

Ciclosporin

This information leaflet aims to answer common questions you may have if your doctor has given you or has discussed using ciclosporin to treat your Ulcerative Colitis (UC), a form of Inflammatory Bowel Disease (IBD). You can obtain further information from your pharmacist or doctor, from the information leaflet supplied with your prescription, or from the website: www.medicines.org.uk.

Why have I been started on this medicine?

You may be started on ciclosporin if you have a severe flare up of your condition which does not respond to intravenous (into a vein) steroid treatment. Ciclosporin is generally used to treat acute severe Ulcerative Colitis when surgery to remove the large bowel is likely to be the alternative option. Ciclosporin is not generally used to treat Crohn's Disease.

How does it work?

Ciclosporin is a type of medicine called an immunosuppressant. The immune system is important in fighting infections, but sometimes immune system cells attack the body's own tissues. Ciclosporin dampens down the activity of these cells and so reduces inflammation in the bowel.

How long does it take to work?

It can often work quite quickly. Some people notice an improvement within a few days and others within two weeks. On average the response rate is four to five days, though approximately two out of ten people do not respond.

What is the normal dosage?

If you are in hospital, ciclosporin may first be given intravenously (into a vein), as absorption of capsules could be erratic if your gut is very inflamed. The usual intravenous dose is 2 mg per kilogram of body weight per day and is given as one or more infusions.

If you take ciclosporin orally (by mouth), the dose is initially based on your weight and rounded up to the nearest capsule size. Ciclosporin capsules come in four different strengths – 100mg (grey), 50mg (white), 25mg (grey) and 10mg (white). The usual dose is from 5 to 8 mg per kilogram of body weight per day. Your dose may be adjusted depending on your response and the levels of the drug in your blood.

How do I take it?

You should swallow the capsules whole with a glass of water.

Ciclosporin is also available as a liquid if you have problems swallowing the capsules. In this case dilute the liquid immediately before taking it with water or juice or squash (**not grapefruit**) to improve the taste. Stir the mixture and drink at once.

You should take ciclosporin twice a day, ideally 12 hours apart at 8.00 am and 8.00 pm. This is because when your blood levels are checked, it is important to know the time the drug was taken beforehand.

You must not take whole grapefruit or grapefruit juice for at least one hour before your dose, as grapefruit juice can increase ciclosporin levels in the blood.

What happens if I forget to take a dose?

If you forget to take a dose, take another one as soon as you remember, unless it is almost time for your next dose. Do not double the dose. If you take too much ciclosporin tell your doctor **immediately**.

How long will I be taking it?

If you respond to ciclosporin, you will usually remain on it for about 3 months, until other slower acting immunosuppressants that you may be given, such as azathioprine, begin to take effect. It is important not to stop taking your medicine before checking with your doctor, however well you feel.

How effective and safe is ciclosporin?

Ciclosporin was first used to prevent the body's rejection of organ transplants and continues to be widely used in transplants. It is also used for some skin conditions and rheumatoid arthritis. In IBD ciclosporin has been used to treat severe Ulcerative Colitis since the 1980s. Research studies show that initially approximately 8 out of 10 people with UC respond to ciclosporin and avoid surgery. In the long-term, half of those who initially respond to treatment subsequently need surgery. This means that ciclosporin may help you to avoid or delay the need for surgery. It may give you time to discuss treatment options and may prevent you from having an urgent operation, which can potentially have more complications.

Like all medicines, ciclosporin can have side effects, although not everybody gets them. On average four out of ten people are at risk of minor side effects. There have been reports of serious infections during ciclosporin treatment, but these were rare. Research suggests that lower doses decrease the risk of side effects.

Do I need any special checks while on ciclosporin?

Ciclosporin can raise your blood pressure and affect the kidneys. Your blood pressure, blood count and kidney function should be checked every 2-4 weeks for 2 months and then at 1-2 monthly intervals.

Your doctor may at times need to check the amount of ciclosporin in your blood. This is usually when the medication is at the lowest level, several hours after taking a dose, which is called a trough level. The trough level is usually taken in the morning before you take your dose, as it will then be many hours since your last dose. This means it is important not to take your ciclosporin tablets before the blood has been taken. If you start by having ciclosporin intravenously in hospital, your cholesterol and magnesium levels will also be checked, as low levels of these may increase your risk of side effects.

Will I need to take any special precautions while being treated with ciclosporin?

Ciclosporin can cause an increase in the amount of potassium in your bloodstream, so you should avoid large amounts of high potassium foods such as bananas, tomatoes and dried fruit. You should also avoid potassium supplements. Try to avoid contact with people who have infections. As ciclosporin affects the way the body's immune system works, you may be more prone to infections.

