

ORTHOCLONE OKT3* Injection

Muromonab CD3

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ORTHOCLONE OKT3. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using ORTHOCLONE OKT3 against the benefits this medicine is expected to have for you.

If you have any concerns about using ORTHOCLONE OKT3 ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What ORTHOCLONE OKT3 is used for

You have received a transplanted kidney from another person because your own was no longer healthy. Your body has recognised this new organ as different to your own organs. Special cells in your blood called T. lymphocytes are rejecting your kidney. It is essential that this rejection be stopped.

ORTHOCLONE OKT3 is a mouse monoclonal antibody. It is an immunosuppressant, and has been designed to stop this rejection process.

Your doctor may have prescribed ORTHOCLONE OKT3 for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before ORTHOCLONE OKT3 is administered

When it must not be used

ORTHOCLONE OKT3 should not be administered if:

- Your lungs are filled with fluid or if you have gained 3% or more weight in the past week.
- You have had fits or have any medical condition that would increase your risk of fits.
- You are pregnant, suspected to be pregnant, or are breast feeding.
- You have high blood pressure that cannot be controlled

Before it is used

You must tell your doctor if:

- You have had allergies to ORTHOCLONE OKT3 or any other product made from mouse proteins.

Taking other medicines:

- Tell your doctor or pharmacist if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.
- You are probably already taking some other immunosuppressants to prevent kidney rejection. Please follow your doctor's instructions about these while you are given ORTHOCLONE OKT3. It is likely that they will be temporarily stopped or their dose reduced.

Effects on driving and operating machinery

ORTHOCLONE OKT3 may cause visual or nervous disturbances. If affected, do not drive or operate machinery.

Using ORTHOCLONE OKT3

How much is to be used

- You can only get ORTHOCLONE OKT3 from your doctor. A single daily dose is given. Your doctor will decide your dose and the number of days of treatment.
- ORTHOCLONE OKT3 will be prepared by drawing the solution into a syringe through a filter. A needle will then be placed on the syringe and the contents will be injected into your vein. One to four hours before the ORTHOCLONE OKT3 is administered your physician may administer a dose of methylprednisolone sodium succinate 8.0 mg per kilogram through the vein. Your doctor may also administer paracetamol or antihistamine

to reduce some early side effects. Your doctor will monitor you closely for the first few injections.

While ORTHOCLONE OKT3 is being administered

Things you must do

- Always follow your doctor's instructions carefully.
- Tell your doctor if you become pregnant while receiving ORTHOCLONE OKT3.

If you need urgent advice

- If you receive ORTHOCLONE OKT3 as an outpatient and you are away from the hospital and suddenly feel ill, immediately telephone your doctor or the Poisons Information Centre for advice, or go to Accident and Emergency at your nearest hospital.

Poisons Information Centre telephone numbers:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766

Keep these telephone numbers handy.

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects.

ORTHOCLONE OKT3 is a powerful immunosuppressant and can produce some serious side effects.

Do not be alarmed by this list of side effects. Your doctor has decided that the benefits of using ORTHOCLONE OKT3 outweigh the risks and side effects.

Tell your doctor if you experience any of the side effects mentioned here:

- Fever
- Chills
- Headache
- Nausea or vomiting
- diarrhoea

There are some more serious and occasionally life threatening systemic (total body), cardiovascular and central nervous system reactions that have been reported following administration of ORTHOCLONE OKT3.

These have included: fluid in the lungs, especially in patients retaining water, low blood pressure, heart failure, cessation of heartbeat or breathing, brain swelling, seizures and coma.

It is possible that administration of this drug at any time could result in a severe allergic reaction manifested by joint pains, shortness of breath and/or low blood pressure. If this should occur, treatment consisting of stopping the drug and administering readily available agents should control the reaction.

Blood clots of the arteries or veins of the transplanted organ and other organs (e.g. heart, lungs, brain, bowel, etc.) have been reported in patients treated with ORTHOCLONE OKT3.

Use of this drug can re-activate old viruses that are currently dormant in a patient's system, or activate new viruses that may be present in the new transplanted organ.

As a result of a depressed immune system from multiple medications used to prevent rejection, organ transplant patients have an increased risk of developing cancers. This risk may be increased when additional immunosuppressants such as ORTHOCLONE OKT3 are used. The long-term risk of cancers in patients being treated with ORTHOCLONE OKT3 has not been determined.

Storage

ORTHOCLONE OKT3 should be stored in a refrigerator from 2 to 8 degrees C. It should not be frozen or shaken.

Keep your medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

Do not store ORTHOCLONE OKT3, or any other medicine, in the bathroom or near a sink. Do not leave medicines in the car or on window-sills. Heat and dampness can destroy some medicines.

Product Description

What it looks like

ORTHOCLONE OKT3 (AUST R 13317) is a clear colourless sterile solution containing 5 mg muromonab CD3 in a 5 ml ampoule (Pack size - 5 ampoules).

Ingredients

Monobasic sodium phosphate, dibasic sodium phosphate, sodium chloride and polysorbate 80.

Sponsor

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