PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

CellCept® I.V. 500 mg Infusion (Parenteral)

WARNING 1: DO NOT USE CELLCEPT I.V.

If you are pregnant or planning to become pregnant, or breastfeeding your baby, you must not receive CellCept (see BEFORE USING CellCept I.V. 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 I.V.

- 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 I.V. CONTAINS

Each vial contains the equivalent of 500 mg mycophenolate mofetil (as hydrochloride salt). It also contains polysorbate, citric acid and sodium chloride.

WHAT CellCept I.V. 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 USING CellCept I.V.

Do not use 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.

Take special care with CellCept I.V.:

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 mechanism. 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 I.V. 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 you are given 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.

Taking other medicines with CellCept I.V.

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 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 are given CellCept.

HOW CellCept I.V. WILL BE ADMINISTERED

You will not be expected to give yourself CellCept. It will be given to you by a person qualified to do so.

Do not share medicines prescribed for you with another person.
You should check with your doctor or pharmacist if you are not sure. Your doctor will manage how you will be given CellCept.

The usual dose is:
Method and route of administration
Cellcept is usually given by a doctor or nurse in hospital. It is given as a slow drip (infusion) into a vein.

How much will be given
The amount you need depends on the type of transplant you have had. The usual doses are shown below. Treatment will continue for as long as your doctor considers you will need to prevent your body from rejecting your transplant organ.
When you are able to swallow, you will be given your medicine by mouth.
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 are given more CellCept I.V. than you should:
Since a healthcare professional will administer CellCept, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.
If you forget to have CellCept:
Your doctor will manage the time that you are given your drip infusion.

If you stop taking CellCept I.V.:
Effects when treatment with CellCept is stopped
Stopping your treatment with CellCept may increase the chance of rejection of your transplanted organ.
If you have any further questions on the use of this product, 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 using 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 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 I.V.

Store all medicines out of reach of children.

CellCept I.V.: Store at or below 30 °C.

Keep the container tightly closed.

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

Diluted infusion 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 I.V.

CellCept I.V: Packs of 4 vials.

IDENTIFICATION OF CellCept I.V.

CellCept I.V.: 20 mℓ glass vials with grey butyl rubber stopper and aluminium seals and with plastic flip-off caps. Vials contain a sterile white to off-white lyophilised powder.

REGISTRATION NUMBER

CellCept I.V. Infusion (Parenteral): 33/34/0201

NAME AND ADDRESS OF REGISTRATION HOLDER

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