



Decitabine

Your body defends itself by means of the immune system. When something “foreign” enters your body, your body’s immune system is triggered and reacts with an “immune response.” The immune response occurs because your body sees the foreign substance as an “antigen.” Specialized cells of the immune system, white blood cells called lymphocytes, seek out antigens and destroy them.

What is decitabine?

Decitabine is a chemotherapy drug that does two things: it stops tumor cells from growing and it helps your body see cancer cells as antigens—enemies to be destroyed.

How does it work?

We hope that decitabine will help your immune system see and kill tumor cells in your body. Researchers at NIH have found that decitabine makes lung cancer cells more open to attack by your body’s immune system.

They also know that 70 percent of all patients with lung cancer have a gene called p16 which is “turned off.” This gene, called a “suppressor gene,” prevents tumor cells from growing. But if the body turns this gene “off” (through a process called “promoter methylation”), the p16 gene does not work and cancer cells can grow.

Decitabine prevents the body from turning off the p16 gene, allowing it to do its job to keep tumors from growing.

Recent studies of patients with leukemia and lung cancer who received decitabine showed that their tumors stopped growing or got smaller.

What are the main side effects?

Low platelet count (thrombocytopenia)

Platelets are the cells in your blood that help stop bleeding. When your platelet count is low, you may bruise or bleed more easily.

Signs and symptoms of a low platelet count

- easy bruising
- little red dots on the skin (petechiae)
- blood in your urine or stool
- nosebleeds
- prolonged bleeding at needle stick sites

How to prevent bleeding

- Avoid shaving with a razor blade. Use an electric razor.
- Use a soft toothbrush only. If your gums bleed, use Toothettes, as you would usually use a toothbrush.
- Blow your nose gently.
- Wear shoes at all times, even while in the hospital or at home.
- Avoid using enemas, rectal thermometers, and suppositories.
- Women should not use tampons, vaginal suppositories, or douches.
- Do not take aspirin or medications containing aspirin.

Low white blood cell count (leukopenia)

White blood cells fight infection. While your white blood cell count is low, you can get infections more easily.

How will I know if I have a fever?

Check your temperature every 4 hours while you are awake.

When should I call my doctor or nurse?

- If you have a temperature of 101.0 °F (38.3 °C).
- If your temperature is 100.4 °F (38.0 °C), wait 1 hour and recheck it. If it is still 100.4 °F (38.0 °C) or higher, call us.
- If you have two fevers of 100.4 °F (38.0 °C) over a 24-hour period.
- If you see redness, swelling, tenderness, or drainage anywhere.
- If you have a rash, fever, chills, cough, headache, or a stiff neck.
- If you have diarrhea.
- If you have bloody or cloudy urine, or if you have painful or frequent urination.
- If you see any signs or symptoms of infection in your mouth, on your skin, or around your rectum.
- Check the site around any catheter you may have (Hickman, Port-A-Cath, Groshong, PICC).
- Check with your doctor or nurse before taking Tylenol. Do not take aspirin, aspirin-containing products, ibuprofen, or Percocet.

How do I prevent infection?

- Wash your hands often, especially before preparing food and eating, after using the toilet, blowing your nose, coughing, or sneezing.
- Shower or bathe daily. If your skin becomes dry, use lotion or oil to soften and prevent cracking.
- Do mouth care before and after meals, and at bedtime. Use a soft toothbrush and mouth rinse without alcohol. Do not floss. Consult your NIH doctor before having dental work done.
- Wear shoes when out of bed.
- Avoid manicures or pedicures.
- If you cut or scrape your skin, clean the area immediately with soap and warm water; then apply a bandage. Check the site daily until it heals.
- Do not use enemas, rectal thermometers, or suppositories.
- Use water-based lubricants such as K-Y jelly to reduce friction during vaginal intercourse. Avoid oral or rectal intercourse.
- Avoid large crowds and people with infections or colds. Be particularly careful around school-age children.
- Avoid people who have recently received the Sabin oral polio vaccine and chicken pox (varicella) vaccines.
- Check with your NIH doctor before receiving immunizations and injections.
- Wear gloves when gardening.
- Do not clean bird cages, cat litter boxes, or fish tanks.
- Limit your exposure to pets, fresh flowers, house plants, and stagnant water.
- Do not swim.
- Do not eat raw or undercooked eggs, fish, shellfish, meat, poultry, or uncooked aged cheese.

What other side effects could I have?

Nausea and vomiting

You will be given medications to prevent these symptoms.

Muscle weakness and muscle pain

Ask your nurse or doctor how to deal with this.

Because this is a Phase I study, it is important that you report all symptoms to your nurse.

How will I receive decitabine?

- Decitabine will be given to you through an I.V. in your arm or through a central I.V. line. It will be a 72-hour continuous infusion beginning on the morning of Monday or Friday until the morning of Thursday or Monday. During the infusion, your blood will be drawn at certain times to track how much decitabine is in your bloodstream.
- Blood will be drawn daily to check your blood cell counts and your liver and kidney function.
- You will have a tumor biopsy before treatment on the Friday or Tuesday after treatment is completed. The same procedure will happen on your second cycle. Depending on the location of your tumor, the biopsy may be done in either the operating room or in the special procedures section of the Diagnostic Radiology Department.

What else do I need to know about treatment?

You must keep to your treatment schedule for receiving decitabine and for getting frequent blood drawings. We ask you to stay on 2 East after your infusion begins and for your blood drawings afterwards. Your nurse will tell you when your blood drawings are scheduled.

What does “nadir” mean?

Nadir is when your white blood count or platelet count is at its lowest. This is when you are most likely to get an infection or bleeding.

- Your platelet count nadir will occur between day 12 and day 14
_____ (dates).
- Your white blood cell nadir will occur between day 21 and day 22
_____ (dates).

When should I have my blood drawn when I leave the hospital?

Because you can expect to nadir when you are not in the hospital, you must have your blood drawn at home, either at your local doctor’s office or at an outpatient facility. Your research nurses, Tricia Kunst, RN, or Ana Hancox, RN, will give you a calendar that shows you when you should have your blood drawn.

Where should the blood test results be sent?

Fax them to 301-402-1788, attention Tricia Kunst, RN, or Ana Hancox, RN.

Whom should I call if I have questions?

If you have questions during business hours (8:30 a.m. to 5 p.m. Monday through Friday), call Ms. Kunst at 301-402-4399 or Ms. Hancox at 301-435-7506.

After hours, call the 2 East nurses' station at 301-496-3191.



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Questions about the Clinical Center? OCCC@cc.nih.gov

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