



Fludarabine Injection

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Contents of this page:

- [Why is this medication prescribed?](#)
- [How should this medicine be used?](#)
- [Other uses for this medicine](#)
- [What special precautions should I follow?](#)
- [What special dietary instructions should I follow?](#)
- [What side effects can this medication cause?](#)
- [In case of emergency/overdose](#)
- [What other information should I know?](#)
- [Brand names](#)
- [Other names](#)

IMPORTANT WARNING:

Fludarabine injection must be given under the supervision of a doctor who is experienced in giving chemotherapy medications for cancer.

Fludarabine injection can cause a decrease in the number of blood cells made by your bone marrow. This decrease may cause you to develop dangerous symptoms and may increase your risk of having a serious or life-threatening infection. Your doctor may prescribe other medications to decrease the risk that you will develop a severe infection during your treatment. Tell your doctor if you have or have ever had a low number of any type of blood cells in your blood or any condition that affects your immune system and if you have ever developed an infection because your blood cell levels were too low. If you experience any of the following symptoms, call your doctor immediately: shortness of breath; fast heartbeat; headache; dizziness; pale skin; extreme tiredness; unusual bleeding or bruising; black, tarry, or bloody stool; vomit that is bloody or that looks like coffee grounds; and fever, chills, cough, sore throat, difficult, painful, or frequent urination, or other signs of infection.

Fludarabine injection can also cause damage to the nervous system . If you experience any of the following symptoms, call your doctor immediately: seizures, agitation, confusion, and coma (loss of consciousness for a period of time).

Fludarabine injection may cause serious or life-threatening conditions in which the body attacks and destroys its own blood cells. Tell your doctor if you have ever developed this type of condition after receiving fludarabine in the past. If you experience any of the following symptoms, call your doctor immediately: dark urine, yellow skin, tiny red or purple dots on the skin, nosebleeds, heavy menstrual bleeding, blood in the urine, coughing up blood, or difficulty breathing due to bleeding in the throat.

In a clinical study, people with chronic lymphocytic leukemia who used fludarabine injection along with pentostatin (Nipent) were at high risk of developing serious lung damage. In some cases, this lung damage caused death. Therefore, your doctor will not prescribe fludarabine injection to be given along with pentostatin (Nipent).

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests to check your body's response to fludarabine injection.

Talk to your doctor about the risks of receiving fludarabine injection.

Why is this medication prescribed?

Fludarabine injection is used to treat chronic lymphocytic leukemia (CLL; a type of cancer of the white blood cells) in adults who have already been treated with at least one other medication and have not gotten better. Fludarabine injection is in a class of medications called purine analogs. It works by slowing or stopping the growth of cancer cells in your body.

How should this medicine be used?

Fludarabine injection comes as a powder to be added to fluid and injected over 30 minutes intravenously (into a vein) by a doctor or nurse in a medical office or hospital outpatient clinic. It is usually injected once a day for 5 days in a row. This treatment period is called a cycle, and the cycle may be repeated every 28 days for several cycles.

Your doctor may need to delay your treatment or adjust your dose if you experience certain side effects. Be sure to tell your doctor how you are feeling during your treatment with fludarabine injection.

Other uses for this medicine

Fludarabine injection is also sometimes used to treat non-Hodgkin's lymphoma (NHL; cancer that begins in a type of white blood cell that normally fights infection) and mycosis fungoides (a type of lymphoma that affects the skin). Talk to your doctor about the risks of using this medication for your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before receiving fludarabine injection,

- tell your doctor and pharmacist if you are allergic to fludarabine, any other medications, or any of the ingredients in fludarabine injection. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention the medication listed in the IMPORTANT WARNING section or cytarabine (Cytosar-U, DepoCyt). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have or have ever had kidney disease. Also tell your doctor about all the other chemotherapy medications you have received and if you have ever been treated with radiation therapy (cancer treatment that uses waves of high energy particles to kill cancer cells). Before you receive chemotherapy or radiation therapy in the future, tell your doctor that you have been treated with fludarabine.
- you should know that fludarabine injection may interfere with the normal menstrual cycle (period) in women and may stop sperm production in men. However, you should not assume that you or your partner cannot become pregnant. If you are pregnant or breast-feeding, you should tell your doctor before you begin receiving this medication. You should not plan to have children while receiving fludarabine injection or for at least 6 months after treatments. Use a reliable method of birth control to prevent pregnancy during this time. Talk to your doctor for further details. Fludarabine injection may harm the fetus.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are receiving fludarabine injection.
- you should know that fludarabine injection may cause tiredness, weakness, confusion, agitation, seizures, and vision changes. Do not drive a car or operate machinery until you know how this medication affects you.
- talk to your doctor before you receive any vaccinations during your treatment with fludarabine injection.

- you should know that you may develop a serious or life-threatening reaction if you need to receive a blood transfusion during your treatment with fludarabine injection or at any time after your treatment. Be sure to tell your doctor that you are receiving or have received fludarabine injection before you receive a blood transfusion.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What side effects can this medication cause?

Fludarabine injection may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- loss of appetite
- nausea
- vomiting
- constipation
- diarrhea
- mouth sores
- hair loss
- numbness, burning, pain, or tingling in the hands, arms, feet, or legs
- muscle or joint pain
- headache
- depression
- sleep problems

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- chest pain or discomfort
- fast or irregular heartbeat
- hearing loss
- pain along the side of the body
- swelling of the arms, hands, feet, ankles, or lower legs
- rash
- hives
- difficulty breathing or swallowing
- peeling or blistering skin

Fludarabine injection may cause other side effects. Call your doctor if you have any unusual problems while receiving this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at <http://www.fda.gov/Safety/MedWatch>] or by phone [1-800-332-1088].

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

Symptoms of overdose may include:

- unusual bruising or bleeding
- fever, chills, cough, sore throat, or other signs of infection
- delayed blindness
- coma

What other information should I know?

Ask your doctor or pharmacist if you have any questions about fludarabine injection.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Fludara®

Other names

- 2-Fluoro-ara-A Monophosphate, 2-Fluoro-ara AMP, FAMP

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