Ciclosporin Patient Information

For more information, head to hunteribd.com or contact the team at
hne-ibdprescription@health.nsw.gov.au

JHH
IBD

CICLOSPORIN (sye-kloe-SPOR-in)

Patient Information Leaflet

Brand Names: Neoral®, Sandimmun®, Cicloral®, Cysporin®

What is Ciclosporin?

Ciclosporin (also spelled cyclosporine) is an immunosuppressant medication that works by inhibiting the activity of certain immune cells, particularly T-lymphocytes, which play a role in inflammation. By reducing the activity of these cells, ciclosporin helps to decrease inflammation in the body.

Ciclosporin is a small molecule medication that has been used in medicine for several decades, primarily in organ transplantation to prevent rejection. It is also effective in certain autoimmune and inflammatory conditions.

What is Ciclosporin used for?

Ciclosporin is approved in Australia for:

- Prevention of organ transplant rejection
- Severe active rheumatoid arthritis
- Severe psoriasis
- Severe atopic dermatitis (eczema)
- Severe uveitis (eye inflammation)
- Nephrotic syndrome (a kidney disorder)

For inflammatory bowel disease, ciclosporin is used "off-label" (not formally approved for this indication, but supported by medical evidence) for:

- Severe acute ulcerative colitis that has not responded to intravenous corticosteroids, to avoid emergency colectomy (surgical removal of the colon)

How is Ciclosporin given?

Ciclosporin is available in different formulations:

For severe acute ulcerative colitis:

- Initial treatment:Usually given as an intravenous (IV) infusion in hospital
  - Typical dose: 2mg per kg of body weight per day, given as a continuous infusion
  - Treatment duration: Usually 5-7 days
- If responding to IV treatment:Transition to oral formulation
  - Capsules or oral solution (microemulsion formulations like Neoral® are preferred)
  - Typical dose: 4-8mg per kg body weight per day, divided into two doses (morning and evening)
  - Treatment duration: Usually as a bridging therapy for 3-6 months until other maintenance medications take effect

Taking oral ciclosporin correctly:

- Take at the same times each day
- Take on an empty stomach or consistently with or without food
- Swallow capsules whole with water, do not crush or chew
- If using oral solution:
  - Measure the prescribed dose with the provided pipette
  - Mix with orange or apple juice (not grapefruit juice) to improve taste
  - Drink immediately after mixing
  - Wipe the pipette on the outside only and do not wash with water

How long does Ciclosporin take to work?

The time to experience benefits from ciclosporin varies:

- For severe acute ulcerative colitis: Effects can be seen within 2-7 days
- Most patients who will respond show improvement within the first week of treatment
- If no improvement is seen within 7-10 days, alternative treatments may be considered

How should Ciclosporin be stored?

- Store at room temperature between 15°C and 25°C
- Do not refrigerate the oral solution
- Protect from light and moisture
- Keep in the original packaging
- Keep out of reach of children
- Once opened, the oral solution should be used within 2 months
- Do not use after the expiry date printed on the package

What monitoring is required while taking Ciclosporin?

Before starting ciclosporin:

- Complete blood count
- Kidney function tests
- Liver function tests
- Blood pressure measurement
- Cholesterol and lipid profile

- Magnesium level
- Check for active infections

During treatment:

- Kidney function: Monitored frequently, especially during the first few months
- Blood pressure: Regular monitoring, sometimes even daily initially
- Ciclosporin blood levels: Regular testing to ensure the dose is appropriate (typically twice weekly initially, then less frequently)
- Liver function: Monitored regularly
- Electrolytes: Potassium, magnesium, and uric acid levels
- Complete blood count: Regular monitoring
- Cholesterol and triglycerides: Periodic monitoring

The frequency of monitoring will depend on your dose, whether you're taking intravenous or oral ciclosporin, and your response to the medication. Initially, monitoring may be very frequent (even daily for some tests), then less frequent as the treatment stabilizes.

Drug interactions

Ciclosporin interacts with many medications, which can either increase or decrease ciclosporin levels in the blood or increase the risk of side effects. Always inform your doctor and pharmacist about all medications you are taking. Key interactions include:

- Medications that can increase ciclosporin levels:
  - Some antibiotics (erythromycin, clarithromycin)
  - Some antifungals (fluconazole, itraconazole)
  - Some calcium channel blockers (diltiazem, verapamil)
  - Some antidepressants
  - Grapefruit juice (avoid completely)
- Medications that can decrease ciclosporin levels:
  - Some antibiotics (rifampicin)
  - Some anticonvulsants (carbamazepine, phenytoin)
  - St. John's wort (herbal supplement - avoid)
- Medications that may increase the risk of kidney damage:
  - NSAIDs (ibuprofen, diclofenac, etc.)
  - Some antibiotics (gentamicin, vancomycin)
  - ACE inhibitors and ARBs (blood pressure medications)

Diet considerations

- Avoid grapefruit and grapefruit juice completely as they can significantly increase ciclosporin levels
- Maintain consistent timing of ciclosporin in relation to meals
- A low-potassium diet may be recommended if potassium levels become elevated

What are the risks associated with Ciclosporin?

