

The logo for TRIENOX (arsenic trioxide) injection. The word "TRIENOX" is written in a bold, blue, sans-serif font. The letter "X" is stylized with a blue outline and a green dot above it. Below "TRIENOX" is the text "(arsenic trioxide) injection" in a smaller, green, sans-serif font. A registered trademark symbol (®) is located to the right of the "X".

**TRIENOX**  
(arsenic trioxide) injection

Questions & Answers  
about your treatment with  
TRIENOX® (arsenic trioxide) injection



Questions & Answers  
about your treatment with  
TRISENOX<sup>®</sup> (arsenic trioxide) injection

Please see accompanying  
full prescribing information.

1 Why has my physician recommended treatment with TRISENOX<sup>®</sup> ?

TRISENOX<sup>®</sup> (Try'-sen-ocks) is an anti-cancer drug that is effective against certain cancers of the blood. Research has proven that TRISENOX<sup>®</sup> may benefit patients with certain cancers, and your doctor believes that TRISENOX<sup>®</sup> can be helpful to you.

2 Isn't TRISENOX<sup>®</sup> arsenic? How can arsenic help my cancer?

Yes, TRISENOX<sup>®</sup> is a form of arsenic known as "arsenic trioxide." It is prepared with the highest quality standards and has been found to be safe and effective when used appropriately by doctors and nurses experienced in the treatment of cancer. Like other cancer medicines, arsenic kills cancer cells, and the federal government approved TRISENOX<sup>®</sup> as a cancer medicine because clinical trials conducted at cancer centers proved that it is safe and effective when used correctly.

Although some people may automatically think of arsenic as a toxic chemical, it is actually a naturally occurring substance that has been used in medicine for over 2,000 years. For example, arsenic was used to fight the plague in the middle ages, and it was one of the first drugs used to treat a certain type of leukemia back in the 1800's. Doctors in Asia have used arsenic for hundreds of years for many different medical problems.

As with all medicines, the dose of arsenic is important. Many cancer drugs would be hazardous if used in the wrong amounts or in the wrong way, and arsenic is no different. The dose of arsenic in TRISENOX<sup>®</sup> is very small, and it is given over time at a carefully measured rate. When used at the right dose and given in the right way, TRISENOX<sup>®</sup> is a safe and effective cancer treatment.

**3** What can I expect TRISENOX<sup>®</sup> to do for me?

In general, the goal of treatment with TRISENOX<sup>®</sup> is to eliminate or reduce the number of cancer cells in the body. Some patients treated with TRISENOX<sup>®</sup> have no evidence of cancer cells after treatment, indicating a complete response. Other patients may have a reduction in the number of cancer cells, or reduced symptoms of their cancer. Some patients will have no response to this treatment.

While TRISENOX<sup>®</sup> has been effective in many patients in clinical trials, no one can predict how you will respond to treatment. Your doctor can give you more information about the likelihood that TRISENOX<sup>®</sup> will be beneficial to you based on your individual situation. Your doctor can also tell you what tests will be done to determine if TRISENOX<sup>®</sup> is working for you.

**4** How does TRISENOX<sup>®</sup> work?

How TRISENOX<sup>®</sup> works is not completely understood, but it appears to cause cancer cells to self-destruct. This process is called “programmed cell death” or apoptosis, a natural mechanism of self-destruction. TRISENOX<sup>®</sup> also may prevent cancer cells from multiplying and may keep cancer cells from being supplied with important nutrients that feed their growth.

**5** How will my treatment with TRISENOX<sup>®</sup> occur?

Each TRISENOX<sup>®</sup> treatment is given directly into a vein (infusion), usually over 1-2 hours. If you experience certain side effects (described below), the infusion may be slowed down, and it may take as long as 4 hours to complete the infusion.

Your doctor or nurse will describe how often and for how long you will receive TRISENOX<sup>®</sup>. In many cases, TRISENOX<sup>®</sup> works gradually, so it may take several weeks before your doctor can tell if TRISENOX<sup>®</sup> is helping you.

