

Ciclosporin

Information for patients



This leaflet contains information about ciclosporin to treat Ulcerative Colitis.

It tells you:

- how the medicine works
- how you should take it
- whether there are any side effects.

Read this alongside the leaflet called *Unlicensed Medicines: Information for Patients* and any information provided by the manufacturer in the medicine package.

Why have I been given this leaflet?

The information in this leaflet will help you to remember what your doctor has told you about this medicine. It will also help you to decide whether you want to go ahead with this treatment.

For most medicines, information is provided by the manufacturer in the medicine package. However, this medicine does not have a licence for use for Ulcerative Colitis in the UK. This means that the information provided by the manufacturer does not tell you everything you need to know. We have written this leaflet to give you some extra information.

This medicine does not have a licence.

What does this mean?

The leaflet called *Unlicensed Medicines: Information for Patients* tells you more about medicine licensing regulations. It also tells you why unlicensed medicines are sometimes prescribed for patients.

Why does ciclosporin not have a licence?

Sometimes a medicine has been licensed for a certain use and later experience or research shows that it works for a different condition. The manufacturer can choose whether they apply to the Government to have the more recent information added to the licence. This costs a lot of money and in some situations, it is not economical for the manufacturer to obtain or extend a licence.

Ciclosporin is an immunosuppressant made by the manufacturer to prevent organ rejection after transplant. However, it is also useful in the treatment of Ulcerative Colitis.

Remember that your doctor will have thought carefully about which medicine is best for your condition.

What is Ciclosporin and how does it work?

Ciclosporin helps to reduce irritation and swelling in the intestines. It works by suppressing the immune system which is thought to be overactive in Ulcerative Colitis. When used in a severe flare of Ulcerative Colitis that has not responded to intravenous steroids, ciclosporin has been shown to prevent the need for surgery in the short term in 8 out of 10 patients. In the longer term (2 to 3 years) about 5 out of 10 patients will still manage to avoid surgery after receiving ciclosporin.

How should I take Ciclosporin?

Ciclosporin will initially be given to you by an injection into a vein, normally in your arm, over 24 hours, for up to seven days. If you respond well to the treatment this will then be changed to a capsule that you will need to take twice a day. This is normally continued for a period of about three months.

You should always receive the same brand of ciclosporin because the amount of ciclosporin absorbed into the bloodstream may vary between different brands made by different manufacturers. Always check you have been given the same brand of ciclosporin.

Regular blood tests will be taken to check that there is the correct level of ciclosporin in your blood, and that your kidneys and liver are working properly. This will be twice a week to begin with, decreasing to weekly then monthly once levels are stable.

You will also be given an antibiotic to take at the same time to decrease your risk of infection.

When should Ciclosporin not be used?

Do not take this medicine if you have known hypersensitivity to ciclosporin, or if you have abnormal renal function, high blood pressure not controlled by treatment, infections not controlled by treatment or any kind of tumor.

Take with extra care if you:

- have any liver problems or you have had any disease which may have affected your liver.
- have high levels of potassium in your blood, you are taking potassium sparing diuretics (water tablets), potassium supplements or your diet is particularly rich in potassium. Ciclosporin may increase the levels of potassium in your blood.
- have gout.

- develop an increased pressure in your head. Ciclosporin may increase the risk of increased pressure in your head. If this happens your doctor may have to stop prescribing Ciclosporin.
- are likely to be exposed to the sun a great deal without protecting your skin with a sun block cream or if you regularly use a sun bed.
- have any skin conditions other than severe psoriasis or severe eczema, or are receiving light treatment (PUVA or other UV treatment) for a skin condition.

Do not take Neoral with grapefruit or grapefruit juice. This is because these can affect how Neoral works

The manufacturers leaflet will explain this in more detail. Please tell your doctor if you have any of the conditions listed.

Are there any side effects?

Most medicines cause side effects. The leaflet provided by the manufacturer for ciclosporin contains a list of the effects reported for this medicine. Everyone reacts differently to medicines. It is very unlikely that you will have all the listed effects.

The most common side effects (occurring in more than 1 in 10 patients) include kidney problems, high blood pressure, headache, tremor and increased levels of lipids (for example cholesterol) in the blood.

As ciclosporin suppresses the immune system you are potentially more at risk of infections. Some studies using ciclosporin for ulcerative colitis have reported death in up to 2 in 100 patients,

though patients in these studies were taking higher doses of ciclosporin than are now prescribed. This increased risk of death has not been seen when ciclosporin is used to treat other diseases.

If you develop a sore throat, any infections or begin to feel generally unwell see your doctor immediately.

Will Ciclosporin affect any other medicines?

If you take any of the following medicines, tell your doctor or pharmacist and they will advise you.

- Medicines to treat infections including antibiotics and antifungal medicines
- Oral contraceptives
- Medicines to treat heart problems or high blood pressure
- Medicines for epilepsy
- Cholesterol lowering medicines
- Sleeping tablets
- Potassium supplements
- Diuretics or “water tablets” that affect the amount of urine you produce
- Anti-inflammatory medicines including medicines used to treat rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, gout, period pains and muscle disorders
- Light treatment (PUVA or other UV treatment) for a skin condition

- Danazol (used to treat menstrual disorders, endometriosis or breast problems)
- Tacrolimus. Tacrolimus dampens down your immune system in a similar way to ciclosporin, so if you take tacrolimus and ciclosporin together, your immune system may be dampened down too much. If this happens you may be more likely to get infections.
- St John's Wort: The herbal remedy St John's Wort (*Hypericum perforatum*) should not be taken at the same time as this medicine. If you are already taking St John's Wort consult your doctor before stopping the St John's Wort preparation.
- Octreotide
- Medicines to treat tuberculosis
- Medicines to treat gout
- Metoclopramide (used to stop sickness)
- Melphalan (used to treat lymphomas or tumours)
- Orlistat (used to help weight loss)
- Ticlopidine
- Ursodeoxycholic acid (used to treat gallstones)
- Protease inhibitors (used to treat Human Immunodeficiency Virus (HIV))
- Vaccinations - if you have recently had a vaccination or are planning to have any vaccinations

Neoral contains alcohol. This may affect your ability to drive and use machines. This is equivalent to nearly 15ml beer or 5ml wine per dose.

Tell your doctor or pharmacist about all the other medicines you take. This includes any medicines you have had prescribed by another doctor, as well as medicines bought from a pharmacy or supermarket and any herbal remedies.

Whenever you are prescribed a new medicine, or want to buy a medicine e.g., from a pharmacy or supermarket, it is important that you tell the doctor or pharmacist about all the medicines that you take, including ciclosporin. You should also tell your dentist when you see him/her.

Can I drink alcohol while I am taking ciclosporin?

Yes, it is safe to drink alcohol while you are taking ciclosporin, however large quantities of alcohol should be avoided.

Where should I store ciclosporin at home?

Store ciclosporin in a cool, dry place, away from direct sunlight. Leave your capsules in the foil. Only remove them when it is time to take your medicine

It is important that all medicines are stored out of reach of children.

Where do I get my next supply?

This medicine is only available from the hospital pharmacy. You will be given enough to last until your next appointment. However, if you need a replacement supply, please contact one of the IBD nurse specialists to arrange a prescription.

How can I find out more?

Your agreement should be obtained before prescribing any medicine.

This leaflet has been written to provide general information about ciclosporin. If you have any further questions or concerns, please speak your doctor or pharmacist.



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