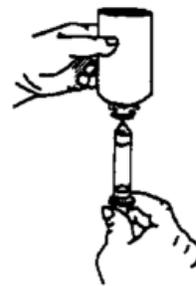
How Do I Take CellCept?

Oral Suspension:

- **Please follow instructions carefully to ensure proper dosing of the oral suspension.**



1. Shake closed bottle well for about 5 seconds before each use.
2. Remove child-resistant cap.
3. Before inserting the tip of the dispenser into bottle adapter, push the plunger completely down toward the tip of the dispenser. Insert tip firmly into opening of the bottle adapter.
4. Turn the entire unit (bottle and dispenser) upside down.
5. Pull the plunger out slowly until the desired amount of medication is withdrawn into the dispenser (see figure).
6. Turn the entire unit right side up and remove the oral dispenser slowly from the bottle.



7. Dispense directly into mouth. Do not mix with any liquid prior to dispensing.
 8. Close bottle with child-resistant cap after each use.
 9. Disassemble oral dispenser, rinse under running tap water and air dry prior to next use.
- Care should be taken to avoid contact of the skin and eyes with both the oral suspension powder and the mixed suspension. In case of contact with the eyes, rinse with water. In case of contact with skin, wash thoroughly with soap and water.
 - Wipe up any spills using wet paper towels. Recap the bottle and wet wipe its outside surfaces. Wearing disposable gloves is recommended when mixing and when wiping the outer surface of the bottle/cap and the table.

Overdose:

If you think you have taken too much CellCept, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

- Never allow your medication to run out between refills. **Plan to order your refills about one week ahead of time.** That way you will always have a supply in case the pharmacy is closed or out of the drug. Also be sure to take enough medication with you when you go on a holiday.
- If you ever do miss a dose of CellCept, do **not** catch up on your own; instead call your doctor or pharmacist right away for advice. It is also a good idea to ask your doctor ahead of time what to do about missed doses. Do not double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

- Like all medicines, along with the beneficial effects of treatment, CellCept may cause side effects in people.
- Because CellCept and the other medicines to be taken suppress your immune system, you are more likely to get infections. To help reduce complications from infections, tell your doctor about any cold or flu-like symptoms (such as fever or sore throat), any boils on your skin, or pain when you urinate (pass your water).
- The following symptoms are some possible warning signs of cancer. To help detect any cancers as soon as possible, report any of these symptoms to your doctor right away:
 - a change in your bowel or bladder habits;

- any sore that doesn't heal;
- unusual bleeding or discharge;
- the appearance of a lump or thickened areas in your breast or anywhere else on your body;
- unexplained stomach upset or any trouble with swallowing;
- an obvious change in a wart or a mole;
- a nagging cough or hoarseness;
- night sweats;
- persistent and severe headaches.
- Patients taking CellCept in combination therapy with cyclosporine and corticosteroids may experience an increase in blood pressure.
- Serious common and uncommon side-effects which have been reported with CellCept, when used in combination with cyclosporine and corticosteroids, are provided in the following table. Tell your doctor right away if you notice any of these symptoms. Do not stop taking this drug on your own.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/Effect		Talk to your doctor or pharmacist		Stop taking the drug and call your doctor or pharmacist †
		Only if severe	In all cases	
Very Common	Abdominal pain, Blood in urine, Constipation, Increased cough, Diarrhea, Fever, Laboured breathing, Headache, Hypertension, Swelling of parts of your body, Vomiting, Weakness		✓	
Common	Chest, or back pain, Dizziness, Heart Burn, Involuntary trembling, Muscle weakness, Nausea, Nosebleed, Sleeplessness, Stomach pain		✓	
Uncommon	Blood or black tarry stools		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/Effect		Talk to your doctor or	Stop taking the drug and
----------------	--	------------------------	--------------------------

		pharmacist		call your doctor or pharmacist †
		Only if severe	In all cases	
Very Common	Abdominal pain, Blood in urine, Constipation, Increased cough, Diarrhea, Fever, Laboured breathing, Headache, Hypertension, Swelling of parts of your body, Vomiting, Weakness		✓	
Common	Chest, or back pain, Dizziness, Heart Burn, Involuntary trembling, Muscle weakness, Nausea, Nosebleed, Sleeplessness, Stomach pain		✓	
Uncommon	Blood or black tarry stools		✓	

† Do not stop your medicines unless you have discussed this with your doctor first.

