

Please read this leaflet carefully before you start to take your capsules.

It contains important information.

If you are not sure about anything, or you want to know more, ask your doctor or a pharmacist.

Keep this leaflet safe, as you may want to read it again.

About your capsules

The brand name for your capsules is Equoral™ Capsules. The common name for your capsules is Ciclosporin Capsules. They are part of a group of drugs known as immunosuppressants.

What is in your capsules

Each capsule contains either:

- Ciclosporin 25 milligrams (mg), 50 mg or 100 mg (active ingredient), and
- Ethanol, polyglycerol (3) oleate, polyglycerol (10) oleate, macroglycerol hydroxystearate and D,L - (alpha) Tocopherol (inactive ingredients).

The constituents of the capsule shell are gelatin, glycine, glycerol 85%, sorbitol solution and titanium dioxide (E171). The 25 mg capsule shell contains yellow iron oxide (E172), the 50 mg capsule shell contains yellow iron oxide (E172), the 100 mg capsule shell contains brown iron oxide (E172).

Equoral 25 mg soft capsules are yellow oval 5 capsules containing a yellowish to yellow-brown oily liquid. The capsules are printed with '25 mg' and a twin triangle logo in blue ink.

Equoral 50 mg soft capsules are ochre oblong 11 capsules containing a yellowish to yellow-brown oily liquid. The capsules are printed with '50 mg' and a twin triangle logo in blue ink.

Equoral 100 mg soft capsules are brown oblong 20 capsules containing a yellowish to yellow-brown oily liquid. The capsules are printed with '100 mg' and a twin triangle logo in blue ink.

The constituents of the blue ink are shellac, propyl glycol and indigo carmine.

Equoral™ Capsules come in packs of 30 capsules and 50 capsules.

Who makes your capsules

The marketing authorisation holder and manufacturer of your capsules is IVAX Pharmaceuticals UK, Royal Docks, London E16 2QJ, UK.

What your capsules do

Equoral™ Capsules can be used to treat more than one illness:

If you have received an organ or bone marrow transplant

Before your organ or bone marrow transplant, you may have been tested to make sure the match between your body and the transplanted organ or bone marrow was as good as possible. However, the donor tissue will not be an exact match to your tissue. Because of this, your body will want to reject the donor tissue by using special cells that form part of its immune response to stop the donor tissue being accepted. By stopping the development of these special cells, Equoral™ helps to reduce this rejection response.

If you have a severe skin complaint

In some cases your immune system may have become over-active. This can lead to skin conditions, such as severe psoriasis or eczema (atopic dermatitis). Suppressing the immune system by Equoral™ may help to reduce or prevent this, leading to an improvement of your skin condition.

If you have severe rheumatoid arthritis or nephrotic syndrome

Unwanted immune responses in your body may cause rheumatoid arthritis and some forms of nephrotic syndrome. Suppressing the immune system by Equoral™ may help to reduce or prevent this, leading to an improvement of your condition.

Before you take Equoral™ Capsules

Please tell your doctor before you start to take Equoral™ capsules if you:

- are pregnant, may become pregnant or are breast-feeding;
- have ever had a bad reaction to any of the ingredients listed in the 'What is in your medicine' section;
- have ever had any problems with your kidneys or liver;
- have high blood pressure;
- have an infection of any type;
- have been told that you have any type of tumour;
- have been told that you have high levels of potassium in your blood or that you have gout;
- have any skin conditions other than severe psoriasis or severe eczema;
- are taking other medicines including ones that you have bought for yourself.

If you see another doctor or visit a hospital, remember to tell them what medicines you are already taking.

Warning: this product contains up to 15 % by volume of ethanol. This may be harmful for those suffering from liver disease, alcoholism, epilepsy, brain injury or disease as well as for pregnant women and children. It may modify or increase the effect of other medicines.

