

DEXIMUNE[®] 25 mg CAPSULES DEXIMUNE[®] 50 mg CAPSULES DEXIMUNE[®] 100 mg CAPSULES

(Ciclosporin)

Read all of this leaflet carefully before you start taking DEXIMUNE capsules. It is an important source of information about your medicine and how to take it safely.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What DEXIMUNE is and what it is used for
2. Before you take DEXIMUNE
3. How to take DEXIMUNE
4. Possible side effects
5. How to store DEXIMUNE
6. Further information

1. WHAT DEXIMUNE IS AND WHAT IT IS USED FOR

What is DEXIMUNE?

The name of your medicine is DEXIMUNE and it contains the active substance ciclosporin. It is one of a group of drugs known as immunosuppressive agents. These drugs are used to dampen down the body's immune reactions.

What is DEXIMUNE used for?

If you have received an organ or bone marrow transplant

Although you may have undergone a series of tests before your organ or bone marrow transplant to ensure that the match between your body and the transplanted organ or bone marrow was as close as possible, the donor tissue will still not be identical to your tissue. As a result, your body's immune system will try to reject the donor tissue. DEXIMUNE helps to stop this rejection response by blocking the development of special cells which would normally attack the transplanted tissue.

If you have a severe skin complaint

Some skin conditions, such as severe psoriasis or eczema (atopic dermatitis) are thought to be caused by your immune system over-reacting. If other drugs have not worked or are not suitable, DEXIMUNE may help to stop this by suppressing the immune system, thereby improving your skin condition.

If you have severe rheumatoid arthritis or nephrotic syndrome

It is thought that rheumatoid arthritis and some forms of nephrotic syndrome (a kidney condition) may be caused by inappropriate immune responses in your body. If other drugs have not worked or are not suitable, DEXIMUNE may help to counter these by suppressing your immune system, thereby improving your rheumatoid arthritis or nephrotic syndrome.

2. BEFORE YOU TAKE DEXIMUNE

Do not take DEXIMUNE:

- if you are allergic (hypersensitive) to ciclosporin or any of the other ingredients of DEXIMUNE (see section 6).
- people with psoriasis or eczema (atopic dermatitis) must not take DEXIMUNE if they have kidney problems, uncontrolled high blood pressure, uncontrolled infections, or any type of cancer except for skin cancer.
- people with rheumatoid arthritis must not take DEXIMUNE if they have kidney problems, uncontrolled high blood pressure, uncontrolled infections, have any type of cancer or if they are under 18 years of age.
- people with nephrotic syndrome (a kidney condition) must not take DEXIMUNE if they have uncontrolled high blood pressure, uncontrolled infections, or have any type of cancer.
- if you are taking a drug called tacrolimus
- if you are taking a drug called rosuvastatin
- if you are breast feeding
- if you are taking herbal medicines containing St John's Wort

Take special care with DEXIMUNE:

- if you have any liver problems or you have had any disease which may have affected your liver.
- if you have high levels of potassium in your blood, are taking potassium supplements, are taking drugs that increase the level of potassium in your blood, or your diet is particularly rich in potassium.
- if you have gout or any skin conditions (such as cold sores), other than severe psoriasis or severe eczema.
- if you recently received vaccinations or you plan to have any vaccinations.
- if you are likely to be exposed to the sun a great deal without protecting your skin with a sun block cream, or if you regularly use a sun bed, or are receiving light treatment (PUVA or other UV treatment) for a skin condition you are at increased risk of developing skin cancer.
- if you are under 16 years of age and DEXIMUNE has been prescribed for the treatment of atopic dermatitis.
- if you are or suspect you might be pregnant.
- DEXIMUNE can cause kidney problems. Your doctor will carry out regular blood tests and may adjust your dose if necessary, particularly if you are elderly or have kidney problems.
- DEXIMUNE may increase your blood pressure. Your doctor will check your blood pressure regularly and may give you drugs to decrease it if necessary.
- if you take DEXIMUNE for a long period of time or with other drugs that dampen your immune system, you are at increased risk of developing skin, blood and solid organ cancers.
- if you take DEXIMUNE for a long period of time or with other drugs that dampen your immune system, you are at increased risk of infections that may become very serious or cause death.
- DEXIMUNE may increase the level of fatty substances (including cholesterol) in your blood.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Some medicines can interfere with your treatment, so make sure you check with your doctor or pharmacist before taking any other medicines. In particular, tell your doctor if you are taking any of the following:

