

CICLORAL[®] CAPSULE

Ciclosporin (25mg, 50mg, 100mg)

What is in the leaflet

1. What Cicloral is used for
2. How Cicloral works
3. Before you use Cicloral
4. How to use Cicloral
5. While you are using it
6. Side effects
7. Storage and Disposal of Cicloral
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Cicloral is used for

Cicloral is used to control the body's immune system following organ or bone marrow transplantation. Cicloral is used for other autoimmune diseases such as eye problems which threaten your vision (endogenous uveitis), severe cases of certain skin diseases (atopic dermatitis, or psoriasis), severe rheumatoid arthritis and a kidney disease called nephrotic syndrome which does not respond sufficiently to conventional therapies.

If you have any questions about how Cicloral works or why this medicine has been prescribed for you, consult your doctor.

How Cicloral works

Cicloral contains the active ingredient ciclosporin. This belongs to a group of medicine known as immunosuppressant. These medicines are used to suppress the body's immune reactions. It prevents rejection of transplanted organs by blocking the development of certain cells which would normally attack the transplanted tissue. Cicloral suppresses the immune reaction in which your body's own immune response attacks the cells in your body (autoimmune disease).

Before you use Cicloral

Cicloral will only be prescribed for you by a doctor with experience in transplants and/or autoimmune disease.

The advice in this leaflet may vary depending on whether you are taking this medicine for a transplant or for an autoimmune disease. Follow all your doctor's instructions carefully. They may differ from the general information contained in this leaflet.

- When you must not use it

Do not take Cicloral:

- If you have known hypersensitivity to ciclosporin or any ingredients listed at the end of this leaflet.
- Cicloral should not be given to children and adolescents (under 16 years of age) for a non-transplant disease, except for treatment of nephrotic syndrome.

Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

• Tell your doctor if you are pregnant or intent to become pregnant. Cicloral should not be taken during pregnancy. If it is necessary for you to take this medicine, your doctor will discuss with you the benefits and potential risks of taking it during pregnancy.

• Tell your doctor if you are breastfeeding. Breastfeeding is not recommended during the treatment with Cicloral as the active ingredient ciclosporin passes into breast milk and may affect your baby.

• Cicloral suppresses the immune system and may affect your body's ability to fight against infection. If you have any signs of infection (e.g. fever, sore throat), inform your doctor immediately.

• Your risk of developing cancers may increase as Cicloral suppresses your immune system, particularly of the skin and lymphoid system. You should limit your exposure to sunlight and UV light by wearing appropriate protective clothing and applying sunscreen with high protection factor in regular.

• Cicloral may affect the levels of magnesium and/or potassium in your body. Hence, you should avoid high dietary potassium intake and not to be given medicines containing magnesium and/or potassium.

Talk to your doctor:

- If you have liver and/or kidney problems. Your doctor will carry out regular blood tests and may change your dose if necessary.
- If you develop high blood pressure. Your doctor will check your blood pressure regularly and may give you medicine to lower blood pressure if necessary.
- If you need to have a vaccination.

If you are taking Cicloral for a non-transplant disease (autoimmune disease), do not take Cicloral if you have:

- Kidney problems (except for nephrotic syndrome).
- Uncontrolled infections.
- History or diagnosed of any type of cancer except skin changes.
- Uncontrolled high blood pressure. If this condition develops during therapy, Cicloral should be stopped.

If you are treated with Cicloral due to psoriasis or atopic dermatitis, you should not concurrently receive UVB-rays or phototherapy.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking any other medicines, including medicines obtained without a prescription, herbal medicines or natural products.

Some medications might cause complications when taken together with Cicloral, for example:

• Medicines/supplements with potassium-sparing diuretics or containing potassium (may affect your potassium levels).

• Reduced clearance of prednisolone, colchicine, digoxin and lovastatin has been observed when used with ciclosporin.

• Medicines which may increase the level of ciclosporin in your blood - antibiotics (e.g. erythromycin, josamycin), antifungals (ketoconazole, fluconazole, itraconazole), medicines used for heart problems or high blood pressure (diltiazem, nicardipine, verapamil, amiodarone), metoclopramide (used to stop sickness), oral contraceptives, nifedipine (used to treat high blood pressure and chest pain), danazol (used to treat menstrual problems), medicines used to treat gout (allopurinol), cholic acid and derivatives (used to treat gallstones), protease inhibitors used to treat HIV.

• Medicines which may decrease the level of ciclosporin in your blood - barbiturates (used to help you to sleep), some anticonvulsant medicines (e.g. carbamazepine, phenytoin), octreotide (used to treat severe watery diarrhoea or flushing of the face and neck caused by certain types of tumours), herbal medicines containing St. John's wort,

ticlopidine (used after stroke).

- Medicines which may affect your kidneys - antibacterial agents (gentamicin, tobramycin, ciprofloxacin), antifungal agents containing amphotericin B, agents against urinary tract infection containing trimethoprim, anti-cancer agents containing melphalan, medicines used to reduce the amount of acid in your stomach (cimetidine, ranitidine), pain killers (non-steroid anti-inflammatory drugs such as diclofenac), fibric acid derivatives (used to lower fat in the blood).

Do not take Cicloral with grapefruit or grapefruit juice since this can influence Cicloral's effects.

How to use Cicloral

Take Cicloral exactly according to the instructions given to you by your doctor. Do not exceed the recommended dosage. If you are unsure, check with your doctor.

- How much to use

Your doctor will work out the correct dose of Cicloral for you. This depends on your body weight and what you are being given the medicine for. Your doctor will also tell you how often to take your medicine.

As the ciclosporin clearance rate is greater in children as compared to adults, a higher dose may be prescribed for your child by your doctor.