How to take your capsules

The correct dose and how often to take Equoral™ Capsules will depend on whether you are taking ciclosporin following a transplant or as a treatment for severe psoriasis, eczema, rheumatoid arthritis or nephrotic syndrome. Your doctor will also use your body weight to work out the correct dose. Your doctor will tell you how much and how often to take your medicine, depending on which condition is being treated. You must take Equoral™ Capsules as your doctor has told you. This information should be on the label. The number of capsules you take is called the 'dose'. The most common adult dose for Equoral™ Capsules is as follows:

For organ or bone marrow transplant: the total dose is usually within the range of 2 to 15 mg/kg body weight per day. Generally, the higher doses are used just after transplantation and the lower doses are used once your transplanted organ or bone marrow has stabilised. Your dose will be adjusted by your doctor to one that is right for you. To do this, some blood tests may need to be conducted.

For the treatment of severe psoriasis and eczema: the total dose is usually within the range of 2.5 to 5.0 mg/kg body weight per day. Treatment of severe eczema usually lasts for 8 weeks.

For the treatment of severe rheumatoid arthritis: the total dose is usually within the range of 2.5 to 4.0 mg/kg body weight per day.

For the treatment of nephrotic syndrome: the total dose is usually within the range of 2.5 to 5.0 mg/kg body weight per day in adults and 2.5 to 6 mg/kg body weight per day in children.

Take your capsules with water. Your capsules should be swallowed whole.

Do not eat grapefruit or drink grapefruit juice for at least 1 hour before taking your medicine,

as it may reduce the effect of ciclosporin.

If you forget to take a dose at the right time, take it as soon as you remember, if it is almost time to take the next dose, wait until then and then carry on as before with the correct dose. Do not take two doses together.

For this medicine it is important to follow your doctor's instructions exactly. Never stop taking or change the dose yourself, however well you feel.

What to do if you take too many capsules

It is important not to take too many capsules. Contact your nearest hospital casualty department or a doctor for advice if you have swallowed too many capsules or if you think a child has swallowed any.

Take this leaflet, and any capsules that you still have to show the doctor.

After taking your capsules

You may have some side effects while you are taking Equoral™ Capsules.

Since the absorption of ciclosporin can vary between individuals, your dosage is controlled according to the level of ciclosporin in your blood. You will have regular blood tests to check ciclosporin levels and find the correct level for you. Too much ciclosporin can affect your kidneys. The side effects detailed below may disappear once the initial higher doses are reduced.

Tell your doctor if you suffer from any of the following for more than a few days.

- Shakiness of the hands
- Upset stomach or abdominal pain
- Swollen gums

- Increased growth of hair on the body or face
- High blood pressure
- Liver problems
- Tiredness
- Sensations of heat in the hands and feet

More rarely the following have also been reported:

Headaches, skin rash, increased weight, fluid retention, confusion, feelings of numbness or tingling, muscle weakness or cramps, fits, gout, raised cholesterol levels, slight swelling of the breast tissue, changes of the menstrual period in women, tumours and loss of vision

In liver transplant patients, vision and movement disturbances and loss of concentration have also been reported as side effects. However although these effects have been reported when using ciclosporin, they may not actually have been due to the medicine.

If you feel unwell in any other way, tell your doctor as soon as you can.

Looking after your capsules

Keep your capsules in a safe place where children cannot see or reach them.

Do not store above 25 °C.

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

Do not take the capsules after the 'use by' date shown on the carton/blister foil.

You should take any capsules that are out of date or which you no longer need back to your pharmacist.

These capsules are only for you. Only a doctor can prescribe them for you. Never give them to anyone else, this may be harmful to them even if their symptoms appear to be the same as yours.

This information applies only to IVAX Pharmaceuticals UK Equoral™ Capsules.

This leaflet was written in May 2003

Equoral™ 25 mg Capsules (PA 282/78/2)

Equoral™ 50 mg Capsules (PA 282/78/3)

Equoral™ 100 mg Capsules (PA 282/78/4)