- antibiotics (especially erythromycin, azithromycin, clarithromycin, gentamycin, tobramycin, amphotericin B, ciprofloxacin, vancomycin, trimethoprim) or antifungal medicines (especially terbinafine, voriconazole, itraconazole, fluconazole, ketoconazole) for treatment of infection
- oral contraceptives
- any medicines for heart problems or high blood pressure such as bosentan, diltiazem, nicardipine, lercanidipine, digoxin and verapamil.
- anti-epileptic medicines (e.g. carbamazepine, oxcarbazepine, phenytoin)
- cholesterol lowering medicines (including statins)
- repaglinide (oral antidiabetic)
- other immunosuppressives (e.g. prednisolone, sirolimus and everolimus)
- barbiturates (used to help you sleep)
- drugs containing potassium or potassium supplements
- drugs that increase the potassium levels in your blood, e.g. angiotensin converting enzyme inhibitors and angiotensin II receptor antagonists (used to treat high blood pressure) and diuretics or 'water tablets' (used to affect the amount of urine you produce)
- anti-inflammatory medicines (i.e. NSAIDs) e.g. diclofenac including medicines used to treat rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, gout, period pains and muscle disorders
- light treatment (PUVA or other UV treatment) for your skin condition
- colchicine
- danazol (used to treat menstrual disorders, endometriosis or breast problems)
- tacrolimus. Because tacrolimus dampens down your immune system in a similar way to ciclosporin, if you take tacrolimus and ciclosporin together, your immune system may be dampened down too much. If this happens you may be more likely to get infections.
- octreotide (known as Sandostatin[®])
- medicines to treat tuberculosis
- medicines to treat gout (e.g. allopurinol)
- metoclopramide (used to stop sickness)
- melphalan (used to treat lymphomas or tumours)
- orlistat (used to help weight loss)
- corticosteroids (used to treat conditions such as asthma, allergic conditions, inflammatory conditions including inflammatory bowel disease, adrenocortical insufficiency and rheumatic disease)
- ticlopidine (used after a stroke)
- ursodeoxycholic acid (used to treat gallstones)
- methotrexate (used to treat tumours, severe psoriasis and rheumatoid arthritis)
- etoposide (used to treat cancer)
- imatinib (used to treat leukaemia or tumours)
- digoxin (used to treat heart problems)
- protease inhibitors (used to treat human immunodeficiency virus (HIV))
- vaccinations - if you have recently had a vaccination or are planning to have any vaccinations
- medicines used to reduce the amount of acid in your stomach (e.g. cimetidine, ranitidine)
- if you take ciclosporin together with nifedipine (used to treat high blood pressure and heart pain) you might get swollen gums that spread over your teeth.

If you take certain medicines while taking DEXIMUNE your doctor will regularly check for kidney problems and for any potential side effects, and will adjust your dose if necessary. If you have received an organ transplant your doctor will also check the levels of DEXIMUNE in your blood and adjust your dose if necessary.

Taking DEXIMUNE with food and drink

Do not eat grapefruit or drink grapefruit juice for 1 hour before taking your dose as it may interfere with your medicine.
Deximune Capsules can be taken with or without food.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.
If you are pregnant or planning to become pregnant, tell your doctor before you start taking DEXIMUNE. If you do become pregnant whilst taking DEXIMUNE, tell your doctor. DEXIMUNE increases the risk of pre-eclampsia (high blood pressure and swelling in the feet and legs), premature births and decreased birth weights. If you are taking Deximune, you should not breast-feed.

Important information about some of the ingredients of DEXIMUNE

This medicine contains polyoxyl 40 hydrogenated castor oil (macrogolglycerol hydroxystearate). It may cause stomach upset and diarrhoea.

3. HOW TO TAKE DEXIMUNE

Your doctor will work out the correct dose of DEXIMUNE for you depending on your body weight and whether you are taking DEXIMUNE following a transplant or as a treatment for severe psoriasis, eczema, rheumatoid arthritis or nephrotic syndrome.

Your doctor will also tell you how often to take your medicine. It is best to take your capsules at the same time each day.

If you have had an organ or bone marrow transplant the total dose is usually within the range of 2-15 mg/kg body weight per day. Generally, higher doses are used just after transplantation and lower doses are used once your transplanted organ or bone marrow is working properly with no signs of rejection. Your doctor will adjust your dose to one that is ideal for you. To do this he may need to do some blood tests.

For the treatment of severe psoriasis and eczema the total dose is usually within the range of 2.5-5 mg/kg body weight per day.

For the treatment of severe rheumatoid arthritis the total daily dose is usually within the range of 2.5-4 mg/kg body weight per day.

For the treatment of nephrotic syndrome the total daily dose is usually within the range of 2.5-5 mg/kg body weight per day in adults and 2.5-6 mg/kg body weight per day in children.