Serious risks:

1. **Kidney toxicity**:
   - One of the most significant concerns with ciclosporin
   - Usually reversible when the dose is reduced or the drug is stopped
   - Long-term use may lead to permanent kidney damage in some cases
   - Symptoms may include decreased urine output, swelling in the legs or feet
2. **High blood pressure:**
   - Affects up to 50% of patients taking ciclosporin
   - Usually controlled with dose adjustment or blood pressure medications
   - Regular blood pressure monitoring is essential
3. **Infections:**
   - Increased risk of various infections due to immunosuppression
   - Can include bacterial, viral, and fungal infections
   - Opportunistic infections may occur in some cases
4. **Neurological effects:**
   - Tremors (shakiness, especially in the hands)
   - Headaches
   - In rare cases, more serious effects such as seizures or confusion
   - Posterior reversible encephalopathy syndrome (PRES) is a rare but serious complication
5. **Malignancies:**
   - Long-term use is associated with an increased risk of certain cancers, particularly skin cancers
   - Regular skin examinations are recommended
6. **Hepatotoxicity (liver damage):**
   - Elevated liver enzymes are common
   - Serious liver damage is rare
   - Regular liver function monitoring is important
7. **Electrolyte disturbances:**
   - Increased potassium levels (hyperkalemia)
   - Decreased magnesium levels (hypomagnesemia)
   - May require supplementation or dietary adjustments

What are the common side effects of Cyclosporin?

Common side effects (affecting more than 1 in 10 people):

- Excessive hair growth (hirsutism), particularly on the face
- Tremor (shakiness in the hands)
- High blood pressure
- Headache
- Kidney function abnormalities
- Elevated blood lipids (cholesterol, triglycerides)
- Gum enlargement (gingival hyperplasia)
- Gastrointestinal discomfort (nausea, vomiting, abdominal pain, diarrhoea)
- Burning sensation in the hands and feet, especially during the first week of treatment

Less common side effects (affecting between 1 in 100 and 1 in 10 people):

- Tiredness
- Muscle cramps
- Weakness
- Loss of appetite
- Acne
- Elevated uric acid levels (may cause gout)
- Elevated potassium levels
- Decreased magnesium levels
- Mild anaemia
- Numbness or tingling (paraesthesia)
- Liver function abnormalities

Vaccinations and Ciclosporin

Before starting ciclosporin:

If possible, update all vaccinations according to the Australian Immunisation Schedule before starting treatment. This includes:

- Influenza vaccine (yearly flu shot)
- Pneumococcal vaccine
- Hepatitis B vaccine (if you are not immune)
- Consider COVID-19 vaccination as per current guidelines

During ciclosporin treatment:

- Live vaccines should be avoided due to the risk of vaccine-induced infection, including:
  - Measles, mumps, rubella (MMR)
  - Varicella (chickenpox)
  - Zoster (shingles) - Zostavax
  - Oral typhoid
  - Yellow fever
  - BCG (tuberculosis)
  - Oral polio vaccine
- Non-live vaccines are generally considered safe but may be less effective while on ciclosporin:
  - Influenza vaccine (yearly)
  - Pneumococcal vaccine
  - Tetanus booster
  - COVID-19 vaccines

Always discuss vaccination plans with your gastroenterologist before receiving any vaccine.

Ciclosporin and Pregnancy

Planning pregnancy:

Ciclosporin is classified as Category C in the Australian pregnancy categorisation system. This means that the drug may cause harmful effects on the foetus or newborn without causing malformations. These effects may be reversible.

Current evidence suggests that:

- Ciclosporin crosses the placenta
- It has been used in pregnant transplant recipients with acceptable outcomes
- The potential benefits may outweigh risks in severe acute ulcerative colitis
- Decisions should be made on a case-by-case basis

During pregnancy:

- If ciclosporin is needed during pregnancy, the lowest effective dose should be used
- Closer monitoring of blood pressure and kidney function is required
- Close collaboration between gastroenterologist and obstetrician is essential

Breastfeeding:

- Ciclosporin passes into breast milk
- Breastfeeding is generally not recommended while taking ciclosporin
- Discuss the benefits and risks with your healthcare providers if breastfeeding is important to you

Special Precautions

Skin protection:

Due to the increased risk of skin cancers, it is important to practise sun safety:

- Use sunscreen (SPF 30+ or higher)
- Wear protective clothing
- Seek shade when possible
- Have regular skin checks with your doctor

Dental care:

- Regular dental check-ups are important due to the risk of gum enlargement
- Maintain excellent oral hygiene
- Inform your dentist that you are taking ciclosporin

Surgery:

If you are planning to have surgery, inform your surgeon that you are taking ciclosporin. The timing of doses around surgery may need adjustment.

Where can I find more information?

- Speak to your gastroenterologist, IBD nurse, or pharmacist
- Contact the Gastroenterological Society of Australia (GESA): www.gesa.org.au
- Contact Crohn's & Colitis Australia: www.crohnsandcolitis.com.au or 1800 138 029
- Call Medicines Line: 1300 MEDICINE (1300 633 424)

This information leaflet is not intended to replace medical advice. Always consult your healthcare team with specific questions about your treatment.

Last updated: April 2025