

Package leaflet: Information for the user
CellCept 500 mg powder for concentrate for solution for infusion
(mycophenolate mofetil)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

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- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What CellCept is and what it is used for
2. What you need to know before you have CellCept
3. How you have CellCept
4. Possible side effects
5. How to store CellCept
6. Contents of the pack and other information
7. Making up the medicine

1. What CellCept is and what it is used for

The full name of your medicine is CellCept 500 mg powder for concentrate for solution for infusion.

- In this leaflet the shorter name CellCept is used.

CellCept contains mycophenolate mofetil.

- This belongs to a group of medicines called “immunosuppressants”.

CellCept is used to prevent your body rejecting a transplanted organ.

- A kidney or liver.

CellCept should be used together with other medicines:

- Ciclosporin and corticosteroids.

2. What you need to know before you take CellCept

WARNING

Mycophenolate causes birth defects and miscarriage. If you are a woman who could become pregnant, you must provide a negative pregnancy test before starting treatment and must follow the contraception advice given to you by your doctor.

Your doctor will speak to you and give you written information, particularly on the effects of mycophenolate on unborn babies. Read the information carefully and follow the instructions. If you do not fully understand these instructions, please ask your doctor to explain them again before you take mycophenolate. See also further information in this section under “Warnings and precautions” and “Pregnancy and breast-feeding”.

Do not take CellCept:

- If you are allergic (hypersensitive) to mycophenolate mofetil, mycophenolic acid, polysorbate 80 or any of the other ingredients in this medicine (listed in Section 6)
- If you are a woman who could be pregnant and you have not provided a negative pregnancy test before your first prescription as mycophenolate causes birth defects and miscarriage.
- If you are pregnant or planning to become pregnant or think you may be pregnant
- If you are not using effective contraception (see Pregnancy, contraception and breast-feeding).
- If you are breast-feeding.

Do not have this medicine if any of the above applies to you. If you are not sure, talk to your doctor or nurse before having CellCept.

Warnings and precautions

Talk to your doctor or nurse straight away before having CellCept:

- If you have a sign of infection such as a fever or sore throat
- If you have any unexpected bruising or bleeding
- If you have ever had a problem with your digestive system such as a stomach ulcer
- If you are planning to become pregnant or if you get pregnant while taking CellCept.

If any of the above apply to you (or you are not sure), talk to your doctor or nurse straight away before having CellCept.

The effect of sunlight

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 protection factor.

Other medicines and CellCept

Please tell your doctor or nurse if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because CellCept can affect the way some other medicines work. Also other medicines can affect the way CellCept works.

In particular, tell your doctor or nurse if you are taking any of the following medicines before you start CellCept:

- azathioprine or other medicines which suppress your immune system – given after a transplant operation
- cholestyramine – used to treat high cholesterol
- rifampicin – an antibiotic used to prevent and treat infections such as tuberculosis (TB)
- phosphate binders – used by people with chronic kidney failure to reduce how much phosphate gets absorbed into their blood.

Vaccines

If you need to have a vaccine (a live vaccine) while having CellCept, talk to your doctor or pharmacist first. Your doctor will have to advise you on what vaccines you can have.

You must not donate blood during treatment with CellCept and for at least 6 weeks after stopping treatment. Men must not donate semen during treatment with CellCept and for at least 90 days after stopping treatment.

Pregnancy, contraception and breast-feeding**Contraception in women taking CellCept**

If you are a woman who could become pregnant you must always use two effective methods of contraception with CellCept. This includes:

- Before you start taking CellCept
- During your entire treatment with CellCept
- For 6 weeks after you stop taking CellCept.

Talk to your doctor about the most suitable contraception for you. This will depend on your individual situation. **Contact your doctor as soon as possible, if you think your contraception may not have been effective or if you have forgotten to take your contraceptive pill.**

You are a woman who is not capable of becoming pregnant if any of the following applies to you:

- You are post-menopausal, i.e. at least 50 years old and your last period was more than a year ago (if your periods have stopped because you have had treatment for cancer, then there is still a chance you could become pregnant)
- Your fallopian tubes and both ovaries have been removed by surgery (bilateral salpingo-oophorectomy)
- Your womb (uterus) has been removed by surgery (hysterectomy)
- Your ovaries no longer work (premature ovarian failure, which has been confirmed by a specialist gynaecologist)
- You were born with one of the following rare conditions that make pregnancy impossible: the XY genotype, Turner's syndrome or uterine agenesis
- You are a child or teenager who has not started having periods.

Contraception in men taking CellCept

You must always use condoms during treatment and for 90 days after you stop taking CellCept.

