PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

CellCept® 250 mg Capsules

CellCept® OS 200 mg/mℓ Powder for Oral Suspension

CellCept® 500 mg Tablets

WARNING 1: DO NOT TAKE CELLCEPT

If you are pregnant or planning to become pregnant, or breastfeeding your baby, you must not receive CellCept (see BEFORE YOU TAKE CellCept and Pregnancy and breastfeeding).

WARNING 2: IMMUNE SYSTEM SUPPRESSED: RISK OF INFECTIONS AND CANCER

Increased likelihood of infection and the possible development of a cancer of the lymph nodes or tissues and other cancers, especially of the skin, may result from the body's immune system being suppressed. Only doctors experienced in medicines which suppress the body's immune response and management of kidney, heart or liver transplant patients should prescribe CellCept. Patients receiving CellCept should be managed by healthcare professionals experienced in relevant laboratory and medical resources and knowledge. The doctor responsible for your maintenance therapy will have complete information available for your follow-up.

WARNING 3: RISK OF BIRTH DEFECTS

CellCept can cause malformations and mutations in unborn foetuses. Before birth malformations and spontaneous abortions have been reported with use of CellCept in pregnancy. Women of childbearing potential must have two negative medical practitioner or laboratory-supervised blood or urine pregnancy tests; the second test should be performed 8-10 days after the first one and 24 hours before starting treatment with CellCept. Repeat pregnancy tests should be performed during routine follow-up visits.

Women of childbearing potential should use two reliable forms of birth control simultaneously, including at least one highly effective method, before beginning CellCept therapy, during therapy, and for 90 days following discontinuation of therapy; unless not having intercourse is the chosen method of birth control.

Sexually active men are recommended to use condoms during treatment and for 90 days after stopping treatment. Condom use applies both for reproductively able men and men who have had a vasectomy, because the risk associated with the transfer of semen also applies to men who have had a vasectomy.

Female partners of male patients are recommended to use highly effective birth control methods during treatment and for a total of 90 days after the last dose of CellCept.

Read all of this leaflet carefully before you start to take/use CellCept

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- CellCept has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT CellCept CONTAINS

Each capsule contains 250 mg mycophenolate mofetil. Excipients of CellCept capsules include pregelatinised maize starch, croscarmellose sodium, polyvidone (K-90) and magnesium stearate.

The capsule shell contains gelatine, sodium lauryl sulphate, sodium carboxymethyl cellulose, silicon dioxide, titanium dioxide (E171), indigo carmine (E132), red, yellow and black iron oxide (E172).

Each 5 mℓ of the reconstituted suspension contains 1 g mycophenolate mofetil. 1 mℓ of the reconstituted suspension contains 200 mg mycophenolate mofetil. Contains 0,3 % *m/v* methyl parahydroxybenzoate as preservative.

Excipients: colloidal anhydrous silica, xanthum gum, soybean lecithin, sorbitol, aspartame, citric acid, sodium citrate, mixed fruit flavour (274869).

Contains sugar (sorbitol).

Contains aspartame.

Each film-coated tablet contains 500 mg mycophenolate mofetil. Excipients of CellCept tablets are microcrystalline cellulose, polyvidone (K-90), croscarmellose sodium and magnesium stearate. The tablet coating consists of hydroxypropyl methylcellulose, hydroxypropyl cellulose, titanium dioxide (E171), polyethylene glycol, indigo carmine (E132) and red iron oxide (E172).

WHAT CellCept IS USED FOR

CellCept is used to prevent your body rejecting a transplanted kidney, heart or liver. CellCept is used together with other medicines.

BEFORE YOU TAKE CellCept

Do not take CellCept:

- If you are allergic (hypersensitive) to mycophenolate mofetil, mycophenolic acid or any of the other ingredients of CellCept.
- If you are pregnant or breastfeeding.
- If you 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.
- If you have phenylketonuria (PKU). CellCept oral suspension contains aspartame (a source of phenylalanine).

Take special care with CellCept:

You should inform your doctor immediately:

- If you experience any evidence of infection (e.g. fever, sore throat), unexpected bruising and/or bleeding.
- If you have or have ever had any problems with your digestive system, e.g., stomach ulcers.
- If you are planning to become pregnant or if you become pregnant while taking CellCept.