If your cancer responds to the initial treatment with TRISENOX<sup>®</sup>, you may receive additional doses to maintain that response. Your doctor will determine what schedule of treatment is right for you.

6 What possible side effects should I be aware of? How will my medical team watch for side effects and prevent them from becoming serious?

In general, side effects with TRISENOX<sup>®</sup> stop when you stop treatment. Your doctor or nurse will carefully monitor your condition during your treatments. This will allow them to manage any side effect you might experience. The three most common potentially serious side effects that have been reported are described below:

Your body may begin to make more white blood cells (the cells that fight infection) than usual in the first few weeks after you start TRISENOX<sup>®</sup> therapy. This is called hyperleukocytosis. It does not generally cause any significant problems, and it does not require the treatment to be stopped or interrupted. Your doctor will monitor your blood counts for hyperleukocytosis during therapy.

You might experience symptoms related to changes in the development of your blood cells, called differentiation syndrome. These symptoms include fever, sudden weight gain, and bone or joint pain. Also, fluid can build up around the heart, or in the lungs, and chest, causing shortness of breath or difficulty breathing. This syndrome is treated immediately with high doses of corticosteroids and diuretics (fluid pills). Your medical team will monitor for these signs or symptoms, but it is also important for you to tell your doctor or nurse promptly if you experience any of

these symptoms. You will be asked to weigh yourself every day during the first few weeks of TRISENOX<sup>®</sup> therapy, and to report any increases in weight right away.

You might experience changes in your heart rhythm. In particular, some patients experience QT interval prolongation, which means that the time it takes the heart to relax in between beats is longer than usual. If extreme, QT prolongation can cause fainting or other more serious effects. Your medical team will perform tests called electrocardiograms (ECGs) during treatment to monitor any changes in heart rhythm. Your doctor will also check your blood frequently and may prescribe daily doses of magnesium or potassium if your blood shows that you have low levels of these electrolytes. Maintaining the right levels of these important electrolytes helps prevent changes in heart rhythm. You may have to stop TRISENOX<sup>®</sup> therapy for a short time if your blood levels of magnesium or potassium are too low or if you develop QT prolongation.

In general, side effects associated with TRISENOX<sup>®</sup> cease after treatment is stopped, and toxicities are manageable if properly monitored and treated when necessary. In addition to QT interval prolongation, the most common drug-related side effects in the U.S. clinical studies of arsenic trioxide in patients with relapsed acute promyelocytic leukemia (APL) included leukocytosis, gastrointestinal (nausea, vomiting, diarrhea and abdominal pain), fatigue, swelling, hyperglycemia

(an abnormal increased content of sugar in the blood), shortness of breath, cough, rash or itching, headaches, and dizziness.

Remember, your medical team will perform frequent laboratory tests to be certain that TRISENOX<sup>®</sup> can be continued safely, to look for side effects, and to monitor the effects that cancer is having on your body.

### 7 Will TRISENOX<sup>®</sup> treatment have any serious impact on my daily life?

TRISENOX<sup>®</sup> may be less likely to have an impact on your daily life than other cancer medications you may have taken in the past. For example, few patients receiving TRISENOX<sup>®</sup> have had hair loss or pain and inflammation of mucus membranes, such as mouth sores.

You may have some mild nausea, stomach upset, or, less commonly, vomiting, during or shortly after administration of TRISENOX<sup>®</sup>. These side effects are usually not severe enough to require treatment with anti-nausea drugs. Of course, anti-nausea drugs can be used if you need them. To reduce the chance of developing nausea or an upset stomach, it is a good idea to have something to eat before going to the clinic for treatment with TRISENOX<sup>®</sup>. Antacids can also provide some relief from stomach discomfort.