If you are planning to have a child, your doctor will talk to you about the risks and the alternative treatments you can take to prevent rejection of your transplant organ.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will talk to you about the risks in case of pregnancy and the alternatives you can take to prevent rejection of your transplant organ if:

- You plan to become pregnant.
- You miss or think you have missed a period, or you have unusual menstrual bleeding, or suspect you are pregnant.
- You have sex without using an effective method of contraception.

If you do become pregnant during the treatment with mycophenolate, you must inform your doctor immediately. However, keep taking CellCept until you see him or her.

Pregnancy

Mycophenolate causes a very high frequency of miscarriage (50%) and of severe birth defects (23-27%) in the unborn baby. Birth defects which have been reported include anomalies of ears, of eyes, of face (cleft lip/palate), of development of fingers, of heart, oesophagus (tube that connects the throat with the stomach), kidneys and nervous system (for example spina bifida (where the bones of the spine are not properly developed)). Your baby may be affected by one or more of these.

If you are a woman who could become pregnant, you must provide a negative pregnancy test before starting treatment and must follow the contraception advice given to you by your doctor. Your doctor may request more than one test to ensure you are not pregnant before starting treatment.

Breast-feeding

Do not take CellCept if you are breast-feeding. This is because small amounts of the medicine can pass into the mother's milk.

Driving and using machines

CellCept is not likely to affect you being able to drive or use any tools or machines.

3. How to take CellCept

Cellcept is usually given by a doctor or nurse in hospital. It is given as a slow drip (infusion) into a vein.

How much to take

The amount you take depends on the type of transplant you have had. The usual doses are shown below. Treatment will continue for as long as you need to prevent you from rejecting your transplant organ.

Kidney transplant

Adults

- The first dose is given within 24 hours of the transplant operation.
- The daily dose is 2 g of the medicine taken as 2 separate doses.
- This will be given as 1 g in the morning and then 1 g in the evening.

Liver transplant

Adults

- The first dose is given to you as soon as possible after the transplant operation.
- You will have the medicine for at least 4 days.
- The daily dose is 2 g of the medicine taken as 2 separate doses.
- This will be given as 1 g in the morning and then 1 g in the evening.
- When you are able to swallow, you will be given this medicine by mouth.

Making up the medicine

The medicine comes as a powder. This needs mixing with glucose before using. Your doctor or nurse will make up the medicine and give it to you. They will follow the instructions under Section 7 “Making up the medicine”.

If you have more CellCept than you should

If you think that you have had too much medicine, talk to your doctor or nurse straight away.

If you forget to take CellCept

If a dose of CellCept is missed, this will be given to you as soon as possible. Your treatment will then continue at the normal times.

If you stop taking CellCept

Do not stop having CellCept unless your doctor tells you to. If you stop your treatment you may increase the chance of rejection of your transplant organ.

If you have any further questions on the use of this product, ask your doctor or nurse.

4. Possible side effects

Like all medicines, CellCept can cause side effects, although not everybody gets them.

Talk to a doctor or nurse straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- you have a sign of infection such as a fever or sore throat
- you have any unexpected bruising or bleeding
- you have a rash, swelling of your face, lips, tongue or throat, with difficulty breathing - you may be having a serious allergic reaction to the medicine (such as anaphylaxis, angioedema).

Usual problems

Some of the more usual problems are diarrhoea, fewer white cells or red cells in your blood, infection and vomiting. Your doctor will do regular blood tests to check for any changes in:

- the number of your blood cells
- the amount in your blood of things like sugar, fat or cholesterol.

Fighting infections

CellCept reduces your body's defences. This is to stop you rejecting your transplant. As a result, your body will not be as good as normal at fighting infections. This means you may catch more infections than usual. This includes infections of the brain, skin, mouth, stomach and gut, lungs and urinary system.

Lymph and skin cancer

As can happen in patients having this type of medicine (immune-suppressants), a very small number of CellCept patients have developed cancer of the lymphoid tissues and skin.

General unwanted effects

You may get general side effects affecting your body as a whole. These include serious allergic reactions (such as anaphylaxis, angioedema), fever, feeling very tired, difficulty sleeping, pains (such as stomach, chest, joint or muscle, pain on passing urine), headache, flu symptoms and swelling.

Other unwanted effects may include:

Skin problems such as:

- acne, cold sores, shingles, hair loss, rash, itching.

Urinary problems such as:

- kidney problems or the urgent need to pass water (urine).

Digestive system and mouth problems such as:

- swelling of the gums and mouth ulcers,
- inflammation of the pancreas, colon or stomach,
- gut problems including bleeding, liver problems,
- constipation, feeling sick (nausea), indigestion, loss of appetite, flatulence.