This is not a complete list of side effects. For any unexpected effects you have while taking CellCept, contact your doctor or pharmacist.

HOW TO STORE IT

- **Keep CellCept out of reach and sight of children.** A child who accidentally takes the drug may be seriously harmed. A locked drawer or cupboard is best if you have small children in the house.
- CellCept suspension should be stored at room temperature (15-30°C). Do not freeze. The pharmacist will write the date of expiration on the bottle label.
- CellCept should not be used after the expiry date (EXP) shown on the package.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/consumer-side-effect-reporting-form.html>
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to:
 - Canada Vigilance Program
 - Health Canada
 - Postal Locator 1908C
 - Ottawa, ON KIA OK9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at

<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/consumer-side-effect-reporting-form.html>

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

www.rochecanada.com or by contacting the sponsor, Hoffmann-La Roche Limited, at 1-888-762-4388.

Last revised: November 14, 2018

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Hoffmann-La Roche Limited
Mississauga, Ontario L5N 5M8

PART III: CONSUMER INFORMATION

PrCellCept® i.v.
mycophenolate mofetil
Hydrochloride for injection
Powder for solution
Manufacturer's Standard

This leaflet is part III of a three-part "Product Monograph" published when CellCept was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CellCept. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

- CellCept is used after kidney, heart and liver transplantation to help prevent organ rejection.
- CellCept belongs to a family of drugs known as "immunosuppressants". These drugs work to "suppress" or reduce the body's immune response.
- CellCept must be given with other drugs such as cyclosporine (Sandimmune® or Neoral®) and corticosteroids (e.g., prednisone, prednisolone, methylprednisolone, prednisolone acetate, methylprednisolone acetate) which also suppress your immune system. Together these drugs help prevent the rejection of your transplanted organ.

What it does:

Your body's immune system works to protect you from infections and other foreign material. When you receive a transplant, your immune system recognizes the new organ as foreign, and will try to reject it. CellCept, works to reduce this reaction, so that your body is more likely to accept the transplanted organ.

When it should not be used:

- CellCept should not be used in patients allergic (hypersensitive) to mycophenolate mofetil, mycophenolic acid or to any component of the drug product (see section titled "What the non-medicinal ingredients are").
- CellCept i.v. should not be used in patients who are allergic to Polysorbate 80 (TWEEN).
- CellCept should not be used if you are pregnant or breastfeeding.
- CellCept should not be used if you can become pregnant and are not using highly effective birth control.
- CellCept should not be used unless you have a pregnancy test result showing that you are not pregnant.

What the medicinal ingredient is:

mycophenolate mofetil

What the non-medicinal ingredients are:

CellCept i.v. 500 mg/vial contains the following nonmedicinal ingredients: citric acid, 5 mg, polysorbate 80, 25 mg, and sodium hydroxide and/or hydrochloric acid to adjust pH.

What dosage forms it comes in:

CellCept i.v. is available for patients who are unable to take oral medications. **CellCept i.v.** is available as a 20 mL sterile vial containing 500 mg of mycophenolate mofetil as the hydrochloride salt.