CellCept reduces your body's defence mechanisms. Because of this, there is an increased risk of cancer including skin cancer. Therefore you should limit your exposure to sunlight and UV light by wearing appropriate protective clothing and using a sunscreen with a high protection factor.

Taking CellCept with food and drink:

Taking food and drink has no influence on your treatment with CellCept.

Pregnancy and breastfeeding:

Do not take CellCept if you are pregnant or breastfeeding.

Use of CellCept during pregnancy may cause miscarriage or damage to your unborn baby (abnormal development of ears for example).

If you plan to become pregnant, discuss with your doctor alternative medicines to best prevent rejection of your transplanted organ. In certain situations, you and your doctor may decide that the benefits of taking CellCept for your health are more important than the possible risks to your unborn baby.

Tell your doctor straight away if:

- You think you may be pregnant
- You are breastfeeding
- You plan to start a family in the near future

You must use 2 different types of effective birth control at the same time –

- four weeks before you start taking CellCept
- during your entire treatment with CellCept
- for 6 weeks after you stop taking CellCept

unless you choose to avoid sexual intercourse (abstinence)

You should talk to your doctor about the most suitable methods for birth control for you, based on your individual situation.

If you could possibly become pregnant, you must have a pregnancy test with a negative result BEFORE starting treatment with CellCept. If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or healthcare professional for advice before taking CellCept.

Driving and using machinery:

- Do not drive because CellCept could interfere with your ability to drive safely.
- Do not operate any tools or machines.

Important information about some of the ingredients of CellCept:

CellCept OS 200 mg/mℓ Powder for Oral Suspension contains aspartame which you should not take if you have phenylketonuria (see Do not take CellCept).

CellCept OS contains sorbitol and may have a laxative effect. If you have been told that you have intolerance to some sugars, you should not take CellCept.

Taking other medicines with CellCept

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines). This is because CellCept can affect the way some medicines work. Some other medicines may also affect the way CellCept works.

Are you taking any medicines containing

- azathioprine or other immunosuppressive agents (which are sometimes given to patients after a transplant operation);
- cholestyramine (used to treat patients with high blood cholesterol);
- rifampicin (used to treat tuberculosis (TB));
- oral ciprofloxacin or amoxicillin plus clavulanic acid (antibiotics);
- antacids, proton pump inhibitors (PPIs) including lansoprazole and pantoprazole;
- phosphate binders (used in patients with chronic renal failure to reduce the absorption of phosphate)

or any other medicines (including those you can buy without a prescription) that your doctor does not know about?

Do you need to receive vaccines (live vaccines)? Your doctor will have to advise you what is indicated for you.

If any of the above applies to you, or if you are not sure, talk to your doctor, nurse, midwife or pharmacist before you take CellCept.

HOW TO TAKE CellCept

Do not share medicines prescribed for you with another person.

Always take CellCept exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

Method and route of administration

Swallow your capsules/tablets whole with a glass of water. Do not break or crush them and do not take any capsules that have broken open or split. Avoid contact with any powder that spills out from damaged capsules. If a capsule breaks open accidentally, wash any powder from your skin with soap and water. If any powder gets into your eyes or mouth, rinse thoroughly with plenty of plain, fresh water.

Treatment will continue for as long as you need immunosuppression to prevent your body rejecting your transplanted organ.

Your doctor will tell you how long your treatment with CellCept will last. Do not stop treatment early. If you have the impression that the effect of CellCept is too strong or too weak for you, tell your doctor or pharmacist.

If you take more CellCept than you should:

If you take more CellCept than you have been told to take, or if someone else accidentally takes your medicine, immediately see a doctor or go to a hospital straight away.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take CellCept:

If you forget to take your medicine at any time, take it as soon as you remember, then continue to take it at the usual times.

Do not take a double dose to make up for a forgotten individual dose.

If you stop taking CellCept:

Effects when treatment with CellCept is stopped

Stopping your treatment with CellCept may increase the chance of rejection of your transplanted organ. Do not stop taking your medicine unless your doctor tells you to.

If you have any further questions on the use of CellCept, ask your doctor.

POSSIBLE SIDE EFFECTS

CellCept can have side effects.

Not all side effects reported for CellCept are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CellCept, please consult your doctor, pharmacist or other healthcare professional for advice.

