



Intravenous Interleukin-2 Treatment

Welcome to the Clinical Center at the National Institutes of Health (NIH). Your health care team prepared this booklet to give you as much information as possible about your immunotherapy treatment. It will describe what immunotherapy is and what to expect from your treatment. It will also tell you how you and your health care team will manage the common side effects of this therapy.

There is a lot of information here, so we encourage you to read one section at a time. You may refer to this booklet throughout your treatment.

If you have questions or concerns about your treatment, do not hesitate to ask a member of your immunotherapy team at any time. Their telephone numbers are included in your packet if you need to call after you are discharged.

What is interleukin-2?

Before you can learn about interleukin-2 (IL-2), you need to know how your body defends itself against infection.

Your body's first response to invading viruses or bacteria is called an immune response. This response is like an alarm. It signals your body that something has entered, which does not belong there.

The immune response is triggered by your immune system: the cells in your body that fight infection.

Your immune system is constantly alert for disease-causing viruses, bacteria, and fungi. It protects you from these unfamiliar substances, including cancer cells, by seeing them as harmful.

When they are detected, the immune system sends fighter cells (white blood cells, WBCs) or makes antibodies to destroy the unfamiliar substance invading your body. A type of white blood cell, called lymphocytes, makes interleukin-2. IL-2 is a protein made in small amounts by your body. IL-2 activates your immune system to help your body fight cancer.

Large amounts of IL-2 can be commercially made, and this is known as "recombinant IL-2." When IL-2 is used to treat patients with cancer, this is called "immunotherapy" or "biologic therapy."

How will I receive intravenous (I.V.) IL-2?

You will receive intravenous IL-2 every 8 hours. The IL-2 infuses over 15 minutes. Therapy usually lasts 3 to 5 days depending on your protocol and your side effects.

You will have I.V. (intravenous) fluids continuously flowing through your I.V. during treatment.

What are the side effects?

IL-2 causes many side effects. Most people have flu-like symptoms such as fever, chills, and joint and muscle aches.

Weight gain, rapid heart rate, decrease in urine output, and a drop in blood pressure are also common. Also, you may have nausea, vomiting, diarrhea, skin flushing, itching, vivid dreams, and confusion.

We will monitor you closely for all side effects. Your vital signs will be taken often. We will also measure your urine output every 4 hours. Each morning, blood will be drawn, and you will be weighed. The medical and nursing team will listen to your lungs, heart, and abdomen, and ask how you are feeling.

Your health care team will monitor you closely and help you manage side effects. You will also be offered medications to help lessen them. For example, you will receive around-the-clock medications, acetaminophen (Tylenol), indomethacin (Indocin), and ranitidine (Zantac), to lessen chills and fever. These medicines will be given to you in tablets.

If you are nauseated and unable to take these tablets by mouth, they can be given to you by suppository.

To prevent you from getting a stress ulcer, we will give you ranitidine through your I.V. It decreases your stomach acid.

Chills

Some patients feel a chill 1 to 2 hours after receiving IL-2.

How you will be helped

- If you begin to feel cold, tell your nurse, who will give you thick blankets.
- If you develop a severe chill, your nurse will give you meperidine hcl (Demerol) through your I.V. to make the chill go away.

Circulatory side effects

IL-2 can cause side effects that affect your heart and blood vessels. These side effects include low blood pressure (hypotension), rapid heartbeat (tachycardia), and swelling (edema).

Low blood pressure (hypotension)

Low blood pressure may make you feel lightheaded or dizzy. If you feel this way, stay in bed and use the call light to call your nurse.

How you will be helped

- Your nurse will take your blood pressure and may lower the head of your bed.
- Your nurse may give you extra fluids (saline) through your I.V. as ordered by your doctor.
- If your blood pressure does not increase, you may be taken to the Intensive Care Unit to receive other medications that will raise your blood pressure.

Rapid heartbeat (tachycardia)

Some patients develop a heartbeat greater than 120 beats per minute.

How you will be helped

- If you have rapid heartbeat, you may be given extra fluid to help your heart slow down.
- Your nurse will check your vital signs closely if rapid heartbeat occurs.

Swelling (edema)

Most patients have swelling of the hands, feet, and face. Edema is caused by fluid leaking into the body tissues. You may gain 10 to 20 pounds during your therapy.

Since your hands may swell, you must take off all rings before beginning therapy. Because your eyes may become sore and dry, you should also remove contact lenses, if you wear them.

How you will be helped

To help reduce swelling once your treatment has ended, you will be given a diuretic such as furosemide (Lasix). This medication helps rid your body of extra fluid by making the kidneys produce more urine. Most of the extra weight will be gone in 48 to 72 hours after treatment stops.

