

**Denileukin Diftox (Ontak®)**

**Condition For Which Treatment is proposed:** \_\_\_\_\_

1. I hereby authorize my physician, Dr \_\_\_\_\_, and/or such other staff physicians or resident physicians as my physician may designate, to administer to me (or the patient for whom I consent) the following chemotherapy consisting of:

**Denileukin diftox**

**The plan for my course of chemotherapy is for \_\_\_\_\_ cycles of chemotherapy, with each cycle given about every \_\_\_\_\_ days.**

2. My physician has discussed with me the items that are briefly summarized below:
- a. The nature and purpose of the proposed therapy is to administer chemotherapy (drugs to fight my cancer, which may also have other effects on my body) by mouth and/or by vein or by other type of injection.
  - b. The risks of the proposed chemotherapy:

**Chemotherapy** may cause nausea, vomiting, loss of appetite, mouth sores, hair loss, fatigue, a lowering of the white blood cell count (which can lead to a serious infections), a lowered platelet count (which can lead to bleeding), and a decrease in my red blood cell count (which can lead to shortness of breath, a rapid heart beat or weakness). Due to these low blood counts, I may require red blood cell or platelet transfusions. My doctor will give me appropriate medications to try to decrease the severity of any side effects. Other side effects could occur, rarely death. It is important that I call my physician or nurse-coordinator with problems which occur during the course of my treatment. I always have the right to refuse chemotherapy at any time. It is possible that this chemotherapy may not be effective and my disease might progress.

**Long-term side effects** of chemotherapy can include injury to lungs, heart, liver and/or bladder. Acute leukemia can also develop as a result of chemotherapy.

**Chemotherapy usually has an adverse effect on sperm and eggs** and can cause me to be unable to have children. Chemotherapy can have harmful effects on an unborn child. If I am a woman, it is important to tell my physician if I think I may be pregnant. It is possible to conceive a child during treatment with chemotherapy. It is important that both men and women who are being treated with chemotherapy and who are sexually active, fertile, and who have a fertile partner use a reliable form of birth control (birth control pills, a reliable barrier method or a hormonal implant.)

You (or the patient for whom you consent) may require **venipuncture** (putting a needle into a vein to remove blood or administer chemotherapy). The discomfort associated with venipuncture is a slight pinch or pinprick when the sterile needle enters the skin. The risks of venipuncture include mild discomfort and/or a black or blue mark at the site of the needle puncture. Less



commonly, a small blood clot, infection or bleeding may occur at the needle puncture site. When chemotherapy is administered into a vein, there is also a small risk of either infection in the bloodstream or the chemotherapy leaking outside the vein causing tissue irritation or damage.

**The drugs which will be used for my planned chemotherapy and their specific side-effects:**

**Denileukin difitox:**

**The following side effects are common (occurring in greater than 30%)**

- Hypersensitivity reaction during the infusion with symptoms such as low blood pressure, back pain, or shortness of breath (see allergic reactions)
- Fever/Chills (usually occurs during or soon after the infusion)
- Nausea and vomiting
- Blood test abnormalities (low albumin level, hypoalbuminemia)
- Liver problems (elevated liver enzymes; transaminase)
- Weakness
- Swelling (usually of hands and feet)
- Infection
- Pain
- Low blood pressure (hypotension)
- Poor appetite
- Rash

**These side effects are less common (occurring in about 10-29%)**

- Diarrhea
- Shortness of breath
- Headache
- Chest pain
- Cough
- Dizziness
- Itching
- Pharyngitis or Rhinitis (inflammation of the throat or nose) (see cold symptoms)
- Low red blood cell count. Your red blood cells may temporarily decrease. This can put you at increased risk for anemia
- Numbness and tingling of hands and feet
- Blood test abnormalities (low calcium level, low albumin level)
- Muscle pain
- Weight loss
- Rapid heart rate (see heart problems)
- Anxiety or nervousness
- Sweating (see skin problems)
- Cloudy urine (see kidney problems)