You may also be at risk of severe infection from the viruses which cause chickenpox and shingles, measles and pneumococcal disease. If you are not already immune you can be vaccinated before starting treatment. Otherwise tell your doctor or nurse as soon as possible if you come into contact with anyone who has any of these conditions and you may be able to have a protective injection.

Ciclosporin may increase the skin's sensitivity to sunlight, so you should use sunscreens, and you should avoid sunlamps or sunbeds.

Can I take other medicines along with ciclosporin?

Many medicines interact with ciclosporin. These include non-steroidal anti-inflammatory drugs, such as ibuprofen, some antibiotics, including erythromycin and clarithromycin, and St John's Wort. These can affect the level of ciclosporin in the blood.

It is important to tell your doctor, nurse specialist or pharmacist about all other medicines or preparations you are taking or thinking of taking, including over-the-counter medicines, herbal, complementary or alternative therapies.

You should always tell any other doctor or dentist treating you that you are taking ciclosporin.

Can I have immunisations while on ciclosporin?

Certain vaccinations and immunisations may be unsafe to take together with ciclosporin, which suppresses the immune system. You should avoid **live** vaccines such as polio, yellow fever, rubella (German measles), MMR (measles, mumps and rubella) and BCG (tuberculosis). An 'inactivated' polio vaccine can be given instead of the 'live' one. Pneumovax and yearly flu vaccines are safe, as they are not live vaccines. The Chief Medical Officer recommends the flu vaccine for people on immunosuppressants. Close relatives and family members may have live vaccines without any risk to you.

Can I drink alcohol while taking ciclosporin?

It is safe to drink alcohol in moderation whilst on ciclosporin. Generally it is best to keep your intake of alcohol to well within the maximum limits when taking ciclosporin. This is 2-3 units a day for women and 3-4 units a day for men. One small study suggests that elements in red wine may affect the absorption of ciclosporin. This may make ciclosporin less effective and it may be advisable to avoid red wine.

Does ciclosporin affect fertility or pregnancy?

It is important to tell your doctor if you want to start a family or become pregnant, as ciclosporin should be used with great caution in pregnancy. While there is limited evidence about its safety, it has not been associated with any harm to an unborn baby. Most doctors advise the continued use of this drug, as there may be more risk if the mother becomes unwell. You will have to make a balanced decision based on the risks and benefits.

What about breastfeeding?

Ciclosporin passes into breast milk and can potentially affect the baby's immune system. For this reason doctors advise you not to breastfeed while taking ciclosporin.

What are the possible side effects?

All medicines can cause unwanted side effects, but we are all different and not everybody gets them. You may feel sick at first, possibly vomiting and have some abdominal discomfort. You may have hot or burning sensations in your hands and feet. This normally gets less after a couple of weeks. The side effects of ciclosporin tend to get better if the

dose is reduced. Some women find their periods stop while on ciclosporin. Others may have cramps and painful periods.

Some other possible side effects include:

- Headaches
- Tiredness
- Growth of hair on the face
- Shakiness of the hands
- A rise of blood pressure
- Metallic taste in the mouth
- Diarrhoea
- Reduced function of the kidneys – usually temporary
- Slightly enlarged or sore gums. (Your dentist should be able to suggest treatment for this.)
- Epileptic fits – uncommon

When should I contact my doctor?

Contact your doctor or IBD nurse specialist: in the following situations:

- If you develop a sore throat or any infection or begin to feel generally unwell.
- If you have severe side effects.
- If you take too much ciclosporin.
- If you are in contact with anyone who has chickenpox or shingles and you are not already immune.
- If you are going to take any new medication or preparation.
- If you are going to start a new oral contraceptive.
- If you become pregnant.

Who should I talk to if I am worried?

Contact your doctor or nurse specialist if you are worried about your treatment or if you have any questions, such as why ciclosporin has been prescribed, what the correct dose and frequency is, what monitoring for adverse effects is in place, and what, if any, alternatives are available for you in your particular circumstance.

Where can I get further information?

You can telephone the **Crohn's and Colitis UK Information Line on 0845 130 2233** or email info@crohnsandcolitis.org.uk for further information.

You can also obtain more information about other drugs used in the treatment of IBD from our booklet *Drugs used in IBD* and from our other Drug Treatment Information leaflets. If you would like information about operations for UC see our leaflet *Surgery for Ulcerative Colitis*. Please call the Information Line for copies or visit our website: www.crohnsandcolitis.org.uk to download Drug Treatment Information leaflets.

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Crohn's and Colitis UK is the working name for the National Association for Colitis and Crohn's Disease (NACC). NACC is a voluntary Association, established in 1979, which has 30,000 members and 70 Groups throughout the United Kingdom.

Membership of the Association costs £12 a year. New members who are on lower incomes due to their health or employment circumstances may join at a lower rate. Additional donations to help our work are always welcomed.