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## Arsenic Trioxide Vial

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### Description

Side Effects Pain/redness/swelling at the injection site, nausea, vomiting, diarrhea, stomach/abdominal pain, tiredness, cough, headache, or dizziness may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly. People using this medication may have serious side effects. However, you have been prescribed this drug because your doctor has judged that the benefit to you is greater than the risk of side effects. Careful monitoring by your doctor may decrease your risk. Both leukemia and this medication can lower the body's ability to fight an infection. Tell your doctor promptly if you develop any signs of an infection such as sore throat that doesn't go away, unexplained fever, or chills. Tell your doctor right away if you have any serious side effects, including: easy bleeding/bruising, nosebleed, increased thirst, signs of kidney problems (such as change in the amount of urine), bone/joint pain, decreased appetite, unusual weight loss, muscle pain/stiffness/spasm, numbness/tingling, swollen hands/legs/feet, symptoms of liver disease (such as nausea/vomiting that doesn't stop, severe stomach/abdominal pain, yellowing eyes/skin, dark urine). Get medical help right away if you have any very serious side effects, including: chest pain, severe dizziness/fainting, fast/irregular heartbeat, coughing up blood, mental/mood changes (such as confusion), muscle weakness, bloody/black/tarry stool, vomit that looks like coffee grounds. People who are treated with this medication may rarely get other cancers. Consult your doctor for more details. A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice any other effects not listed above, contact your doctor or pharmacist. In the US – Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at [www.fda.gov/medwatch](http://www.fda.gov/medwatch). In Canada – Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345. Uses Arsenic trioxide is used to treat a type of leukemia (acute promyelocytic leukemia-APL). How to use Arsenic Trioxide Vial Read the Patient Information Leaflet if available from your pharmacist before you start using arsenic trioxide and each time you get a treatment. If you have any questions, ask your doctor or pharmacist. This medication is given by injection into a vein by a health care professional over 2 hours as directed by your doctor, usually once daily. The injection may be injected more slowly (such as over 4 hours) if you have a reaction to the medication such as dizziness, flushing, or fast heartbeat. The dosage, treatment schedule, and length of treatment are based on your weight, medical condition, and response to treatment. Your doctor will order tests (such as EKG, blood minerals) to find the right dose for you. Your

next dose may need to be rescheduled if your heartbeat or blood tests are abnormal. Warnings Arsenic trioxide is a strong medication that can cause serious, rarely fatal side effects. To decrease your risk, your doctor will monitor you closely during treatment. Rarely, this medication may cause a serious condition called APL differentiation syndrome. Tell your doctor right away if the following effects occur: unusual/unexplained fever, shortness of breath/difficulty breathing, and/or weight gain. Your doctor may direct you to weigh yourself regularly and report any sudden weight gain. Your doctor may also perform certain exams or tests (such as lung exam, X-rays) to determine if this syndrome has developed. Rarely, this medication can also cause serious (rarely fatal) heart problems (such as AV block, torsades de pointes-type arrhythmias). Tell your doctor if you have any medical history of heart problems (such as fast/irregular heartbeat, heart failure), kidney problems, low levels of minerals in your blood (such as calcium, potassium, magnesium). Also tell your doctor if you take any medications that increase your risk for these heart problems or low levels of minerals (see also Drug Interactions section). To decrease your risk, your doctor may order a heart rhythm test (EKG) or blood tests before and during treatment. Get medical help right away if you develop severe dizziness, fainting, or fast/irregular heartbeat. This medication may increase your risk of getting a rare but very serious (possibly fatal) brain disorder. This risk may be higher if you have low levels of thiamine (vitamin B1), alcohol use disorder, or difficulty absorbing nutrition from food (malabsorption syndrome). Get medical help right away if you have any of these side effects: clumsiness, loss of coordination/balance, weakness, sudden change in your thinking (such as confusion, difficulty concentrating, memory loss), difficulty talking/walking, seizures, vision changes. Interactions Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval. Many drugs besides arsenic trioxide may affect the heart rhythm (QT prolongation), including amiodarone, dofetilide, pimozide, procainamide, quinidine, sotalol, macrolide antibiotics (such as erythromycin), ziprasidone, among others. Before using arsenic trioxide, report all medications you are currently using to your doctor or pharmacist. Some products that may interact with this drug are: drugs that lower blood minerals (such as amphotericin B), drugs that may harm the immune system (such as chemotherapy), other drugs that can cause bleeding/bruising (including antiplatelet drugs such as clopidogrel, NSAIDs such as ibuprofen/naproxen, "blood thinners" such as warfarin/dabigatran). Aspirin can increase the risk of bleeding when used with this medication. However, if your doctor has directed you to take low-dose aspirin for heart attack or stroke prevention (usually 81-162 milligrams a day), you should continue taking it unless your doctor instructs you otherwise. Ask your doctor or pharmacist for more details. Precautions Before using this medication, tell your doctor or pharmacist if you are allergic to arsenic; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Before using this medication, tell your doctor or pharmacist your medical history, especially: kidney disease, diabetes. Arsenic trioxide may cause a condition that affects the heart rhythm (QT prolongation). QT prolongation can rarely cause serious (rarely fatal) fast/irregular heartbeat and other symptoms (such as severe dizziness, fainting) that need medical attention right away. The risk of QT prolongation may be increased if you have certain medical conditions or are taking other drugs that may cause QT prolongation. Before using arsenic trioxide, tell your doctor or pharmacist of all the drugs you take and if you have any of the following conditions: certain heart problems (heart failure, slow heartbeat, QT prolongation in the EKG), family history of certain heart problems (QT prolongation in the EKG, sudden cardiac death). Low levels of potassium or magnesium in the blood may also increase your risk of QT prolongation. This risk may increase if you use certain drugs (such as diuretics/"water pills") or if you have conditions such as severe sweating, diarrhea, or vomiting. Talk to your doctor about using arsenic trioxide safely. This drug may make you dizzy. Alcohol or marijuana (cannabis) can make you more dizzy. Do not drive, use machinery, or do anything that needs alertness until you can do it safely. Limit alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis). Arsenic trioxide can make you more likely to get infections or may make current infections worse. Stay away from anyone who has an infection that may easily spread (such as chickenpox, COVID-19, measles, flu). Talk to your doctor if you have been exposed to an infection or for more details. Tell your health care professional that you are using arsenic trioxide before having any immunizations/vaccinations. Avoid contact with people who have recently

received live vaccines (such as flu vaccine inhaled through the nose). To lower the chance of getting cut, bruised, or injured, use caution with sharp objects like razors and nail cutters, and avoid activities such as contact sports. Older adults may be more sensitive to the side effects of this drug, especially QT prolongation (see above). Tell your doctor if you are pregnant or plan to become pregnant. You should not become pregnant while using arsenic trioxide. Arsenic trioxide may harm an unborn baby. Your doctor should order a pregnancy test before you start this medication. Women using this medication should ask about reliable forms of birth control during treatment and for 6 months after the last dose. Men using this medication should ask about reliable forms of birth control during treatment and for 3 months after the last dose. If you or your partner becomes pregnant, talk to your doctor right away about the risks and benefits of this medication. This medication passes into breast milk. Because of the possible risk to the infant, breast-feeding is not recommended while using this drug and for 2 weeks after the last dose. Consult your doctor before breast-feeding.

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## Side Effects

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## Uses

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## Interactions

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## Other Details

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