Deximune® 25 mg soft capsules
Deximune® 50 mg soft capsules
Deximune® 100 mg soft capsules

(Ciclosporin)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

1. What Deximune is and what it is used for
2. What you need to know before you take Deximune
3. How to take Deximune
4. Possible side effects
5. How to store Deximune
6. Contents of the pack and other information

1. What Deximune is and what it is used for

What Deximune is

The name of your medicine is Deximune. It contains the active substance ciclosporin. This belongs to a group of medicines known as immunosuppressive agents. These medicines are used to lower the body's immune reactions.

What Deximune is used for and how Deximune works
- **If you have had an organ transplant, bone marrow and stem cell transplantation**, the function of Deximune is to control your body's immune system. Deximune prevents rejection of transplanted organs by blocking the development of certain cells which would normally attack the transplanted tissue.
- **If you have an autoimmune disease**, in which your body's immune response attacks your body's own cells, Deximune stops this immune reaction. Such diseases include eye problems which threaten your vision (endogenous uveitis, including Behçet's uveitis), severe cases of certain skin diseases (atopic dermatitis, or eczema and psoriasis), severe rheumatoid arthritis and a kidney disease called nephrotic syndrome.

2. What you need to know before you take Deximune

If you are taking Deximune following a transplant it will only be prescribed for you by a doctor with experience in transplants and/or autoimmune diseases.
The advice in this leaflet may vary depending on whether you are taking the 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.

Do not take Deximune:
- if you are allergic to ciclosporin or any of the other ingredients of this medicine (listed in section 6).
- with products containing *Hypericum perforatum* (St. John's Wort).
- with products containing *dabigatran etexilate* (used to avoid blood clots after surgery) or *bosentan* and *aliskiren* (used to reduce high blood pressure).

Do not take Deximune and **tell your doctor** if the above applies to you. If you are not sure, talk to your doctor before taking Deximune.

Warnings and precautions

Before and during treatment with Deximune, tell your doctor straight away:
- if you have any signs of infection, such as fever or a sore throat. Deximune suppresses the immune system and may also affect your body's ability to fight against infection.
- if you have liver problems.
- if you have 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 a medicine to lower blood pressure if necessary.
- if you have low levels of magnesium in your body. Your doctor may give you magnesium supplements to take, especially just after your operation if you have had a transplant.
- if you have high levels of potassium in your blood.
- if you have gout.
- if you need to have a vaccination.

If any of the above applies to you before or during treatment with Deximune, tell your doctor straight away.

Sunlight and sun protection

Deximune suppresses your immune system. This increases your risk of developing cancers, particularly of the skin and lymphoid system. You should limit your exposure to sunlight and UV light by:
- Wearing appropriate protective clothing.
- Often applying a sunscreen with a high protection factor.

Talk to your doctor before taking Deximune:
- if you have or have had alcohol-related problems.
- if you have epilepsy.
- if you have any liver problems.
- if you are pregnant.
- if you are breast-feeding.
- if this medicine is being prescribed for a child.

If any of the above apply to you (or you are not sure), tell your doctor before taking Deximune. This is because this medicine contains an ingredient which is broken down into alcohol (see section below "Deximune contains ethyl lactate").

Monitoring during your treatment with Deximune

Your doctor will check:
- the levels of ciclosporin in your blood, especially if you have had a transplant,
- your blood pressure before the start of your treatment and regularly during treatment,
- how well your liver and kidneys are working,
- your blood lipids (fats).

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

In addition, if you are taking Deximune for a non-transplant disease (intermediary or posterior uveitis and Behçet's uveitis, atopic dermatitis, severe rheumatoid arthritis or nephrotic syndrome), do not take Deximune:
- if you have kidney problems (except for nephrotic syndrome).
- if you have an infection which is not under control with medication.
- if you have any type of cancer.
- if you have high blood pressure (hypertension) which is not under control with medication. If you get high blood pressure during treatment and it cannot be controlled, Deximune should be stopped by your doctor.

Do not take Deximune if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Deximune.

If you are being treated for Behçet`s uveitis, your doctor will monitor you particularly carefully if you have neurological symptoms (for example: increased forgetfulness, personality changes noticed over time, psychiatric or mood disorders, burning sensation in limbs, decreased sensation in limbs, tingling sensation in limbs, weakness of limbs, walking disturbances, headache with or without nausea and vomiting, vision disturbances including restricted movement of eyeball).
Your doctor will closely monitor you if you are elderly and are being treated for psoriasis or atopic dermatitis. If you have been prescribed Deximune to treat your psoriasis or atopic dermatitis, you must not be exposed to any UVB-rays or phototherapy during treatment.