Organ transplantation

- Generally, higher doses are used before and just after your transplant (between 10-15 mg/kg body weight per day divided in two doses).
- Lower doses are used once your transplanted organ has stabilised, with a daily maintenance dose of 2–6mg/kg body weight.
- Your doctor will adjust your dose to one that is ideal for you. To do this, your doctor may need to do some blood tests.

Bone marrow transplantation

- Ciclosporin is used over a short term in combination with methotrexate in order to prevent GVHD and is then discontinued.
- The total daily dose is usually between 2.5-12.5 mg/kg body weight.

Acute Graft-versus-Host Disease (GVHD)

- The initial dose is between 12.5-15 mg/kg body weight per day, and can be reduced by

5% at weekly intervals before ciclosporin is discontinued. If GVHD recurs after discontinuation of ciclosporin, therapy with ciclosporin can be reinitiated.

Severe endogenous uveitis

- The total daily dose is usually between 5-10 mg/kg body weight. For maintenance treatment, the daily dose should not exceed 5mg/kg per day.

Severe psoriasis and atopic dermatitis

- The total daily dose is usually between 2.5-5 mg/kg body weight divided in two doses.

Nephrotic syndrome

- The total daily dose is depending on your kidney function and usually for adult is 5 mg/kg body weight and children is 6 mg/kg body weight. In people with kidney problems, the initial dose should not exceed 2.5 mg/kg body weight.

Severe rheumatoid arthritis

- The total daily dose is usually between 2.5-4 mg/kg body weight divided in two doses.

If your doctor switched you from one oral formulation of ciclosporin to another:

- Your doctor will monitor you more closely for a short time.
- You may have side effects. If this happens, tell your doctor or pharmacist. Your dose may need to be changed. NEVER change your dose yourself, unless a doctor has told you to.

- When and how to use it

- Take Cicloral at the same time every day. This is very important if you have had a transplant.
- Your daily doses should always be taken in two divided doses. Remove the capsules from the blister. Swallow the capsules whole with water.

- How long to use it

- Your doctor will tell you how long you need to take Cicloral for, depending on whether you are taking it after a transplant or for the treatment of autoimmune disease.
- Keep taking Cicloral for as long as your doctor tells you.
- If you have any questions on the use of Cicloral, ask your doctor or pharmacist.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next

dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. The symptoms of overdose may include vomiting, sleepiness, headache, rapid heartbeat and, in some people, moderate reversible kidney failure have been observed.

While you are using it

- Things you must do

- Tell all the doctors, dentists and pharmacists treating you that you are taking Cicloral.
- Tell your doctor immediately if you become pregnant while taking this medicine.

Monitoring during your treatment with Cicloral

Your doctor will check:

- The levels of ciclosporin in your blood, especially if you have had a transplant.
- Your blood pressure before initiation of treatment and regularly during treatment.
- Your liver and kidneys function.
- Your blood lipids/fats.

- Things you must not do

- Do not stop taking Cicloral unless your doctor tells you to.
- Keep taking Cicloral even if you feel well. Stopping your treatment with Cicloral may increase the risk of your transplanted organ being rejected.
- Do not take any new medicines without consulting your doctor or pharmacist.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Cicloral can cause side effects, although not everybody gets them.

Some side effects could be serious. Tell your doctor if you notice any of the following symptoms:

- Kidney and/or liver problems
- High blood pressure
- Headache
- Seizure
- Involuntary shaking of the body
- Excessive growth of body and facial hair
- Gastrointestinal disturbances (e.g. loss of appetite, nausea, vomiting, abdominal pain, diarrhoea, stomach ulcer)
- High level of lipids in your blood
- Tiredness
- Acne
- Fever
- Burning sensation in hands and feet (usually during the first week of treatment)
- Gum tissue overgrowing and covering teeth
- Rashes (possibly allergic)
- Weight gain
- Inflammation of the pancreas with severe upper stomach pain
- Muscle weakness

Low level of red blood cells or platelets which may be associated with pale skin, tiredness, breathlessness, dark urine (sign of breakdown of red blood cells), bruising or bleed with no obvious reasons, confusion and decreased alertness.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety)

Storage and Disposal of Cicloral

- Storage

Do not store above 25 °C.

Protect from light.

Keep out of reach of children.

- Disposal

The expiry date of Cicloral is printed on the carton and blister. Do not use if after expiry date.

Medicines should not be disposed of via wastewater or household waste. If your doctor tells you to stop taking Cicloral or the expiry date has passed, ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Cicloral 25mg Capsule: Red brown soft gelatine capsule contains clear solution, 5 minims oval, printed with 25 and HEXAL logo.

Cicloral 50mg Capsule: Red brown soft gelatine capsule contains clear solution, 9.5 minims oblong, printed with 50 and HEXAL logo.

Cicloral 100mg Capsule: Red brown soft gelatine capsule contains clear solution, 20 minims oblong, printed with 100 and HEXAL logo.

- Ingredients

- Active ingredient

Ciclosporin

- Inactive ingredients

Vitamin E TPGS, ethanol absolute, polyethylene glycol 400, macroglycerol hydroxystearate, succinylated gelatin, purified water, sorbitol 70%, glycerol and ferric oxide red (E172).

- Packing

Blister pack of 5 capsules, pack in box of 10 and 20 strips.

- MAL Number

CICLORAL 25MG CAPSULE
(MAL20041273ACZ)

CICLORAL 50MG CAPSULE
(MAL20041274ACZ)

CICLORAL 100MG CAPSULE
(MAL20041275ACZ)

Manufacturer

Salutas Pharma GmbH
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Product Registration Holder

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