Frequent:

Some of the more usual problems are **diarrhoea**, fewer white cells and/or red cells in your blood, infection and vomiting. Your doctor will do regular blood tests to monitor any changes in the number of your blood cells or changes in the levels of any of the substances carried in your blood, e.g. sugar, fat, cholesterol.

Children may be more likely than adults to have side effects such as diarrhoea, infections, fewer white cells and fewer red cells in the blood.

CellCept reduces your body's own defence mechanisms to stop rejection of your transplanted kidney, heart or liver. Consequently your body will not be as good as normal at fighting

infections. So if you are taking CellCept you may therefore catch more **infections** than usual, such as infections of the brain, skin, mouth, stomach and intestines, lungs and urinary tract.

Less frequent:
A small number of CellCept patients have developed cancer of the lymph tissues and skin.
General side effects affecting your body as a whole could include **hypersensitivity** (such as anaphylaxis, angioedema, fever, lethargy, difficulty in sleeping, pains (such as abdominal, chest, joint/muscle, pain on passing urine), headache, flu symptoms and swelling.

Other unwanted effects may include:
Disorders of the skin such as acne, cold sores, shingles, skin growth, hair loss, rash, itching.
Urinary disorders such as kidney problems or the urgent need to pass urine.
Disorders of the digestive system and mouth such as constipation, nausea, indigestion, pancreas inflammation, intestinal disorders including bleeding, inflammation of the stomach, liver problems, inflammation of the colon, loss of appetite, flatulence and mouth ulcers.
Disorders of the nerves and senses such as convulsions, tremor, dizziness, depression, drowsiness, numbness, muscle spasms, anxiety, changes in thinking or mood.
Metabolic, blood and vascular disorders such as weight loss, gout, high blood sugar, bleeding, clots and bruises, change in blood pressure, abnormal heart beat and dilation of blood vessels may be seen.
Disorders of the lungs such as pneumonia, bronchitis, shortness of breath, cough, fluid on the lungs/chest cavity, sinus problems.
If you notice any side effects not listed in this leaflet please inform your doctor or pharmacist.
If you are concerned about these or any other unexpected effect(s), talk to your doctor. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF CellCept
Store all medicines out of reach of children.
CellCept 250 mg capsules and CellCept 500 mg tablets: Store at or below 25 ^{o}C.
CellCept OS powder for oral suspension: Store at or below 30 ^{o}C.
The shelf life of the constituted suspension is 60 days when stored below 30 °C. Any unused suspension must be discarded after 60 days.
Keep the container tightly closed.
Because mycophenolate mofetil has demonstrated teratogenic effects in rats and rabbits, CellCept capsules should not be opened or crushed. Avoid inhalation, or direct contact with skin

or mucous membranes, of the powder contained in CellCept capsules. If such contact occurs, wash thoroughly with soap and water, rinse eyes with plain water.

Do not use CellCept after the expiry date that has been printed on the container.

Reconstituted solution

Store at 15 – 30 °C.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF CellCept

CellCept 250 mg capsules: Packs containing multiple opaque PVC blister strips, each strip containing 10 capsules.

CellCept OS powder for oral suspension: White plastic bottle with a child-resistant closure and a closure liner. A plastic press-in bottle adapter and a 5 mℓ graduated plastic oral dispenser.

CellCept 500 mg tablets: Packs containing multiple opaque PVC blister strips, each strip containing 10 tablets.

IDENTIFICATION OF CellCept

CellCept 250 mg capsules: An opaque hard gelatine capsule containing a white to off white powder, branded with black ink “CellCept 250” on the blue capsule cap, and “Roche” on the brown capsule body.

CellCept OS powder for oral suspension: White to off-white powder contained in a white plastic bottle.

Reconstituted suspension: A white to off-white, odourless suspension.

CellCept 500 mg tablets: Lavender coloured caplet-shaped tablet, engraved with “CellCept 500” on one side and “Roche” on the other side.

REGISTRATION NUMBERS

CellCept 250 mg capsules:	31/34/0134
CellCept OS powder for oral suspension:	35/34/0057
CellCept 500 mg tablets:	A39/34/0230

NAME AND ADDRESS OF REGISTRATION HOLDER

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DATE OF PUBLICATION

Registration: 20 May 1997 (31/34/0134)
7 March 2003 (35/34/0057)
7 July 2006 (A39/34/0230)

Last revision: 23 March 2023