Children and adolescents

Deximune should not be given to children for a non-transplant disease, except for treatment of nephrotic syndrome.

Elderly population (65 years of age and older)

There is limited experience with Deximune in elderly patients. Your doctor should monitor how well your kidneys work. If you are over 65 and have psoriasis or atopic dermatitis, you should only be treated with Deximune if your condition is particularly severe.

Other medicines and Deximune

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines before or during Deximune treatment:
- Medicines that may affect your potassium levels. These include medicines which contain potassium, potassium supplements, water tablets (diuretics) called potassium-sparing diuretics and some medicines which lower your blood pressure.
- Methotrexate. This is used to treat tumours, severe psoriasis and severe rheumatoid arthritis.
- Medicines which may increase or decrease the level of ciclosporin (the active substance of Deximune) in your blood. Your doctor might check the level of ciclosporin in your blood when starting or stopping treatment with other medicines.
  - Medicines which may increase the level of ciclosporin in your blood include: antibiotics (such as erythromycin or azythromycin), anti-fungals (voriconazole, itraconazole), medicines used for heart problems or high blood pressure (diltiazem, nicardipine, verapamil, amiodarone), metoclopramide (used to stop sickness), oral contraceptives, 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, imatinib (used to treat leukaemia or tumours), colchicine, telaprevir (used to treat hepatitis C), cannabidiol (uses amongst others include treatment of seizures).
  - Medicines which may decrease the level of ciclosporin in your blood include: barbiturates (used to help you to sleep), some anti-convulsant medicines (such as carbamazepine or phenytoine), octreotide (used to treat acromegaly or neuroendocrine tumours in the gut), anti-bacterial medicines used to treat tuberculosis, orlistat (used to help weight loss), herbal medicines containing St. John's wort, ticlopidine (used after a stroke), certain medicines which lower blood pressure (bosentan), and terbinafine (an anti-fungal medicine used to treat infections of the toes and nails).
- Medicines which may affect your kidneys. These include: anti-bacterial medicines (gentamycin, tobramycin, ciprofloxacin), anti-fungal medicines which contain amphotericin B, medicines used for urinary tract infections which contain trimethoprim, medicines for cancer which contain melphalan, medicines used to lower the amount of acid in your stomach (acid secretion inhibitors of the H2-receptor antagonist type), tacrolimus, pain killers (non-steroid anti-inflammatory medicines such as diclofenac), fibric acid medicines (used to lower the amount of fat in the blood).
- Nifedipine. This is used to treat high blood pressure and heart pain. You might get swollen gums that might grow over your teeth if you are taking nifedipine during your treatment with ciclosporin.
- Digoxin (used to treat heart problems), medicines which lower cholesterol (HMG-CoA reductase inhibitors also called statins), prednisolone, etoposide (used to treat cancer), repaglinide (oral anti-diabetic medicine), immunosuppressives (everolimus, sirolimus), ambrisentan and specific anti-cancer medicines called anthracyclines (such as doxorubicin).
- Mycophenolate sodium or mycophenolate mofetil (an immunosuppressant) and eltrombopag (used to treat bleeding disorders).

If any of the above applies to you (or you are not sure), talk to your doctor or pharmacist before taking Deximune.

Deximune with food and drink

Do not take Deximune with grapefruit or grapefruit juice. This is because these can affect how Deximune works. Deximune Capsules can be taken with or without food.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking this medicine.
- **Tell your doctor if you are pregnant or intend to become pregnant.** Experience with Deximune in pregnancy is limited. In general, Deximune 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 breast-feeding.** Breast-feeding is not recommended during treatment with Deximune. This is because ciclosporin, the active substance, passes into breast milk. This may affect your baby.

Hepatitis C

Tell your doctor if you have hepatitis C. Your liver function may change with treatment of hepatitis C and this may affect the levels of ciclosporin in your blood. Your doctor may need to closely monitor ciclosporin blood levels and make adjustments to the dose after you start treatment for hepatitis C.

Driving and using machines

You may feel sleepy, disoriented, or have blurred vision after taking Deximune. Be careful driving or operating machinery while you are taking Deximune until you know how it affects you.

