



## Patient Information Sheet

### Alemtuzumab (marketed as Campath)

This is a summary of the most important information about Campath. For more information, talk to your healthcare professional.

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**FDA ALERT [11/2005] Three patients in a clinical study of the drug Campath for the treatment of Multiple Sclerosis (MS) developed severe idiopathic thrombocytopenic purpura (ITP). One of the patients died.**

**ITP happens when the body attacks and kills its own blood platelets. Platelets are a type of blood cell that controls bleeding. Bruising and bleeding may be warning signs of ITP.**

**Campath is not approved to treat MS. Campath is only approved for treating a form of blood cancer called B-cell chronic lymphocytic leukemia (B-CLL). The label for Campath has a warning about serious and rare blood problems that may happen with the use of this medicine.**

**Talk to your healthcare professional if you have concerns about taking Campath.**

*This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information.*

*FDA intends to update this sheet when additional information or analyses become available.*

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#### What Is Campath?

Campath is a type of medicine called a monoclonal antibody. It is used to treat B-cell chronic lymphocytic leukemia (B-CLL) in patients who have failed treatment with certain other cancer medicines. It is not known if Campath improves symptoms in patients with B-CLL or if it helps them live longer.

Campath is not approved to treat Multiple Sclerosis.

#### Who Should Not Be Treated With Campath?

You should not be given Campath if you have any of the following conditions:

- an infection in your body

- an immune system problem such as being HIV positive
- ever had a serious allergic reaction to Campath

#### What Are The Risks?

*The following are the major potential risks and side effects of Campath therapy. However, this list is not complete.*

- **Infusion-related side effects.** Campath is given in a vein through a tube. This is called an I.V. infusion. An I.V. infusion of Campath may cause side effects such as low blood pressure, shaking, fever, shortness of breath, chills, and rash. Your healthcare professional may give you medicine before Campath to lower the chance of these side effects.
- **Immunosuppression and Infections.** Campath may weaken your immune system, making it easier for you to get infections. Your healthcare professional may give you medicine to reduce the chance of infection.
- **Bone Marrow Effects.** Campath may lower the ability of the bone marrow to make blood cells. Some of these effects can be severe and lead to death.
- **Some common side effects** that may occur with Campath treatment include:
  - shaking
  - fever
  - low blood cell counts
  - nausea
  - vomiting
  - rash
  - tiredness
  - low blood pressure
  - itching

#### What Should I Tell My Healthcare Professional?

Before you start taking Campath, tell your healthcare professional about all of your medical conditions, including if you:

- have any infections





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- are HIV positive
- are pregnant. Women should not get pregnant during treatment with Campath. Women and men should use effective birth control during treatment with Campath and for 6 months after stopping treatment.
- are breast-feeding. Women should not breastfeed during treatment with Campath and for 3 months after stopping treatment.

professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them with you to show your healthcare professional.

**Campath Approved 2001**

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#### **Can Other Medicines Or Food Affect Campath?**

It is not known if Campath and other medicines can interact with each other. Tell your healthcare

