

Proleukin[®] - aldesleukin or high dose Interleukin-2 (IL-2) for Kidney Cancer

Proleukin is a medication used to treat advanced kidney cancer in adults.

Dosage: 600,000 International Units/kg dose given every 8 hours based on tolerance.

Route of administration: Intravenous infusion

Schedule: see "How will I receive IL-2?"

Tests needed before treatment to be sure it is safe to give you IL-2:

- Pulmonary functions tests
- Cardiac stress tests
- Brain MRI
- Blood tests
- CT scans

How will I receive IL-2?

Proleukin will be administered in a hospital setting under the supervision of a qualified physician and registered nurses experienced in the use of this anticancer agent. Some of the potential side effects are serious; the hospital must have an intensive care unit available during IL-2 treatment.

You will be hospitalized for 6-7 days to receive high-dose IL-2:

- A special intravenous line (central venous catheter) will be placed to administer the IL-2.
- IL-2 is administered every 8 hours as a 15-minute infusion for a maximum of 14 doses. It is rare to get all 14 doses due to side effects.
- Following one week of rest at home, you will be re-admitted to the hospital and treated with IL-2 again.
- The number of doses you receive depends on the severity of side effects.
- CT scans will be done 4-7 weeks following completion of your IL-2 treatment to determine if it was beneficial.

What is the most important information I should know about IL-2?

IL-2 causes many side effects. Although some are serious, they are generally predictable and reversible. Most of the side effects resolve shortly after treatment is completed. The nursing and medical staff will ask you how you are feeling and examine you every day during your treatment in the hospital. They will offer medications to help decrease the severity of the side effects.

One of the most common side effects during high dose IL-2 therapy is a condition known as capillary leak syndrome (CLS). It can result in swelling caused by fluids leaking out of blood vessels into surrounding tissues (edema).

Most patients experience swelling of the hands, feet and face. You may gain up to 20-30 pounds during your therapy. Once your therapy has ended you may be given a diuretic such as furosemide (Lasix) that helps rid your body of extra fluid by making the kidneys produce more urine. Most of the extra weight will be gone 5 days after treatment stops.

CLS may cause a drop in blood pressure (hypotension) and decreased blood flow to body organs. When your blood pressure is low you may feel dizzy or light headed. If you feel this way, stay in bed and use the call light to notify the nurse. You may receive extra fluids or medicines through your IV to raise your blood pressure. Some patients develop an elevated heart rate or abnormal heart rhythm. You will be closely monitored while having your IL-2 treatment.

IL-2 therapy can affect your lungs and your ability to breathe. You may begin to collect fluid in your lungs and feel short of breath. You may be given oxygen to help you breathe more easily.

Because IL-2 causes fluid to collect in the body tissues you may not urinate as much as you normally would and your urine may look darker and more concentrated. Kidney function often worsens during IL-2; this is monitored closely by checking a blood test, creatinine, which measures kidney function. It is safe to get IL-2 with one kidney; the health care team will monitor the creatinine and amount of urine you produce to make sure it is adequate. Kidney function improves once IL-2 is done.

IL-2 affects how your stomach and intestines work. You may develop nausea, vomiting or diarrhea. There are a variety of medications to lessen these side effects. If one medication does not help, let the nurse know, because others may be available to you. You may get mouth sores or a sore throat which can be eased by mouth rinses.

During therapy with IL-2 you may have changes in the way you think and feel. You may become moody, confused, agitated, or lethargic. Some people will have changes in their sleep patterns or experience vivid dreams. These side effects do not happen to everyone and vary widely from person to person. Your health care team is experienced at helping you cope with these distressing side effects. Your friends and family can also give you a lot of support at this time. If these side effects become too intense, the IL-2 therapy may be stopped. These side effects will resolve after treatment is complete, but may take several days.

Some patients experience shaking chills a few hours after the IL-2 is given. If you begin to feel cold, let your nurse know and they will offer you warm blankets or medication to take the chills away. Fevers and aches are also possible. You will be given medications to help with these flu-like side effects.

Nearly everyone receiving IL-2 will develop some dry skin or rash. This can range from dry, red skin with itching to flaking or peeling skin. It may last for several weeks. Moisturizing creams and lotions applied liberally may help. You

may also be offered medicines to relieve the itching. Be sure to apply sun block when outdoors.

Avoid steroids, including any over the counter skin products. If you have questions contact your health care provider.

Fatigue is a common side effect and may last for several weeks after discharge. Try to combine periods of activity with periods of rest. Be aware that some medicines to control other side effects (like lorazepam or diphenhydramine) may also make you sleepy. If you take these medicines you should not operate machinery or drive a car.

You are at increased risk if an infection develops so you will be placed on antibiotics when IL-2 treatment starts.

If you have a known autoimmune condition, make sure your health care team is aware of it as IL-2 could worsen it.

These are not all of the possible side effects of IL-2 treatment. Not everyone experiences this treatment in the same way. Do not expect that the side effects will be completely gone when you are discharged from the hospital. You may have some ongoing side effects like rash, fatigue and mild shortness of breath (particularly when lying flat) for up to a week or more after you get home. Taking prescribed medicines for these side effects should help.. If you have any questions or concerns do not hesitate to contact your health care team. Discuss your treatment and possible side effects with your healthcare provider for more complete information.

When I am at home, what should I call my health care provider for?

- Fever over 100.5 F (38 C) or shaking chills
- Shortness of breath
- Diarrhea that is not controlled with medicines
- Swelling that does not go away in a week
- Any symptoms that do not improve or get worse

How does IL-2 work?

Proleukin® (interleukin-2) therapy is a form of immunotherapy that uses the body's natural immune system to fight cancer. Interleukin-2 (IL-2) is a protein that occurs naturally in your body and plays an important role in activating your immune system. The immune system protects the body from foreign substances, cells, and tissues by responding to and resisting diseases. Proleukin® is a genetically engineered version of IL-2 and possesses the same properties as naturally occurring IL-2. It helps activate the immune system to recognize and eliminate certain kinds of cancer cells. It is used for treatment in adults with metastatic kidney cancer (it is also used for treatment of metastatic melanoma).

Your immune system is composed of various types of cells that kill and remove foreign substances from the body. IL-2 activates specialized white blood cells called T cells and natural killer (NK) cells to help attack and destroy invading germs or diseases. IL-2 can also stimulate these cells to attack and destroy cancerous tumors.

Patient Assistance Program: Proleukin Patient Assistance Program is a program from Prometheus designed to help with access or reimbursement. Call 1-877-Proleukin (776-5385), Monday through Friday, 7:30-4:30 PM, PT.

Resources: Proleukin Product Information Line at 1-877-378-4919

www.proleukin.com

www.proleukin.com/mrcc/

Adapted from the Proleukin (aldesleukin) package insert.

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KCA disclaimer statement: you should rely primarily upon your doctor for medical information.

www.kidneycancer.org