

## 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 being treated with Phenasen?

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

For more information, see Section [1. Why am I being treated with Phenasen?](#) in the full CMI.

### 2. What should I know before I am treated with Phenasen?

Do not use if you have ever had an allergic reaction to Phenasen 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 am treated with Phenasen?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Phenasen 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 is How is Phenasen used?

Phenasen is diluted and then given as a slow infusion into a vein by a doctor or nurse experienced in managing patients with acute leukaemia.

More instructions can be found in Section [4. How is Phenasen used?](#) in the full CMI.

### 5. What should I know while I am being treated with Phenasen?

<b>Things you should do</b>	<ul style="list-style-type: none"> <li>Remind any doctor, nurse, dentist or pharmacist you visit that you are using Phenasen.</li> <li>If you are pregnant, plan to become pregnant or breastfeeding or are about to have any blood tests tell your doctor that you are being given this medicine.</li> <li>Tell your doctor if you have allergies to any other medicine, food, preservatives or dyes.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>You should not fall pregnant or breastfeed whilst being treated with Phenasen nor for a time period following the completion of the last dose of the last cycle.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>Be careful driving or operating machinery while you are being treated with Phenasen until you know how Phenasen affects you.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>Phenasen 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.</li> </ul>

For more information, see Section [5. What should I know while I am being treated with Phenasen?](#) in the full CMI.

### 6. Are there any side effects?

Some of the serious side effects include tiredness, fever, nausea, vomiting, diarrhoea, stomach pain, sore mouth, unusual bleeding or bruising, blood clotting, sore throat, cough, difficulty breathing, headache, difficulty sleeping, fast heartbeat, skin rash, itching, bone or joint pain, numbness, aching or weakness of the arm and leg or other muscles, tingling in the hands and feet, fits or convulsions, mood change, liver dysfunction, low potassium level, low white blood cell and platelet count, infection, signs of high blood sugar like large amounts of urine, excessive thirst, dry mouth and skin. Very serious side effects include chest pain, difficulty or pain when breathing, stroke, passing little or no urine, signs of APL differentiation syndrome like unexplained fever, shortness of breath, 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.

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Phenasen. **You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about using Phenasen.**

### Where to find information in this leaflet:

- [1. Why am I being treated with Phenasen?](#)
- [2. What should I know before I am treated with Phenasen?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Phenasen used?](#)
- [5. What should I know while I am being treated with Phenasen?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I being treated with Phenasen?

**Phenasen contains the active arsenic trioxide.** Phenasen is an anticancer drug.

**Phenasen is used to treat acute promyelocytic leukaemia also known as APL.**

## 2. What should I know before I am treated with Phenasen?

### Warnings

#### You should not be given Phenasen if:

- you are allergic to any medicine containing arsenic or arsenic trioxide, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are pregnant or breastfeeding
- the solution is cloudy, discoloured, turbid, or a precipitate or particles are present. The solution is normally clear and colourless.
- when diluted with another solution, it causes the solution to precipitate, become cloudy, turbid, discolour, or particles are visible
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

#### Check with your doctor if you have or have had:

- low levels of potassium or magnesium in the body (electrolyte imbalance)
- taken any medicines for any other condition
- congestive heart failure
- rapid or irregular heartbeat
- 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 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 Phenasen.

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

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

Women of childbearing age must use effective birth control while they are being treated with Phenasen and for 6 months following completion of treatment.

Pregnancy tests should be done in women of childbearing age prior to treatment with Phenasen.

Men must use effective contraceptive measures and not father a child while receiving Phenasen and for 3 months following completion of treatment.

#### Do not breastfeed if you are being given this medicine.

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

The active ingredient in Phenasen passes into breast milk and there is a possibility that your baby may be affected. Do not breastfeed prior to and throughout all cycles of administration and for two weeks after the last dose of the final cycle.

If you have not told your doctor about any of the above, tell him/her before you are given Phenasen.

