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CellCept (*mycophenolate mofetil*)

An overview of CellCept and why it is authorised in the EU

What is CellCept and what is it used for?

CellCept is a medicine used in adults and children from 1 year of age to prevent the body from rejecting a newly transplanted kidney, heart or liver. It is used together with ciclosporin and corticosteroids (other medicines to prevent the rejection of a transplanted organ).

CellCept contains the active substance mycophenolate mofetil.

How is CellCept used?

CellCept can only be obtained with a prescription. Treatment should be started and supervised by a doctor specialised in organ transplants.

CellCept is available as capsules, tablets or a powder to be made up into a liquid to be taken by mouth; in adults it can also be given by injection (drip) into a vein. How CellCept is given depends on the type of organ transplant. In children and adolescents, CellCept is only taken by mouth.

For more information about using CellCept, see the package leaflet or contact your doctor or pharmacist.

How does CellCept work?

The active substance in CellCept, mycophenolate mofetil, is an immunosuppressant (a medicine that reduces the activity of the immune system). It is converted in the body into mycophenolic acid, which blocks an enzyme called inosine monophosphate dehydrogenase. This enzyme is important for the formation of DNA in cells, particularly in lymphocytes (a type of white blood cell involved in the rejection of organ transplants). By preventing the production of new DNA, CellCept reduces the rate at which the lymphocytes multiply. This makes them less effective at recognising and attacking the transplanted organ, lowering the risk of the organ being rejected.

What benefits of CellCept have been shown in studies?

Treatment with CellCept was shown to be effective at preventing the rejection of a newly transplanted kidney, heart or liver in adults and children from 1 year of age.

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In all studies, CellCept was given with ciclosporin and corticosteroids, and the main measure of effectiveness was the proportion of patients whose new organ was rejected within six months of receiving the transplant. In most studies, CellCept was compared with azathioprine (another medicine to prevent transplant rejection) or placebo (a dummy treatment).

Kidney transplant

Three main studies involved a total of 1,493 adults who had received a kidney transplant. CellCept was as effective as azathioprine and more effective than placebo in preventing rejection of the new kidney in the first 6 months after transplantation.

A fourth study looked at the effects of CellCept in 100 children who had received a kidney transplant. This study did not compare CellCept with any other medicine or placebo. The proportion of children whose new kidney was rejected was similar to that seen in adults and lower than that seen in other studies of children who underwent a kidney transplant but did not receive CellCept.

Heart transplant

A main study involved 650 adults who had undergone a heart transplant. In the first 6 months after the transplant, the new heart was rejected in 37% of patients taking CellCept, compared with 38% of patients taking azathioprine.

Liver transplant

A main study involved 565 adults who had undergone a liver transplant. In the first 6 months after the transplant, the new liver was rejected in around 38% of patients taking CellCept, compared with around 48% of patients taking azathioprine. The proportion of patients whose new liver was lost after one year was similar in the two groups, at around 4%.

Use in children

The company provided data showing that CellCept behaves in the body in the same way across all age groups from 1 to 18 years of age. It is therefore expected to be effective in preventing rejection following a kidney, heart or liver transplant in these children. This is supported by data from the medical literature on the use of CellCept in children and adolescents.

What are the risks associated with CellCept?

For the full list of side effects and restrictions with CellCept, see the package leaflet.

The most common side effects with CellCept combined with ciclosporin (which may affect more than 1 in 10 people) include diarrhoea, leucopenia, bacterial infections and vomiting.

Using CellCept during pregnancy can cause miscarriage and serious harm to a developing baby. Therefore, CellCept must not be used by women who are pregnant unless no other suitable treatment option is available to prevent rejection of the transplant. Women able to have children must take a pregnancy test before starting treatment to confirm that they are not pregnant. Both women and men should use an effective form of contraception before and during treatment with CellCept and for at least 6 weeks after. CellCept must not be used by women who are breastfeeding.

Why is CellCept authorised in the EU?

Treatment with CellCept in combination with ciclosporin and corticosteroids is effective at preventing the rejection of a newly transplanted kidney, heart or liver in adults and children from 1 year of age.

The most serious risks with CellCept are the possible development of cancer (particularly lymphoma and skin cancer), infections (including serious infections), and serious harm to a developing baby. Considering the measures in place to minimise these risks and what the medicine is used for, the safety profile of CellCept is considered acceptable.

The European Medicines Agency therefore decided that CellCept's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of CellCept?

The company that markets CellCept will provide educational materials for patients and healthcare professionals, explaining the risk of serious harm to a developing baby, the precautions to be taken to avoid pregnancy during treatment and the course of action if a woman becomes pregnant during treatment. The materials will also inform patients not to donate blood during treatment or for at least 6 weeks after, and men not to donate semen during, or for at least 3 months after, treatment.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of CellCept have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of CellCept are continuously monitored. Suspected side effects reported with CellCept are carefully evaluated and any necessary action taken to protect patients.

Other information about CellCept

CellCept received a marketing authorisation valid throughout the EU on 14 February 1996.

Further information on CellCept can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/cellcept.

This overview was last updated in 12-2024.