

Arsenic trioxide - AFT

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Arsenic trioxide - AFT?

Arsenic trioxide - AFT contains the active ingredient arsenic trioxide. Arsenic trioxide - AFT is used to treat acute promyelocytic leukaemia also known as APL.

For more information, see Section [1. Why am I using Arsenic trioxide - AFT?](#) in the full CMI.

2. What should I know before I use Arsenic trioxide - AFT?

Do not use if you have ever had an allergic reaction to arsenic trioxide or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Arsenic trioxide - AFT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Arsenic trioxide - AFT and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Arsenic trioxide - AFT?

Arsenic trioxide – AFT injections are administered to you by doctors or nurses in hospital.

More instructions can be found in Section [4. How do I use Arsenic trioxide - AFT?](#) in the full CMI.

5. What should I know while using Arsenic trioxide - AFT?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, surgeon, dentist or pharmacist you visit that you are using Arsenic trioxide - AFT.• If you become pregnant or are about to have any blood tests, tell your doctor that you are being given this medicine.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Arsenic trioxide - AFT affects you. Refer to full CMI for details.
Looking after your medicine	<ul style="list-style-type: none">• Arsenic trioxide – AFT will be stored in the pharmacy or on the hospital ward and is kept below 30 °C.

For more information, see Section [5. What should I know while using Arsenic trioxide - AFT?](#) in the full CMI.

6. Are there any side effects?

Some of the serious side effects include nausea, vomiting, diarrhea, sore mouth/ throat, unusual bleeding or blood clots, infection, fever, cough, skin rash/ itching, pain in joints, numbness, aching or weakness of arms/ legs or other muscles, tingling in hands/ feet, tiredness, difficulty sleeping, fast heartbeat, fits, mood changes, liver dysfunction, low potassium or white blood cells or platelets, signs of high blood sugar levels. Very serious side effects include chest pain, difficulty or pain while breathing, stroke, passing little or no urine, signs of APL differentiation syndrome like unexplained fever, shortness of breath, difficulty breathing, weight gain.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Arsenic trioxide - AFT

Active ingredient: *arsenic trioxide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Arsenic trioxide - AFT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Arsenic trioxide - AFT.**

Where to find information in this leaflet:

- [1. Why am I using Arsenic trioxide - AFT?](#)
- [2. What should I know before I use Arsenic trioxide - AFT?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Arsenic trioxide - AFT?](#)
- [5. What should I know while using Arsenic trioxide - AFT?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Arsenic trioxide - AFT?

Arsenic trioxide - AFT contains the active ingredient arsenic trioxide. Arsenic trioxide - AFT works by interfering with the growth of cancer cells and slowing their growth and spread in the body.

Arsenic trioxide - AFT is used to treat acute promyelocytic leukaemia also known as APL.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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.

2. What should I know before I use Arsenic trioxide - AFT?

Warnings

Do not use Arsenic trioxide - AFT if:

- you are allergic to any medicine containing arsenic or arsenic trioxide, or 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 face, lips, tongue or other parts of body, rash, itching or hives on skin. Always check the ingredients to make sure you can use this medicine.
- 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 – AFT. Your doctor will discuss this with you.

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

The active ingredient in Arsenic trioxide - AFT 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.

Check with your doctor if you:

- allergies to any other medicines, foods, preservatives or dyes
- 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 heart beat
 - liver problems
 - a history of kidney problems

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor can discuss with you the risks and benefits involved in using Arsenic trioxide – AFT.

Pregnancy tests should be done in women of childbearing age prior to the treatment with Arsenic trioxide – AFT.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

These medicines may be affected by Arsenic trioxide – AFT or may affect how well it works. You may need different

amounts of your medicines, or you may need to take different medicines.

Some medicines may interfere with Arsenic trioxide-AFT and affect how it works. 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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Arsenic trioxide - AFT. Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given this medicine.

4. How do I use Arsenic trioxide?

How much to use

- Your doctor will decide what dose you will receive and how long you will receive it. This depends on your medical condition and other factors, such as your weight.
- Follow the instructions provided and use Arsenic trioxide - AFT until your doctor tells you to stop.

When to use Arsenic trioxide - AFT

Your doctor will decide the dosing schedule for you.

How to use Arsenic trioxide - AFT

- Arsenic trioxide – AFT must only be given by a doctor or nurse under the supervision of a doctor experienced in managing patients with acute leukaemia.
- Arsenic trioxide – AFT is diluted and then given as a slow infusion into a vein.

If you forget to use Arsenic trioxide - AFT

Arsenic trioxide – AFT will be given to you under close medical supervision. It is unlikely that a dose would be missed.

However, tell your doctor or pharmacist if you think that a dose has been forgotten.

If you use too much Arsenic trioxide - AFT

As Arsenic trioxide – AFT is given to you under the supervision of your doctor, it is unlikely that you will have too much.

However, if you experience any side effects after being given Voriconazole - AFT, **you should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while using Arsenic trioxide - AFT?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you have been given Arsenic trioxide – AFT.
- 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 – AFT.
- 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.
- Keep all of your doctor's appointments so that 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 you should not do

- Do not stop using this medicine suddenly. Follow all you doctor's instructions regarding the dosing schedule.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Arsenic trioxide - AFT 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.

Looking after your medicine

Arsenic trioxide – AFT 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.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
Digestion-related: <ul style="list-style-type: none">• Nausea• Vomiting• Diarrhea and/ or stomach pain• Sore mouth Bleeding-related: <ul style="list-style-type: none">• Bleeding or bruising more easily than usual• Bleeding, blood clot Infection/ allergy-related: <ul style="list-style-type: none">• Infection• Fever• Sore throat• Cough• Skin rash, itching Muscles/ bones-related: <ul style="list-style-type: none">• Bone or joint pain• Numbness, aching or weakness of the arms and legs or other muscles• Tingling in hands and feet Body as a whole: <ul style="list-style-type: none">• Tiredness• Difficulty sleeping• Fast heart beat• Fits or convulsions• Mood changes• Liver dysfunction, abnormal liver enzymes• Low potassium levels• Low white blood cell and platelet count• Signs of hyperglycemia (high blood sugar):<ul style="list-style-type: none">• Large amounts of urine• Excessive thirst• Dry mouth or skin	Tell your doctor or nurse as soon as possible if you notice any of these side effects. <p>These are serious side effects and may require medical attention. This list includes the most common side effects of your medicine.</p> <p>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.</p>

Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none">• Chest pain• Difficulty or pain while breathing• Stroke• Passing little or no urine• Signs of APL differentiation syndrome as listed below:<ul style="list-style-type: none">• Unexplained fever• Shortness of breath, difficulty breathing, and/or• Weight gain	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects. <p>You may need urgent medical attention or hospitalization.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Arsenic trioxide - AFT contains

Active ingredient (main ingredient)	Arsenic trioxide
Other ingredients (inactive ingredients)	Sodium hydroxide (for pH adjustment) Hydrochloric acid (for pH adjustment)
Potential allergens	Nil

Do not take this medicine if you are allergic to any of these ingredients.

What Arsenic trioxide - AFT looks like

Arsenic trioxide – AFT is a clear, colourless solution in a clear glass ampoule or vial.

It is available in a 10 mL ampoule (Aust R 337670) and 12 mL vial (Aust R 384971).

Who distributes Arsenic trioxide - AFT

AFT Pharmaceuticals Pty Ltd.

North Ryde, NSW

Email: customer.service@aftpharm.com

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