

CICLOSPORIN

What are the aims of this leaflet?

This leaflet has been written to help you understand more about ciclosporin. It tells you what it is, how it works, how it is used to treat skin conditions, and where you can find out more about it.

What is ciclosporin, and how does it work?

Like penicillin, ciclosporin is a substance produced by a fungus. Ciclosporin was found to suppress the immune system. It was initially developed for suppressing the immune system of transplant patients to prevent them from rejecting their transplanted kidneys and other organs. It was subsequently found to help patients with a wide range of diseases caused by immune reactions.

Why suppress the immune system?

There are several reasons:

- In auto-immune diseases, the immune system attacks the body itself. These diseases can affect just one organ - such as the heart, liver or skin - or several organs.
- There are also diseases in which the body's immune system becomes overactive, letting a disease persist or even worsen. Suppressing the immune system can then be helpful.
- After transplant surgery, the immune system has to be suppressed to stop the transplanted organ from being rejected. Most patients who have had a kidney or heart transplant take ciclosporin as part of the combination of drugs used to suppress their immune system.

Which skin conditions are treated with ciclosporin?

Ciclosporin is prescribed for conditions in which the immune system is playing a role in maintaining the disease. Currently, it is only licensed to treat psoriasis and atopic eczema. This means that enough research has been focused on these conditions to allow the drug to be marketed for treating them. However, drugs are also sometimes used 'off-license', i.e. for other conditions, if they are considered helpful, providing this is under medical supervision. In the case of ciclosporin, these include other types of eczema, <u>hidradenitis suppurativa</u>, <u>lichen planus</u>, <u>pyoderma gangrenosum</u>, <u>urticaria</u> and <u>vasculitis</u>.

Will ciclosporin cure my skin condition?

As far as we know, none of the skin conditions for which ciclosporin is used are 'cured' by this treatment. However, it can be very effective in keeping the conditions under control. If ciclosporin will be effective, an improvement is usually seen within the first few days or weeks of treatment. Then the drug will be continued, if necessary, to keep the skin problem under control. The drug dosage will be reduced in steps to the lowest effective dosage to reduce side effects to the extent possible whilst keeping your skin condition under control.

What dose should I take?

Your doctor will advise you here, as the dose prescribed depends partly on your body weight. The total dose is usually within the range of 2-5 mg for every kg of body weight per day. Usually, short courses are prescribed lasting 2-4 months, but some patients may need a longer course; your doctor will advise you on this.

Grapefruit or grapefruit juice is best avoided by patients taking ciclosporin as it may alter the drug's metabolism, meaning the drug's actions become unpredictable.

Please note that different brands of ciclosporin might be absorbed by the body differently, so it is always recommended to use the same brand. If you change the brand, then you may need a slightly different dose. Occasionally a blood test is performed to measure the level of the drug in your blood.

What are the possible side effects of ciclosporin?

The long-term (usually over several months or years) side effects of ciclosporin include reduced function of the kidneys and raised blood pressure. Kidney function can be measured using a blood test or a nuclear medicine test. The dose of ciclosporin has to be reduced or stopped if there is a rise in blood pressure or effects on the kidneys. Provided the treatment is monitored and appropriate adjustments are made, these side effects are largely reversible. Ciclosporin can also cause increased levels of lipids (such as cholesterol) in the blood.

The functions of the immune system include protection from infections and cancers. Taking ciclosporin may, therefore, reduce your resistance to severe infections (e.g. tuberculosis or hepatitis). Minor infections, such as colds, are probably not increased. If you have not had chickenpox, and you come into contact with someone who has chickenpox or <u>shingles</u> (which is also caused by the chickenpox virus), you should inform your doctor promptly as it may be necessary for you to be given treatment to protect you (see Patient Information Leaflet on <u>immunisation</u> for recommendations on adult patients taking immune-suppressing medicines).

If you develop any infective symptoms, it is crucial to seek medical advice. Some symptoms to keep in mind are fever/flu-like illness, mouth ulceration, tiredness, unexplained bruising or bleeding of gums, nausea, vomiting, abdominal pain or dark urine and breathlessness or cough. This is not a full list, but you should remain alert to this and seek advice if necessary.

In transplant patients who h ave taken ciclosporin with other drugs, which also suppress the immune system, there is an increased risk of many types of cancer. If you develop cancer while taking ciclosporin, this might grow faster due to the immunosuppression. You should take part in national cancer screening programmes such as those for breast, bowel and cervical cancer. People taking ciclosporin should avoid exposing their skin to the sun and apply sunscreen to exposed skin when out of doors, especially in the summer due to increased skin cancer risk (for more information on sun protection, see <u>https://www.skinhealthinfo.org.uk/sun-awareness/</u>). Skin cancer is a risk in people who have received a lot of treatment with ultraviolet light, particularly those with <u>psoriasis</u> or who have exposed their skin to a lot of sun over the years. You should talk to your doctor about this if you have any concerns, if you find any new growths on your skin, or if any mole or area of skin grows or changes colour or shape.