Respiratory side effects

IL-2 therapy may affect your lungs and your ability to breathe. You may begin to keep fluid in your lungs. If you have any trouble breathing, call your nurse. You will be asked to stay in bed with the head of the bed raised.

How you will be helped

- When you need to get out of bed, ask your nurse for help.
- You may be given oxygen to help you breathe more easily.
- Your nurse will monitor your respiratory rate and check whether you are having trouble breathing.
- Your nurse will measure the amount of oxygen in your blood with a finger probe called a “pulse oximeter.”

Urinary side effects

Because IL-2 causes fluid to leak into the body tissues, you will not urinate as much as you normally would. You will notice that your urine will become dark, concentrated, and may smell bad. The amount of fluid you drink and the urine you pass will be measured. These amounts will be written on an “intake and output” sheet, which will be placed on your bathroom door.

When you are admitted, and from time to time during treatment, you will need to give us a “clean catch” urine specimen. We will give you a sterile container and teach you how to collect a clean-catch specimen.

How you will be helped

- If you cannot urinate, or if your urine output decreases greatly, extra I.V. fluids may be given, or a Foley catheter may be inserted into your bladder. This catheter is a flexible, plastic tube that helps to drain your urine. The amount of urine draining from the Foley catheter will help us know how much fluid you need through your I.V. line. This catheter may stay in place until therapy is over.

- When you have completed the entire cycle of IL-2 therapy, you will receive a diuretic (such as Lasix) to help you lose the extra fluid your body retained. Diuretics help you urinate a lot and more often.

Gastrointestinal side effects

IL-2 will affect how your stomach and intestines work. You may be nauseated, vomit, or have diarrhea. These side effects will be uncomfortable, and the nursing staff will provide you with medications to help control them. Please let your nurse know if a medication does not help you. There are other medications that may work.

By the third day of IL-2 therapy, many patients develop diarrhea. As soon as your bowel movements become softer than usual, tell your nurse so that medications can be given. The sooner you begin taking them, the less likely it will be that you develop severe diarrhea. Many medications can control diarrhea, but they will not stop it completely. Keep your nurse informed whenever diarrhea starts and whenever you pass loose stools.

How you will be helped

- If your stools become watery, your nurse will need to measure them in a container that fits in the toilet.
 - If you pass many loose stools at once and find it hard to get to the bathroom quickly, then you will be given a bedside commode chair.
- Do not try to walk to the bathroom if you are not feeling well. Just ask for help by pressing the call button.

Stomatitis (mouth irritation)

IL-2 therapy causes stomatitis. Your mouth may become dry, swollen, sore, red, make less saliva, and feel slightly burning. Your lips may be dry, and you might have a change of taste in your mouth.

To prevent stomatitis, use a soft nylon-bristled toothbrush when you brush your teeth. Rinse your toothbrush well after each use and store it in a dry place. Rinse your mouth or brush your teeth within 30 minutes after eating.

Do not use over-the-counter mouthwashes that contain alcohol.

How you will be helped

- The nursing staff will give you a bicarbonate of soda mouth rinse to use after brushing and every 4 hours during the day. Be sure to inform your nurse whether this rinse helps lessen your mouth soreness.
- To keep you comfortable, your nurse can also give you a liquid anesthetic to numb your mouth, as well as an artificial saliva spray to decrease soreness. A humidifier may be put in your room to prevent your mouth from becoming too dry.
- Other ways to prevent or lessen mouth pain can be found in the National Cancer Institute publication, Eating Hints for Cancer Patients in the “Answers to Nutrition Questions” section.

Skin effects

Almost everyone receiving IL-2 treatment will have some degree of dry skin or rash. This can range from dry, red skin with itching, to flaking or peeling skin. Dry, peeling skin can occur anywhere on your body and may last for several weeks.

How to cope

- Some lotions may help, such as Lubriderm, Eucerin, aloe vera, and Aveeno. Using these oils, creams, and lotions may help relieve symptoms. Aveeno baths may also provide some relief. This product contains oatmeal to ease itchiness. Use mild soap for bathing. It is important to continue careful skin care until all dryness goes away.
- Because your skin is so sensitive, you must protect yourself from direct sun. Use a sun block with a sun protection factor (SPF) of 15 or greater.
- Because ultraviolet rays can go through clouds, use sun block even on cloudy days,
- Reapply sun block if you sweat or swim. Wear a hat and loose-fitting cotton clothes.
- Show all over-the-counter skin products you use to your nurse. Many contain steroids, which prevent IL-2 from working. Do not use any product containing steroids.

Fatigue

Fatigue is a common side effect of immunotherapy that lasts for a few days after discharge.