Nervous system problems such as:

- feeling drowsy or numb,
- tremor, muscle spasms, convulsions,
- feeling depressed, changes in your mood or thoughts.

Heart and blood vessel problems such as:

- change in blood pressure, blood clots, unusual heartbeat,
- pain, redness and swelling of the blood vessels where you had the infusion.

Lung problems such as:

- pneumonia, bronchitis,
- shortness of breath, cough, which can be due to bronchiectasis (a condition in which the lung airways are abnormally dilated) or pulmonary fibrosis (scarring of the lung). Talk to your doctor if you develop a persistent cough or breathlessness
- fluid on the lungs or inside the chest,
- sinus problems.

Other problems such as:

- weight loss, high blood sugar, bleeding, bruising.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below).

Ireland

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971

Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

5. How to store CellCept

- Keep out of the sight and reach of children.
- Do not use after the expiry date stated on the carton and vial label (EXP).
- Powder for concentrate for solution for infusion: do not store above 30°C.
- Reconstituted solution and the diluted solution: store between 15°C and 30°C.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What CellCept contains

- The active substance is mycophenolate mofetil.
- The other ingredients are: polysorbate 80, citric acid, hydrochloric acid, sodium chloride.

What CellCept looks like and contents of the pack

- CellCept is provided in a 20 mL type I clear glass vial with a grey butyl rubber stopper and aluminium seal with a plastic flip-off cap.
- It is available in packs of 4 vials.

7. MAKING UP THE MEDICINE

Method and route of administration

CellCept 500 mg powder for concentrate for solution for infusion does not contain an antibacterial preservative; therefore, reconstitution and dilution of the product must be performed under aseptic conditions.

The contents of CellCept 500 mg powder for concentrate for solution for infusion vials must be reconstituted with 14 mL of glucose intravenous infusion 5% each. A further dilution with glucose intravenous infusion 5% is required to a final concentration of 6 mg/mL. This means that to prepare a 1 g dose of mycophenolate mofetil the content of 2 reconstituted vials (approx. 2 x 15 mL) must be further diluted into 140 mL glucose intravenous infusion 5% solution. If the infusion solution is not prepared immediately prior to administration, the commencement of administration of the infusion solution should be within 3 hours from reconstitution and dilution of the medicinal product.

Take care not to let the made-up medicine get into your eyes.

- If this happens, rinse your eyes with plain water.

Take care not to let the made-up medicine get on your skin.

- If this happens, wash the area thoroughly with soap and water.

CellCept 500 mg powder for concentrate for solution for infusion must be given as an intravenous (IV) infusion. The infusion flow rate should be controlled to equate to a 2 hour period of administration.

CellCept IV solution should never be administered by rapid or bolus intravenous injection.

Marketing Authorisation Holder

Roche Registration Limited
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Manufacturing Authorisation holder responsible for batch release:

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For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

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Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>

**AL MINISTERO DELLA SALUTE
USMAF-SASN
UNITA' TERRITORIALE.....**

Richiesta di importazione di medicinali ai sensi del D.M. 11/02/1997.

Il sottoscritto Dr.

Residente in via

Tel.

Iscritto nell'Albo dell'Ordine dei Medici-Chirurghi di

al n. cod. regionale

chiede di importare il medicinale (contenente il seguente/i principio/i attivo/i):

..... **micofenolato**

nome commerciale: **CELLCEPT**

forma farmaceutica: **500 mg / 20 ml**

nella quantità di numero confezioni contenenti **4 FIALA** di farmaco cadauno.

Prodotto dalla ditta: **ROCHE** (specificare il nome dell'azienda).

Precisa che tale medicinale è regolarmente registrato nel Paese di provenienza:

OLANDA / SPAGNA / UK

Per il trattamento di

Tale medicinale è indispensabile per la cura del Sig. (iniziali o codice)

affetto da:

Dichiara altresì che il farmaco:

- Non ha valida alternativa terapeutica con altri medicinali registrati in Italia;
- Non contiene sostanze stupefacenti o psicotrope;
- Non è un emoderivato;
- Verrà impiegato sotto la propria responsabilità, dopo aver ottenuto il consenso informato scritto dal paziente;
- Che le generalità del paziente ed i documenti relativi al consenso informato sono custoditi presso il medico curante per la durata prevista dalla normativa vigente.

Particolari condizioni di conservazione del medicinale:

Temperatura (es. -20°C, da 2 a 8°C, <25°C, <30°C, nessuna indicazione):

Altro:

Luogo e data _____

Timbro e firma leggibile del medico