Your doctor will tell you how much DEXIMUNE to take and how long you will need to take it for, depending on whether you are taking it following transplantation or for the treatment of a severe skin condition, rheumatoid arthritis or nephrotic syndrome.

Follow your doctor's instructions exactly and never change the dose yourself, however well you feel. Do not stop taking your medicine unless your doctor tells you to, however well you feel. Ask your doctor or pharmacist if you are unsure about how much medicine to take or when to take it.

Place the capsule in your mouth. Take a mouthful of water, then swallow the capsule whole. You may drink more water afterwards.

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 casualty department.

If you forget to take DEXIMUNE

If you forget to take a dose, take another one as soon as you remember, unless it is almost time for your next dose. Then continue as before. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, DEXIMUNE can have side effects, although not everybody experiences them. Most people benefit from taking this medicine, but a few people can be upset by it. **The dose of this medicine needs to be carefully adjusted by your doctor. You will, therefore, have regular blood tests and visits to the hospital, particularly after transplantation.** This will give you the chance to talk to your doctor about your treatment and mention any problems you are having.

If you develop a sore throat, any infections or begin to feel generally unwell, see your doctor immediately.

Very common side-effects, reported in more than 1 in 10 people include:

Kidney problems, high blood pressure, headache, tremor and increased levels of fats (for example cholesterol) in the blood, chest infection, urinary infections and infection with CMV (cytomegalovirus).

Common side-effects, reported in between 1 in 10 and 1 in 100 people include:

Numbness or tingling, loss of appetite, feeling or being sick, stomach pain, diarrhoea, swollen gums, liver problems, high level of uric acid or potassium in the blood, low levels of magnesium in the blood, muscle pain or cramp, increased hair growth on the body, tiredness, herpes infection, candida infection, blood poisoning, skin disorders, skin cancer and blood disorders resulting from the over production of white blood cells including cancer of the white blood cells.

Uncommon side-effects, reported in between 1 in 100 and 1 in 1000 people include:

Seizures, confusion, disorientation, decreased responsiveness, agitation, sleeplessness, visual disturbances, blindness, coma, partial paralysis, loss of co-ordination, changes in blood (for example anaemia), allergic rash, water retention which may cause swelling, weight increase, a reduction in blood platelets which increases the risk of bleeding and bruising, benign skin growths, skin cancer and solid organ cancers.

Rare side-effects, reported in between 1 in 1000 and 1 in 10000 people include:

Problems with the nerves that control muscles, inflammation of the pancreas, high levels of glucose in the blood, muscle weakness, wasting of muscles, destruction of red blood cells which may be associated with kidney problems, changes in the menstrual cycle in women and slight swelling of breast tissue in men and women.

Very rare side-effects, reported in less than 1 in 10000 people include:

Swelling at the back of the eye which may be associated with an increase in pressure inside the head (benign intracranial hypertension) and visual disturbances.

Other side-effects (it is unknown how many people may be affected):

In patients who have received a kidney transplant there have been reports of harmless breast lumps.

Tell your doctor or pharmacist if you suffer from any of these side effects, or if you notice any side effects not listed in this leaflet.

5. HOW TO STORE DEXIMUNE

Leave your capsules in the foil. Only remove them when it is time to take your medicine.

When a packaged blister is opened, a characteristic smell is noticeable. This is normal and does not mean that there is anything wrong with the capsule.

Do not store above 25°C.

Do not refrigerate or freeze.

Do not use after the expiry date stated on the carton/blister foil. The expiry date refers to the last day of that month.

If your doctor decides to stop your treatment, return any leftover medicine to the pharmacist. Only keep it if your doctor tells you to.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Keep out of the reach and sight of children.

6. FURTHER INFORMATION

What DEXIMUNE contains

DEXIMUNE Capsules contain the active substance ciclosporin.

The Capsules are available in 3 strengths. They contain either 25 mg ciclosporin, 50 mg ciclosporin or 100 mg ciclosporin.

All capsule strengths contain the following other ingredients: polysorbate 20, sorbitan oleate, lecithin, triglyceride, polyoxyl 40 hydrogenated castor oil (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 Capsules are grey soft gelatin capsules with a "DX 25 mg" imprint.

DEXIMUNE 50 mg Capsules are grey soft gelatin capsules with a "DX 50 mg" imprint.

DEXIMUNE 100 mg Capsules are grey soft gelatin capsules with a "DX 100 mg" imprint.

There are 30, 50 or 60 capsules in a pack. Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

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This leaflet was revised in September 2010.

DEXIMUNE is a registered Trade Mark.

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