Deximune contains ethyl lactate

Deximune contains ethyl lactate that changes into ethanol (alcohol) and lactic acid in your gastrointestinal tract. Each Deximune 25 mg, 50 mg and 100 mg capsule contains 32 mg, 65 mg and 129 mg alcohol, respectively, which is equivalent to 14.2% v/v.

A 500 mg dose of Deximune contains a quantity of alcohol that is equivalent to approximately 17 ml beer or 7 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Deximune contains lecithin (soya)
Deximune contains lecithin from soya. If you are allergic to peanut or soya, do not use this medicine.

Deximune contains macrogolglycerol hydroxystearate
Deximune contains macrogolglycerol hydroxystearate. It may cause stomach upset and diarrhoea.

3. How to take Deximune

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.
Do not take more than the recommended dose.
The dose of this medicine will be carefully adjusted to your individual needs by your doctor. Too much of the medicine can affect your kidneys. You will have regular blood tests and visits to the hospital, especially after a transplant. This will give you the chance to talk to your doctor about your treatment and talk about any problems you may be having.

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

- **In adults:**

Organ, bone marrow and stem cell transplantation
- The total dose each day is usually between 2 mg and 15 mg per kilogram body weight. This is divided in two doses.
- Usually, higher doses are used before and just after your transplant. Lower doses are used once your transplanted organ or bone marrow has stabilised.
- 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.

Endogenous uveitis
- The total dose each day is usually between 5 mg and 7 mg per kilogram body weight. This is divided in two doses.

Nephrotic syndrome
- The total dose each day for adults is usually 5 mg per kilogram body weight. This is divided in two doses. In patients with kidney problems, the first dose taken each day should not be more than 2.5 mg per kilogram body weight.

Severe rheumatoid arthritis
- The total dose each day is usually between 3 mg per kilogram of your body weight and 5 mg per kilogram body weight. This is divided in two doses.

Psoriasis and atopic dermatitis
- The total dose each day is usually between 2.5 mg per kilogram of your body weight and 5 mg per kilogram body weight. This is divided in two doses.

- **In children:**

Nephrotic syndrome
- The total dose each day for children is usually 6 mg per kilogram body weight. This is divided in two doses. In patients with kidney problems, the first dose taken each day should not be more than 2.5 mg per kilogram body weight.

Follow your doctor's instructions exactly and never change the dose yourself, even if you feel well.

If your doctor switches you from one oral formulation of ciclosporin to another
After you change from one oral formulation of ciclosporin to another:
- Your doctor will monitor you more closely for a short time.
- You may have some 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 to take Deximune
Take Deximune **at the same time every day**. This is very important if you have had a transplant.

How to take Deximune
Your daily doses should always be taken in 2 divided doses.
Remove the capsules from the blister. Swallow the capsules whole with water.

How long to take Deximune
Your doctor will tell you how long you need to take Deximune for. This depends on whether you are taking it after a transplant or for the treatment of a severe skin condition, rheumatoid arthritis, uveitis or nephrotic syndrome. For severe rash, the treatment usually lasts for 8 weeks.
Keep taking Deximune for as long as your doctor tells you.
If you have questions about how long to take Deximune, talk to your doctor or your pharmacist.

If you take more Deximune than you should
If you accidentally take too much of your medicine, tell your doctor immediately or go to your nearest hospital emergency unit. You may need medical attention.

If you forget to take Deximune
- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose. Then go on as before.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Deximune
Do not stop taking Deximune unless your doctor tells you to.
Keep taking Deximune even if you feel well. Stopping your treatment with Deximune may increase the risk of your transplanted organ being rejected.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Some side effects could be serious
Tell your doctor straight away if you notice any of the following serious side effects:
- Like other medicines that act on the immune system, ciclosporin may influence your body's ability to fight against infection and may cause tumours or other cancers, particularly of the skin. Signs of infection might be fever or sore throat.
- Changes in your sight, loss of coordination, being clumsy, memory loss, difficulty speaking or understanding what others say, and muscle weakness. These might be signs of an infection of the brain called progressive multifocal leukoencephalopathy.
- Brain problems with signs such as seizures, confusion, feeling disorientated, being less responsive, personality changes, feeling agitated, sleeplessness, changes to your sight, blindness, coma, paralysis of part or all of the body, stiff neck, loss of coordination with or without unusual speech or eye movements.
- Swelling at the back of the eye. This may be associated with blurred vision. It may also affect your sight because of the higher pressure inside your head (benign intracranial hypertension).
- Liver problems and damage with or without yellow skin and eyes, nausea, loss of appetite and dark urine.
- Kidney problems which may greatly reduce the amount of urine you produce.
- Low level of red blood cells or platelets. The signs include pale skin, feeling tired, being breathless, having dark urine (this is a sign of the breakdown of red blood cells), bruising or bleeding with no obvious reasons, feeling confused, feeling disorientated, being less alert and having kidney problems.