How to cope

- Combine periods of activity with periods of rest.
- Drink plenty of fluids each day.
- In addition to fatigue, you may feel sad or depressed after treatment. Balancing periods of rest and activity may help control these feelings. Gradually increase your exercise, work, and sexual activity.
- Some of the medications that ease the side effects of therapy, lorazepam (Ativan), and diphenhydramine hcl (Benadryl), may also make you drowsy. If you take these medications, do not operate machinery or drive a car.

Psychological side effects

During IL-2 therapy, you may have changes in your emotions and patterns of thought. While these side effects may distress you, be assured that the members of your health care team are experienced in helping patients cope with these feelings. They will do all they can to keep you comfortable and safe. There is also a psychiatrist available to the IL-2 team.

Psychological changes may begin on the third or fourth day of therapy. You may become moody, irritable, disoriented, confused, agitated, forgetful, or lethargic. The severity of these side effects will vary and may depend on how much IL-2 you receive. These side effects do not happen to everyone, and they vary greatly from one person to another.

Later during therapy, feelings of sadness, increased irritability, difficulty sleeping, nightmares, clumsiness, and moderate

confusion may occur. Some patients have had hallucinations (seeing or hearing things that are not there). Others have had disturbed sleep patterns, vivid dreams, and mood shifts. As a safety measure, your nurse may pull up the side rails on your bed and ask you to call a nurse with the call bell when you need to use the bathroom.

How to cope

- Less than half of patients receiving IL-2 have mild disorientation, and only a small number have intense changes. If you have any of these changes, turning on the radio or television may help distract you. Having the company of a friend or family member may also help.
- Family members and friends can give you a lot of support at this time. Included in the Resource List at the back of this booklet is the name of a health care team member who may be able to help you and your family.

If psychological side effects become too intense, IL-2 treatment may be stopped. These side effects will go away when treatment is over. Some patients continue to have vivid dreams for 1 to 2 weeks after IL-2 therapy ends.

Discharge instructions

You will be able to go home when you recover from IL-2 treatment. Recovery may take a few days. To help you recover at home, follow these guidelines:

- Gradually increase your fluid intake to 8 to 12 or more glasses each day.
- Gradually increase your food intake. Start eating bland starches such as rice, noodles, and mashed potatoes. Milkshakes and instant breakfast drinks are also good ways to keep you nourished. Eat small, frequent meals. As your appetite returns, add high protein foods such as meat, eggs, milk, and cheese.
- Use a strong sun block (SPF 15 or greater) whenever you go outside, even in winter. Remember to reapply sun block if you swim, sweat, or if you are outside for a long time. Protect yourself from the direct rays of the sun. Wear loose-fitting cotton clothes and a hat.
- Do not operate machinery or drive a car while taking medications that make you sleepy.
- Slowly increase your activity level and plan rest periods. Drinking plenty of fluids will help lessen fatigue. (Fatigue is an expected side effect of therapy.)
- Maintain contact with your local doctor.
- In case of emergency, first call your local doctor. After you have spoken with your local doctor, call your immunotherapy doctor.
- Do not drive for 1 week after discharge.
- Always carry your medical advisory card. Show this to any doctor or emergency staff you visit.

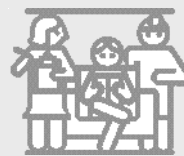
How to reach your health care team

- During weekdays from 8 a.m. to 4 p.m., call the immunotherapy research nurses first at **1-866-820-4505**.
- After 4 p.m. Monday through Friday, Saturday, Sunday, and holidays, call the 3 NW nurses' station: **301-451-0789**.

The nurses on 3 NW will address your questions or concerns. Please note the name of the nurse you speak with. If the 3NW nurses are unable to help you, they will page the immunotherapy doctor on call at **301-496-1211**.

Helpful resources

- <http://www.cancer.gov/cancertopics/coping>
- Dutcher, J. Current status of interleukin-2 therapy for metastatic renal cell carcinoma and metastatic melanoma. *Oncology*. 16 (11), [supplement], 4-10; 2002.
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- Proleukin® (interleukin 2) [prescribing information]. Emeryville, Calif: Chiron.
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- Sharp, E. The interleukins. In: P.T. Rieger, ed. *Biotherapy, A comprehensive overview*. Boston: Jones and Bartlett., 1995: p. 93-111.
- Shelton, BK. Flu-like syndrome. In P.T. Rieger, ed., *Biotherapy: A comprehensive overview*, 2nd edition. Boston: Jones and Bartlett, 2001: p. 519-543.



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This information is prepared specifically for patients participating in clinical research at the Clinical Center at the National Institutes of Health and is not necessarily applicable to individuals who are patients elsewhere. If you have questions about the information presented here, talk to a member of your healthcare team.

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