## 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.

#### Some medicines may interfere with Phenasen and affect how it works.

- 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 Phenasen.**

These medicines may be affected by Phenasen 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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Phenasen.**

#### 4. How is Phenasen used?

##### How much to use

- Phenasen is diluted and then given as a slow infusion into a vein.
- Your doctor will decide what dose of Phenasen you will receive and for how long you will receive it. This depends on your medical condition and other factors, such as your weight.

**Phenasen must only be given by a doctor or nurse under the supervision of a doctor experienced in managing patients with acute leukaemia.**

##### If you use too much Phenasen

**Phenasen 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.

#### 5. What should I know while I am being treated with Phenasen?

##### 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 Phenasen.**

**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.**

Women of childbearing age must use effective birth control while they are being treated with Phenasen and for 6 months following completion of treatment.

Pregnancy tests should be done in women of childbearing age prior to treatment with Phenasen.

Men must use effective contraceptive measures and not father a child while receiving Phenasen and for 3 months following completion of treatment.

**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.

**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.

##### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Phenasen 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.

##### Looking after your medicine

- Phenasen 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.

**Keep it where young children cannot reach it.**

#### 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, nurse or pharmacist if you have any further questions about side effects.

## Serious side effects

Serious side effects	What to do
<p><b>Digestion related:</b></p> <ul style="list-style-type: none"> <li>• nausea</li> <li>• vomiting</li> <li>• diarrhoea</li> <li>• stomach pain</li> <li>• sore mouth</li> </ul> <p><b>Bleeding related:</b></p> <ul style="list-style-type: none"> <li>• bleeding or bruising more easily than usual</li> <li>• bleeding, blood clot</li> </ul> <p><b>Muscle/bone related:</b></p> <ul style="list-style-type: none"> <li>• numbness, aching or weakness of the arms and legs or other muscles</li> <li>• bone or joint pain</li> <li>• tingling in the hands and feet</li> </ul> <p><b>Nervous system related:</b></p> <ul style="list-style-type: none"> <li>• fits or convulsions</li> <li>• mood changes</li> <li>• headache</li> <li>• difficulty sleeping</li> </ul> <p><b>Other:</b></p> <ul style="list-style-type: none"> <li>• tiredness</li> <li>• fever</li> <li>• sore throat</li> <li>• cough</li> <li>• difficulty breathing</li> <li>• fast heartbeat</li> <li>• skin rash</li> <li>• itching</li> <li>• liver dysfunction, abnormal liver enzymes</li> <li>• low potassium levels</li> <li>• low white blood cell and platelet count</li> <li>• signs of hyperglycaemia (high blood sugar): <ul style="list-style-type: none"> <li>• large amounts of urine</li> <li>• excessive thirst</li> <li>• dry mouth and skin</li> </ul> </li> </ul>	<p><b>Speak to your doctor if you have any of these serious side effects and they worry you.</b></p>

## Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none"> <li>• chest pain</li> <li>• difficulty or pain when breathing</li> <li>• stroke</li> <li>• passing little or no urine</li> <li>• signs of APL differentiation syndrome as listed below: <ul style="list-style-type: none"> <li>• unexplained fever</li> <li>• shortness of breath, difficulty breathing, and/or</li> <li>• weight gain.</li> </ul> </li> </ul>	<p><b>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.</b></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](http://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 Phenasen contains

<b>Active ingredient (main ingredient)</b>	arsenic trioxide
<b>Other ingredients (inactive ingredients)</b>	sodium hydroxide (for pH adjustment) hydrochloric acid (for pH adjustment)

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

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

### What Phenasen looks like

Phenasen is a clear, colourless solution in a clear glass vial sealed with a grey rubber stopper and aluminium seal with a plastic flip off cap.

Phenasen is available in a 10 mL vial.

(Aust R 152760).

### Who distributes Phenasen

Phenasen is manufactured and supplied in Australia by:

Phebra Pty Ltd  
19 Orion Road, Lane Cove West,  
NSW 2066, Australia.  
Telephone: 1800 720 020

This leaflet was prepared in August 2023.

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