WARNINGS AND PRECAUTIONS**Warning**

- **If you use mycophenolate mofetil in combination with other medicines used to prevent organ rejection when you are pregnant; you are likely to have early pregnancy loss and infant birth defects (see Special Note for Female Patients).**
- **Because CellCept suppresses your immune system, you are more likely to get infections and have a greater chance of developing cancer. The chances of developing either are similar to the chances seen in patients taking other immunosuppressants.**

Special Note For Female Patients

- Women must not take CellCept while they are pregnant as CellCept may cause an increased risk of first trimester pregnancy loss or damage to the unborn baby (affecting development of ears, limbs, face, heart, brain for example). **For this reason it is recommended that you discuss with your doctor if you are pregnant or become pregnant or plan on becoming pregnant while taking CellCept.** You will want to discuss the possible benefits and risks of continuing with this drug.
- If you think you may be pregnant tell your doctor straight away. However, keep taking CellCept until you see him or her. Your doctor will talk to you about other medicines you can take to prevent rejection of your transplant organ.
- Women (who have the potential of becoming pregnant) should have two negative serum (blood) or urine pregnancy tests. The second test should be performed 8-10 later. You can only start CellCept if the tests are negative. Repeat pregnancy tests should be performed during routine follow-up visits.
- You must always use two reliable methods of birth control:
 - Before you start taking CellCept,
 - During your entire treatment with CellCept and
 - For 6 weeks after stopping your treatment with CellCept.
 Talk to your doctor about the most suitable methods of contraception for you. This will depend on your individual situation.
- If you take oral contraceptives (birth control pills) while using CellCept you must also use another form of birth control method as CellCept may adversely affect the efficacy of an oral contraceptive.
- **Do not** breastfeed your baby if you are taking CellCept as it may pass into breast milk and may harm your baby.
- Be sure to keep **all** appointments at your transplant clinic. During these visits, pregnancy tests may be administered by

your doctor.

Special Note For Male Patients

- Sexually active male patients and/or their female partners are recommended to use effective birth control while taking CellCept and for at least 90 days after stopping treatment. If pregnancy occurs, talk to your doctor. (See Special Note For Female Patients, above.)
- Men should not donate semen during therapy and for 90 days after taking of CellCept

All Patients

- Tell all health professionals you see (doctor, dentist, nurses, pharmacists) that you are taking CellCept.
- Be sure to keep **all** appointments at your transplant clinic. During these visits, complete blood counts will need to be measured weekly in the first month, twice monthly for the second and third months of treatment, and then monthly for the remainder of the first year. Your doctor may sometimes order additional blood tests.
- Patients should not donate blood during therapy and for at least 6 weeks after taking CellCept
- CellCept reduces your body’s defences. As a result, there is an increased risk of skin cancer. Limit the amount of sunlight and UV light you get. Do this by:
 - wearing protective clothing which also covers your head, neck, arms and legs.
 - using a sunscreen with a high sun protection factor (SPF).
- Patients should use caution when driving or using machines.

BEFORE you use CellCept talk to your doctor or pharmacist:

- If you have had a bad, unusual or allergic reaction to CellCept, mycophenolic acid, or mycophenolate sodium;
- If you are pregnant, plan to become pregnant, are breastfeeding a baby, or plan to breastfeed;
- About all other health conditions you have now, or have had in the past, especially problems with your stomach or bowel movements;
- About all other medicines or treatments you have used or are using, including any products you buy at a pharmacy, supermarket or health food store.

INTERACTIONS WITH THIS MEDICATION

- Tell your doctor if you are taking medicines containing telmisartan, rifampicin or azathioprine.
- Do not take any other drugs without asking your doctor or pharmacist first.
- Taking combinations of antibiotics at the same time as CellCept may affect the way CellCept works for you. Do not take any other drugs without asking your doctor or pharmacist first.
- During treatment with CellCept, vaccinations may be less effective and live vaccines should not be given. **Do** discuss this with your doctor before you get any vaccinations or

immunizations.

- Do not take cholestyramine, which is used to treat high blood cholesterol.