A serious side effect of denileukin difitox is “capillary leak syndrome” or “vascular leak syndrome”. Capillary leak syndrome is a potentially serious disease in which fluids within the vascular system (veins and capillaries) leak into the tissue outside the bloodstream. This results in low blood pressure and poor blood flow to the internal organs. Capillary leak syndrome is characterized by the presence of 2 or more of the following 3 symptoms; low blood pressure, swelling, and low levels of protein in the blood. Your doctor immediately if you notice dizziness (especially when changing position), sudden swelling, or rapid weight gain, little or no urine output (for 8-12 hours), shortness



of breath, difficulty breathing, irregular heartbeats, or chest pains. If this symptom occurs, it will likely be delayed, within about 2 weeks of treatment.

Not all side effects are listed above. Some that are rare (occurring in less than 10% of patients) are not listed here. However, you should always inform your health care provider if you experience any unusual symptoms.

**When to contact your doctor or health care provider:** Contact your health care provider immediately, day or night, if you should experience any of the following symptoms:

Dizziness (especially when changing position), sudden swelling or rapid weight gain, little or no urine output (for 8-12 hours), shortness of breath, difficulty breathing, irregular heartbeats, or chest pain. The following symptoms require medical attention, but are not an emergency. Contact your health care provider within 24 hours of noticing any of the following:

- Fever of 100.5°F (38° C) or higher, chills occurring 1-2 days after infusion or later (possible signs of infection).
- Nausea (interferes with ability to eat and unrelieved with prescribed medication)
- Vomiting (vomiting more than 4-5 times in a 24 hour period)
- Diarrhea (4-6 episodes in a 24 hour period)
- Unusual bleeding or bruising
- Blood in urine
- Cloudy urine
- Pain or burning with urination
- Extreme fatigue or weakness (unable to carry on self-care activities)
- Anxiety or nervousness that interferes with your ability to function
- Yellowing of the skin or eyes

3. The medically reasonable alternative treatments and the risks associated with these alternative treatments have been described by my physician. These alternatives include no treatment, combinations of different chemotherapy drugs, or the same drugs given in different doses or on a different schedule.
4. Without the proposed treatment my disease may progress, it could remain stable or, rarely, improve.
5. I understand that during the course of this chemotherapy, unforeseen conditions may arise which could require the planned chemotherapy to be altered. All alterations to the planned chemotherapy will be discussed with me.
6. I am aware that the practice of medicine is not an exact science, and I acknowledge that no guarantees have been made to me concerning the results of the proposed therapy.
7. I acknowledge that the information I have received, as summarized on this form, is sufficient for me to consent to and authorize the chemotherapy described above. I have had the opportunity to ask questions concerning my condition, the chemotherapy, the alternatives and risks, and all questions have been answered to my satisfaction.
8. I impose the following limitation(s) regarding my treatment (if none, so state): \_\_\_\_\_  
\_\_\_\_\_
9. I authorize the staff of The Hershey Medical Center to preserve for scientific or teaching purposes any



tissues or parts which may be removed in the course of this procedure, and to dispose of them.

10. I authorize The Hershey Medical Center to permit other persons to observe this therapy with the understanding that such observation is for the purpose of advancing medical knowledge. I authorize The Hershey Medical Center to obtain photographic or other pictorial representations of this therapy, and to use such representations for scientific or teaching purposes.
11. I certify that all blanks requiring insertion of information were completed before I signed this consent form.

\_\_\_\_\_ provided the information summarized above and obtained the  
(fill in name) consent for the procedure

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
(Patient's Signature) (Date) (Time)  
(or signature of person consenting on behalf of the patient)

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
(Optional: Witness to Patient's Signature) (Date) (Time)

\_\_\_\_\_/\_\_\_\_\_  
(Physician's Signature) (Date)