Less serious side effects of ciclosporin include sickness (nausea), diarrhoea, gum overgrowth, tiredness and excessive hair growth. It can also produce a mild tremor. Sometimes a burning sensation of the hands and feet occurs early in treatment. These side effects tend to get better if the dose is reduced and often go away completely if ciclosporin is stopped. Maintaining good oral hygiene by cleaning teeth and having dental check-ups reduces the chances of developing gum overgrowth (gingival hyperplasia).

How will I be monitored for the side effects of ciclosporin treatment?

As ciclosporin can affect the kidneys and blood pressure, your doctor will arrange for you to have regular blood tests and checks on your blood pressure. These tests will be carried out frequently at first and less often once the dose is stable. You may be asked to keep a record booklet with your test results. Take this with you when you visit your General Practitioner or go to the hospital.

You must not take ciclosporin unless you have regular checks.

Does ciclosporin affect fertility or pregnancy?

It is preferable not to take ciclosporin during pregnancy, but your doctor will discuss your options. If you are planning a family, or if you become pregnant while taking ciclosporin, you should discuss this with your doctor as soon as possible. You should not breastfeed while taking ciclosporin.

May I drink alcohol while taking ciclosporin?

There is no particular reason for you to avoid alcohol (within the recommended guidelines) while taking ciclosporin.

Can I take other medicines at the same time as ciclosporin?

Ciclosporin may be prescribed in combination with other drugs. However, many other drugs interact with it, and you should always tell all doctors and medical professionals treating you that you are taking ciclosporin. You should not take over-the-counter drugs or dietary supplements such as St John's wort without discussing this first with your doctor or pharmacist. Drugs that may interact with ciclosporin include:

- Aspirin and non-steroidal anti-inflammatory drugs (NSAIDs): such as ibuprofen and diclofenac.
- *Antibiotics*: erythromycin, clarithromycin, trimethoprim, ciprofloxacin, rifampicin and doxycycline.
- *Antifungals*: fluconazole, itraconazole, ketoconazole and amphotericin B.
- Treatment for seizures: phenytoin and carbamazepine.
- *Blood pressure treatments*: ACE inhibitors, beta-blockers and calcium channel blockers.
- Digoxin.
- This is not a complete list.

Can I have immunisation injections while on ciclosporin?

You should not take 'live' vaccines such as yellow fever injections, polio drops, chickenpox and shingles (herpes zoster) vaccines whilst on ciclosporin. The COVID vaccines used in the UK at the time of writing (December 2021) are safe and recommended for people taking ciclosporin as these are not 'live' vaccines. For vaccines such as the COVID vaccines that require more than a single dose, these should be taken as per your doctors' recommendations, usually at the licensed interval. If you need to have immunisations, wait at

least 1 month before starting ciclosporin. 'Live' vaccines should also be avoided for 3 months after stopping ciclosporin. Where ciclosporin is used in people with organ transplants, 'live' vaccines should be avoided for 6 months after stopping ciclosporin. Most flu vaccines and Pneumovax are safe and recommended.

Where can I get more information about ciclosporin?

If you would like any further information about ciclosporin, or if you have any concerns about your treatment, you should discuss this with your doctor or pharmacist. This information sheet does not list all the side effects this drug can cause. For full details, please see the drug information leaflet that comes with your medicine. Your doctor will assess your medical circumstances and draw your attention to side effects that may be relevant in your particular case.

The BAD Biologic Interventions Register (BADBIR)

You may be asked to take part in a national register if you are prescribed a biologic medication. This register will collect valuable information on side effects and benefits of the drug. It will also inform doctors on how best to use biologic drugs. No information will be passed to the register without your informed consent.

References:

British Association of Dermatologists' guidelines for the safe and effective prescribing of ciclosporin June 2019

BAD patient information leaflet on immunisation

BAD information on sun protection

A complete list of Patient Support Groups is available at the BAD – Skin Health website:

https://www.skinhealthinfo.org.uk/support-resources/patient-support-groups/

This leaflet aims to provide accurate information about the subject and is a consensus of the views held by representatives of the British Association of Dermatologists: individual patient circumstances may differ, which might alter both the advice and course of therapy given to you by your doctor.

This leaflet has been assessed for readability by the British Association of Dermatologists' Patient Information Lay Review Panel

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