You may develop diarrhea while receiving courses of TRISENOX<sup>®</sup>. Ask your doctor whether over-the-counter (OTC) medicines that you can buy in the drugstore or grocery

store can be used if you have diarrhea. You should drink plenty of fluids if you do develop diarrhea. Tell your doctor or nurse if you develop diarrhea, since he or she may want to take a culture just to make sure there is no infection.

You may develop a rash during TRISENOX<sup>®</sup> treatment. Rashes can develop anywhere on the body, but most frequently occur on the back, chest, or abdomen. Rashes are usually not severe, although they may itch. You should tell your doctor if you develop a rash, and if the rash is itchy or bothersome, your doctor may prescribe a topical medication for you to put on your skin. Rashes may get better on their own during treatment, but if not, they will disappear after all the courses of TRISENOX<sup>®</sup> are complete. It is a good idea to avoid oil-based or perfumed skin products that can irritate the skin during treatment. Water-based soaps and lotions are a better choice to prevent skin irritation, and if a rash does occur, these products make it less likely that a skin infection will develop.

### 8 Will TRISENOX<sup>®</sup> interfere with other medications that I am taking?

Studies of TRISENOX<sup>®</sup> in combination with other medications have not been done, but some information is available. You should tell your doctor all of the medications you are taking, both prescription and over-the-counter, and including any vitamins or herbal supplements. Your doctor will monitor your condition very closely, especially if you are taking any drugs that affect

your heart. For example, some anti-nausea drugs, antidepressants, and antibiotics can cause QT interval prolongation, the same heart rhythm change that can happen with TRISENOX®.

**9** What about vitamins, herbs, or natural remedies? Will TRISENOX® interact with them?

Because very little information is available about the possible side effects and interactions of natural remedies, such as Ginkgo Biloba or St. John's Wort, your doctor may suggest you stop taking them during therapy. For example, some herbs can affect electrolyte levels or cause diarrhea, and potentially increase the chances of side effects with TRISENOX®.

You may be able to continue to take your vitamins, but you should discuss this with your doctor to be sure.

**10** Will I need someone to accompany me when I go for treatment?

If you are being treated as an outpatient, you can drive yourself to treatment. If you have a particularly long drive, however, you might find that you are tired after treatment. As a precaution, it is a good idea to let your family or friends know that you might need their help to get to and from the treatment center.

**Apoptosis** – (a-pop-toe´ -sis)

The self-destruction, or suicide, of cancer cells. Apoptosis is one of the likely mechanisms for how TRISENOX® works.

**Corticosteroids** – (kor-ti-koe-stair´ -oyds)

Also called "steroids," corticosteroids are powerful anti-inflammatory agents used to treat many diseases and conditions. They are similar to a protein called cortisol that is made in the adrenal glands. Some corticosteroids that you may have heard of are prednisone and dexamethasone.

**Differentiation Syndrome** – (diff-er-en-sheeay´ -shun sin´ -drome)

A group of related symptoms that can occur during treatment with TRISENOX® because of changes in the development and death of blood cells. Symptoms of differentiation syndrome include fever, weight gain, joint or muscle aches, and difficulty breathing. This syndrome is treated with corticosteroids.

**Diuretics** – (dye´ yur-et-iks) Medications that reduce the amount of fluid, or water, in the body.

**Electrocardiogram** – (ee-lek´ -troe-kardeeo gram)

Also called an ECG, is a non-invasive test to evaluate heart rhythms. Electrodes are placed on the body, and an electrical reading of the heart's contractions is produced. From this reading, doctors can tell if there are any abnormal changes in the heart's rhythm.







This booklet has been  
prepared by  
Cell Therapeutics, Inc. (CTI),  
a company committed to  
developing oncology products  
aimed at making cancer  
more treatable. For more  
information about TRISENOX<sup>®</sup>,  
visit our website:  
[www.cticseattle.com](http://www.cticseattle.com)



Making cancer more treatable

Cell Therapeutics, Inc. 501 Elliott Ave., West Suite 400 Seattle, WA 98119

SA-70-12/30/02