

ARSENIC TRIOXIDE ACCORD

Arsenic Trioxide Concentrated Injection 10 mg/10 mL

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Arsenic Trioxide Accord. It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Arsenic Trioxide Accord against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Arsenic Trioxide Accord is used for

Arsenic Trioxide Accord is used to treat acute promyelocytic leukaemia also known as APL.

This medicine works by interfering with the growth of cancer cells and slowing their growth and spread in the body.

Your doctor may have prescribed it for another reason.

Ask your doctor if you have any questions about why Arsenic Trioxide Accord has been prescribed for you.

This medicine is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children under the age of 5 years.

Before Receiving Arsenic Trioxide Accord

When you must not be given it

You should not be given Arsenic Trioxide Accord if you have an allergy to:

- any medicine containing arsenic or arsenic trioxide
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

You should not be given this medicine if you are pregnant.

It may affect your developing baby if you are given it during pregnancy.

Men and women of childbearing age must use effective birth control while they are being treated with Arsenic Trioxide Accord. Your doctor will discuss this with you.

Do not breast-feed if you are being given this medicine.

The active ingredient in Arsenic Trioxide Accord passes into breast milk and there is a possibility that your baby may be affected.

You should not be given this medicine if the solution is cloudy, discoloured, turbid, or a precipitate or particles are present. The solution is normally clear and colourless.

You should not be given this medicine if, when diluted with another solution, it causes the solution to precipitate, become cloudy, turbid, discolour, or particles are visible.

You should not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are given this medicine after the expiry date has passed, it may not work as well.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- low levels of potassium or magnesium in the body (electrolyte imbalance)
- congestive heart failure
- rapid or irregular heartbeat
- liver problems
- a history of kidney problems.

Tell your doctor if you are pregnant, plan to become pregnant or breast feeding.

Your doctor can discuss with you the risks and benefits involved in using Arsenic Trioxide Accord.

Pregnancy tests should be done in women of childbearing age prior to the treatment with Arsenic Trioxide Accord.

If you have not told your doctor about any of the above, tell him/her

before you are given Arsenic Trioxide Accord.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket, health food shop, naturopath or herbalist.

Some medicines and Arsenic Trioxide Accord may interfere with each other.

These include:

- fluid or water tablets (diuretics)
- some medicines used to treat fungal infections such as amphotericin B
- medicines which affect heart rhythm (prolong the Q-T interval) for example:
 - some antibiotics e.g. erythromycin
 - antipsychotics e.g. thioridazine
 - some types of antiarrhythmics e.g. quinidine
 - antidepressants e.g. amitriptyline
 - some antihistamines e.g. terfenadine.

Ask your doctor for more information on which medicines to be careful with or avoid while using Arsenic Trioxide Accord.

These medicines may be affected by Arsenic Trioxide Accord or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given this medicine.

How Arsenic Trioxide Accord is given

Arsenic Trioxide Accord must only be given by a doctor or nurse under the supervision of a doctor

experienced in managing patients with acute leukaemia.

Arsenic Trioxide Accord is diluted and then given as a slow injection into a vein.

Your doctor will decide what dose of Arsenic Trioxide Accord you will receive and how long you will receive it. This depends on your medical condition and other factors, such as your weight.

If you receive too much (overdose)

Arsenic Trioxide Accord must only be given by a doctor or nurse so an overdose is not likely to occur. Contact your doctor if you are concerned about the dose.

Symptoms of an overdose are similar to side effects but are more severe and are listed under Side Effects below.

While you are given Arsenic Trioxide Accord

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you have been given Arsenic Trioxide Accord.

Tell any other doctors, dentists, and pharmacists who treat you that you have been given this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you have been given this medicine.

It may affect other medicines used during surgery.

If you become pregnant while being given this medicine, tell your doctor immediately.

Men and women of childbearing age should take effective birth control precautionary method while they are being treated with Arsenic Trioxide Accord.

If you are about to have any blood tests, tell your doctor that you are being given this medicine. It may interfere with the results of some tests.

Be sure to keep all your doctor's appointments so your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things to be careful of

Be careful driving or operating machinery until you know how Arsenic Trioxide Accord affects you.

This medicine may cause dizziness, tiredness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side Effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Arsenic Trioxide Accord.

This medicine helps most people with APL, but it may have unwanted side effects. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- tiredness
- fever
- nausea , vomiting, diarrhoea, stomach pain, sore mouth
- bleeding or bruising more easily than usual
- sore throat
- cough
- difficulty breathing
- headache
- difficulty sleeping
- fast heart beat
- skin rash, itching
- bone or joint pain
- numbness, aching or weakness of the arms and legs or other muscles
- tingling in the hands and feet
- fits or convulsions
- mood changes
- liver dysfunction, abnormal liver enzymes
- low potassium levels
- low white blood cell and platelet count
- bleeding, blood clot
- infection
- signs of hyperglycaemia (high blood sugar):
 - large amounts of urine
 - excessive thirst
 - dry mouth and skin.

The above list includes serious side effects that may require medical attention. The above list includes the most common side effects of your medicine.

If any of the following happen, tell your doctor immediately or go to the Emergency Department at your nearest hospital:

- chest pain
- difficulty or pain when breathing
- stroke
- passing little or no urine
- signs of APL differentiation syndrome as listed below:

- unexplained fever
- shortness of breath, difficulty breathing
- and/or weight gain.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation .

Tell your doctor or nurse if you notice any other effect that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects, for example, change in number of white blood cells can only be found when your doctor does tests from time to time to check your progress.

Storage

Arsenic Trioxide Accord will be stored in the surgery, pharmacy or ward of a hospital. The injection is kept in a cool dry place where the temperature stays below 30°C.

Once diluted the solution should be used as soon as possible. It is a sterile solution for single use. If storage is necessary the prepared solution should be refrigerated between 2°C and 8°C and stored for no longer than 24 hours before discarding.

Product Description

What it looks like

Arsenic Trioxide Accord is a clear colourless solution in a vial. It is available in packs of 1, 5 or 10.

Ingredients

Active Ingredient:

Arsenic trioxide

Inactive Ingredients:

Sodium hydroxide

Hydrochloric acid

Water for injections

This medicine does not contain lactose, sucrose, gluten, tartrazine, or other azo dyes or preservatives.

Name and Address of the Sponsor

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Australian Register numbers

10 mg/10 mL: AUST R 324603

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