

MOST IMPORTANT INFORMATION ABOUT ADCETRIS

ADCETRIS can cause serious side effects, including a rare, serious brain infection called progressive multifocal leukoencephalopathy (PML) that can lead to death.

Symptoms of PML can begin at different times after starting ADCETRIS treatment, some within 3 months after the first dose. PML may also be caused by prior treatments or diseases that weakened your immune system.

Tell your doctor right away if you notice, or anyone close to you notices, the following signs or symptoms:

- Changes in mood or usual behavior
- Confusion, problems in thinking, or loss of memory
- Changes in vision, speech, or walking
- Decreased strength or weakness on one side of the body

Do not take ADCETRIS if you are receiving bleomycin.

ABOUT ADCETRIS

ADCETRIS is a prescription medicine directed against the CD30 protein. It is used to treat:

- **Adults with previously untreated Stage 3 or 4 classical Hodgkin lymphoma**, in combination with chemotherapy (Adriamycin, vinblastine, and dacarbazine)
- **Children 2 years of age and older with previously untreated high risk classical Hodgkin lymphoma**, in combination with chemotherapy (doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide)
- **Adults with classical Hodgkin lymphoma at high risk** of coming back or becoming worse after a stem cell transplant
- **Adults with classical Hodgkin lymphoma after a stem cell transplant** fails or after at least 2 chemotherapy treatments fail and stem cell transplant is not an option
- **Adults with previously untreated systemic anaplastic large cell lymphoma or other CD30-expressing peripheral T-cell lymphomas**, including angioimmunoblastic T-cell lymphoma and peripheral T-cell lymphomas not otherwise specified, in combination with chemotherapy (cyclophosphamide, doxorubicin, and prednisone)
- **Adults with systemic anaplastic large cell lymphoma** after at least 1 combination chemotherapy treatment fails
- **Adults with primary cutaneous anaplastic large cell lymphoma or CD30-expressing mycosis fungoides** after systemic therapy (drugs that spread throughout the body)

IMPORTANT FACTS

This is only a brief summary of important information about ADCETRIS. Talk to your doctor or pharmacist to learn more.

HOW YOU WILL RECEIVE ADCETRIS

ADCETRIS is given as an intravenous (IV) infusion, usually at an outpatient clinic.

BEFORE RECEIVING ADCETRIS

Tell your doctor about all your medical conditions, including if you:

- Have or have had any kidney or liver problems.
- Have a history of high blood sugar or diabetes.
- Are pregnant, plan to become pregnant, or have a partner who plans to become pregnant. ADCETRIS can harm a fetus (unborn baby).
 - Women should not become pregnant during treatment and for 6 months after the last dose of ADCETRIS.
 - **Women, and men with female partners, should use effective birth control during treatment and for 6 months after the final dose of ADCETRIS to avoid the risk of pregnancy.**
 - Talk to your doctor about birth control methods that may be right for you during this time.
 - If you are able to become pregnant, your doctor should give you a pregnancy test before you start treatment with ADCETRIS.
 - If you become pregnant or think you are pregnant, tell your doctor right away.
- Are breastfeeding or plan to breastfeed.
 - Do not breastfeed during treatment with ADCETRIS.

Tell your doctor about all the medicines you take:

- Keep a list that includes all prescription and over-the-counter medicines, vitamins, and herbal supplements, or show it to your doctor or pharmacist.
- Ask your doctor or pharmacist about medicines that interact with ADCETRIS.
- Do not start taking a new medicine without telling your doctor. Your doctor can tell you if it is safe to take ADCETRIS with other medicines.

POSSIBLE SIDE EFFECTS OF ADCETRIS

ADCETRIS can cause other serious side effects, including:

- **Nerve damage (peripheral neuropathy).**
Symptoms include:
 - Numbness or tingling in the hands or feet (sensory)
 - Weakness in the arms or legs (motor)

IMPORTANT FACTS (cont'd)

POSSIBLE SIDE EFFECTS OF ADCETRIS (cont'd)

- **Allergic and infusion reactions.** Allergic reactions, including severe forms, during infusion or up to 24 hours after ADCETRIS infusion. If you have a reaction to the infusion, you may be given medicines before your ADCETRIS treatment.

Symptoms include:

- Fever
- Rash
- Chills
- Breathing problems

ADCETRIS can cause other serious side effects, including:

- **Blood problems/fever.** Serious cases, including death, of fever with a low number of white blood cells (neutropenia) or weakened immune system have occurred with ADCETRIS.

Symptoms include:

- A fever of 100.5°F or higher
- Pain on urination
- Chills
- Cough

- **Infections.** Serious infections and infections caused by bacteria, fungi, or viruses have been reported after treatment with ADCETRIS.

Symptoms include:

- Fever
- Chills
- Flu-like symptoms

- **Tumor lysis syndrome (TLS).** TLS is caused by the fast breakdown of cancer cells. Your doctor may do blood tests to check you for TLS.

- ADCETRIS patients with **severe kidney problems or moderate or severe liver problems** may have more side effects and deaths than patients without kidney or liver problems. Tell your doctor if you have or have had any kidney or liver problems.

- **Liver problems.** Serious liver problems, including death, have been reported after treatment with ADCETRIS.

Symptoms include:

- Tiredness
- Pain on the upper right side of your stomach area (abdomen)
- Dark urine
- Loss of appetite
- Yellowing of your skin or the whites of your eyes (jaundice)

- **Lung problems.** Serious lung problems, including death, have been reported after treatment with ADCETRIS.

Symptoms include:

- Cough
- Shortness of breath

- **Skin problems.** Rare but serious skin conditions, including death, have been reported after treatment with ADCETRIS.

Symptoms include:

- Skin rash
- Hives
- Sores in the mouth
- Blistering or peeling of the skin

POSSIBLE SIDE EFFECTS OF ADCETRIS (cont'd)

- **Gastrointestinal (GI) problems.** Serious problems, including death, related to the pancreas, stomach, intestine, and colon have been reported.

Symptoms include:

- Severe abdominal pain
- Vomiting
- Fever
- Chills
- Nausea
- Diarrhea

- **High blood sugar (hyperglycemia).** You can develop high blood sugar after treatment with ADCETRIS.

Symptoms include:

- Frequent urination
- Increased thirst
- Blurred vision
- Confusion
- It becomes harder to control your blood sugar

Call your doctor right away if you have any of the signs or symptoms of the serious side effects listed above.

The most common side effects in any study of ADCETRIS were:

- nerve damage (peripheral neuropathy)
- feeling tired
- nausea
- diarrhea
- a low number of white blood cells
- infection of the nose or sinuses
- fever
- constipation
- vomiting
- hair loss
- weight loss
- upper stomach pain
- a low number of red blood cells
- sores or swelling in the mouth and/or in the digestive tract
- decrease in platelets
- fever with a low number of white blood cells

These are not all the possible side effects of ADCETRIS. Tell your doctor about any side effect that bothers you or does not go away.

If you have certain side effects, your doctor may lower your dose, delay, or stop your ADCETRIS treatment. Your doctor will need to do tests to monitor your health before and during treatment with ADCETRIS.

GET MORE INFORMATION

- This is only a brief summary of important information about ADCETRIS. Talk to your doctor or pharmacist to learn more.
- Go to www.adcetriss.com or call **1-855-4SEAGEN**.
- If you need help paying for your medicine, visit www.seagensecure.com for program information.