Other side effects include:
Very common: may affect more than 1 in 10 people.
- Kidney problems.
- High blood pressure.
- Headache.
- Shaking of your body which you cannot control.
- Excessive growth of body and facial hair.
- High level of lipids in your blood.

If any of these affects you severely, **tell your doctor.**

Common: may affect up to 1 in 10 people.
- Fits (seizures).
- Liver problems.
- High level of sugar in your blood.
- Tiredness.
- Loss of appetite.
- Nausea (feeling sick), vomiting, abdominal discomfort/ pain, diarrhoea.
- Excessive hair growth.
- Acne, hot flushes.
- Fever.
- Low level of white blood cells.
- Feeling numb or tingling.
- Pain in your muscles, muscle spasm.
- Stomach ulcer.
- Gum tissue overgrowing and covering your teeth.
- High level of uric acid or potassium in your blood, low levels of magnesium in your blood.

If any of these affects you severely, **tell your doctor.**

Uncommon: may affect up to 1 in 100 people.
- Symptoms of brain disorders including sudden fits, mental confusion, sleeplessness, disorientation, disturbance of vision, unconsciousness, sense of weakness in the limbs, impaired movements.
- Rash.
- General swelling.
- Weight gain.
- Low level of red blood cells, low level of platelets in your blood which could increase the risk of bleeding.

If any of these affects you severely, **tell your doctor.**

Rare: may affect up to 1 in 1,000 people.
- Nerve problems with numbness or tingling in fingers and toes.
- Inflammation of the pancreas with severe upper stomach pain.
- Muscle weakness, loss of muscle strength, pain in muscles of the legs or hands or anywhere in the body.
- Destruction of red blood cells, involving kidney problems with symptoms such as swelling of the face, stomach, hands and/or feet, decreased urination, breathing difficulty, chest pain, fits, unconsciousness.
- Changes in menstrual cycle, breast enlargement in men.

If any of these affects you severely, **tell your doctor.**

Very rare: may affect up to 1 in 10,000 people.
- Swelling at the back of the eye which may be associated with an increase in pressure inside the head and eyesight disturbances.

If this affects you severely, **tell your doctor.**

Not known: Frequency cannot be estimated from the available data.
- Serious liver problems both with and without yellowing of the eyes or skin, nausea (feeling sick), loss of appetite, dark coloured urine, swelling of the face, feet, hands and/or the whole body.
- Bleeding underneath the skin or purple skin patched, sudden bleeding with no apparent cause.
- Migraine or severe headache often with feeling and being sick (nausea, vomiting) and being sensitive to light.
- Pain in legs and feet.
- Hearing impairment.

If any of these affects you severely, **tell your doctor.**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Additional side effects in children and adolescents
There are no additional side effects to be expected in children and adolescents compared to adults.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website:
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Deximune

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the package.
- Do not store above 25°C. Do not refrigerate and/ or freeze.
- Leave your capsules in the foil. Only remove them when it is time to take your medicine.
- When a blister is opened, a characteristic smell is noticeable. This is normal and does not mean that there is anything wrong with the capsules.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Deximune contains
Deximune soft capsules are available in 3 strengths containing 25 mg, 50 mg or 100 mg of the active substance, ciclosporin.
All capsule strengths contain the following other ingredients: polysorbate 20, sorbitan oleate, lecithin from soya, triglyceride, macrogolglycerol hydroxystearate, ethyl lactate.
Ingredients of the capsule shell: gelatin, glycerol, ferric oxide black (E172), titanium dioxide (E171).

What Deximune looks like and contents of the pack
Deximune 25 mg soft capsules are grey, opaque, oval, soft gelatin capsules (approximate dimensions: 8 mm width, 12 mm length). Deximune 50 mg soft capsules are grey, opaque, oblong, soft gelatin capsules (approximate dimensions: 8 mm width, 19 mm length). Deximune 100 mg soft capsules are grey, opaque, oblong, soft gelatin capsules (approximate dimensions: 10 mm width, 24 mm length). There are 30, 50 or 60 capsules in a pack. Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer
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This leaflet was last revised in November 2025.
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