PROPER USE OF THIS MEDICATION

- Your doctor has decided the dose you should take based on your medical condition and response to the drug.
- The initial dose of CellCept should be taken as soon as possible following transplantation. If you are not sure of your dose, or when to take it, ask your doctor, pharmacist or nurse.
- If you have trouble remembering doses, or if you are uncertain about how to take them talk to your doctor, nurse or pharmacist and be sure to discuss any concerns you have about taking the drug as prescribed.
- CellCept must be taken with other immunosuppressive medicines (such as cyclosporine and corticosteroids). Discuss with your doctor if you are to stop, or to continue, the other immunosuppressant drugs you had been taking.
- **Do not change the dose on your own, no matter how you are feeling. Call your doctor.**
- **Do not stop taking CellCept on your own even if you have been taking it for several years.**

Usual Dose:

Kidney Transplant Patients

Adults:

A dose of 1 g taken twice a day (daily dose of 2 g) is recommended after kidney transplantation.

Heart Transplant Patients

Adults:

A dose of 1.5 g twice a day (daily dose of 3 g) is recommended after heart transplantation in adults.

Liver Transplant Patients

Adults:

A dose of 1.5 g taken twice a day (daily dose of 3 g) is recommended after liver transplantation in adults.

How Do I Take CellCept?

CellCept i.v. medicine comes as a powder. Your doctor or nurse will make up the medicine and give it to you.

Overdose:

If you think you have taken too much CellCept, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

- If you miss a dose of CellCept i.v., your doctor will decide when you should receive your next dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

- Like all medicines, along with the beneficial effects of treatment, CellCept may cause side effects in people.
- Because CellCept and the other medicines to be taken suppress your immune system, you are more likely to get infections. To help reduce complications from infections, tell your doctor about any cold or flu-like symptoms (such as fever or sore throat), any boils on your skin, or pain when you urinate (pass your water).
- The following symptoms are some possible warning signs of cancer. To help detect any cancers as soon as possible, report any of these symptoms to your doctor right away:
 - a change in your bowel or bladder habits;
 - any sore that doesn't heal;
 - unusual bleeding or discharge;
 - the appearance of a lump or thickened areas in your breast or anywhere else on your body;
 - unexplained stomach upset or any trouble with swallowing;
 - an obvious change in a wart or a mole;
 - a nagging cough or hoarseness;
 - night sweats;
 - persistent and severe headaches.
- Patients taking CellCept in combination therapy with cyclosporine and corticosteroids may experience an increase in blood pressure.
- Serious common and uncommon side-effects which have been reported with CellCept, when used in combination with cyclosporine and corticosteroids, are provided in the following table. Tell your doctor right away if you notice any of these symptoms. Do not stop taking this drug on your own.

Common	Chest, or back pain, Dizziness, Heart Burn, Involuntary trembling, Muscle weakness Nausea, Nosebleed, Sleeplessness, Stomach pain		✓	
Uncommon	Blood or black tarry stools		✓	

† Do not stop your medicines unless you have discussed this with your doctor first.

This is not a complete list of side effects. For any unexpected effects you have while taking CellCept, contact your doctor or pharmacist.

HOW TO STORE IT

- **Keep CellCept out of reach and sight of children.** A child who accidentally takes the drug may be seriously harmed. A locked drawer or cupboard is best if you have small children in the house.
- CellCept i.v. powder for solution should be stored at room temperature (15-30°C). The healthcare professional will store the reconstituted/infusion solutions at room room temperature (15-30°C).
- CellCept should not be used after the expiry date (EXP) shown on the package.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/Effect		Talk to your doctor or pharmacist		Stop taking the drug and call your doctor or pharmacist †
		Only if severe	In all cases	
Very Common	Abdominal pain, Blood in urine, Constipation, Increased cough, Diarrhea, Fever, Laboured breathing, Headache, Hypertension, Swelling of parts of your body, Vomiting, Weakness		✓	

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/consumer-side-effect-reporting-form.html>
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, ON KIA OK9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at

<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/consumer-side-effect-reporting-form.html>

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: http://rochecanada.com/PMs/CellCept/CellCept_PM_E.pdf or by contacting the sponsor, Hoffmann-La Roche Limited, at 1-888-762-4388.

Last revised: November 14, 2018

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