

# PROVEBLUE®

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## 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.

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### 1. Why am I using PROVEBLUE?

PROVEBLUE contains the active ingredient methylene blue. PROVEBLUE is used to treat abnormal blood pigment levels. These abnormal blood pigments do not carry oxygen properly.

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

### 2. What should I know before I use PROVEBLUE?

Do not use if you have ever had an allergic reaction to methylene blue, any other dyes, or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if your blood disorder has been caused by cyanide or chlorate poisoning, 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 PROVEBLUE?](#) in the full CMI.

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

Some medicines may interfere with PROVEBLUE 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 PROVEBLUE?**

- PROVEBLUE must only be given by a doctor or nurse
- Your doctor will decide what dose of PROVEBLUE you will receive and how long you will receive it

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

### **5. What should I know while using PROVEBLUE?**

#### **Things you should do**

- Remind any doctor, dentist or pharmacist you visit that you are using PROVEBLUE
- Keep all of your doctor's appointments

	<ul style="list-style-type: none"> <li>• Call your doctor straight away if you become pregnant while being given this medicine</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful before you drive or use any machines or tools until you know how PROVEBLUE affects you</li> <li>• PROVEBLUE may cause dizziness in some people</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Tell your doctor if you drink alcohol</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• PROVEBLUE Injection will be stored in the surgery, pharmacy or ward of a hospital</li> <li>• The injection is kept in a cool, dry place where the temperature is below 25°C</li> </ul>

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

## 6. Are there any side effects?

PROVEBLUE will cause a blue colour in your urine or bowel motions. Common less serious side effects include: nausea, vomiting, diarrhoea, headaches, dizziness, redness or swelling at the injection site, change in the colour of your skin, saliva, urine and/or faeces, tingling or numbness of the hands or feet, increased sensitivity to the sun or light. You may need urgent medical attention if you experience any of the following: chest pain, fast or irregular heartbeat, have problems with speaking, writing or reading, have signs of allergic reaction, signs of low blood pressure, signs of anaemia, yellowing of the skin and/or eyes (also called jaundice). This is not a full list of side effects. 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.

# PROVEBLUE®

**Active ingredient(s):** *methylene blue*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using PROVEBLUE. **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 PROVEBLUE.**

**Where to find information in this leaflet:**

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

## 1. Why am I using PROVEBLUE?

**PROVEBLUE contains the active ingredient methylene blue.** PROVEBLUE belongs to a group of medicines called dyes.

**PROVEBLUE is used to treat abnormal blood pigment levels. These abnormal blood pigments do not carry oxygen properly.**

## **PROVEBLUE is also used:**

- To stain bacteria to make them easier to see
- As a visible dye to help in the diagnosis of a number of conditions
- As a stain to dye certain body tissues during surgery

**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.

## **2. What should I know before I use PROVEBLUE?**

### **Warnings**

#### **Do not use PROVEBLUE if:**

- Your blood disorder has been caused by cyanide
- Your blood disorder has been caused by chlorate poisoning
- You are allergic to methylene blue, or any of the ingredients listed at the end of this leaflet
- You are allergic to any other dyes
- Always check the ingredients to make sure you can use this medicine
- You have glucose-6-phosphate dehydrogenase deficiency. This is an inherited condition
- You have or have had severe kidney problems

## **Check with your doctor if you:**

- Have any other medical conditions, such as:
  - kidney problems
  - diabetes. PROVEBLUE may need to be diluted with glucose solution. The amount of glucose may affect your blood glucose levels
- Take any medicines for any other condition
- Have allergies to any other medicines, foods, preservatives or dyes
- Have been given PROVEBLUE before. Tell them how long it was given for
- Have aniline poisoning

**PROVEBLUE is not recommended for long-term use.**

**The use of methylene blue in infants under 4 months of age is not recommended. Your doctor will discuss use of this medicine in infants younger than 4 months if needed.**

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.

You should not be given this medicine if you are pregnant or plan to become pregnant.

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

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.

**Some medicines may interfere with PROVEBLUE and affect how it works. These include:**

- Medicines used to treat depression known as serotonin reuptake inhibitors (SRIs) such as fluoxetine, sertraline and paroxetine and others such as fluvoxamine, escitalopram and citalopram, and serotonin and noradrenaline reuptake inhibitors (SNRIs) like clomipramine, venlafaxine, duloxetine and sibutramine, and monoamine oxydase inhibitors (MAOIs). When used in combination with these medicines PROVEBLUE may cause serotonin syndrome, which can be potentially life-threatening
- Opioids, such as, tramadol, pethidine, and dextromethorphan. When used in combination with these medicines PROVEBLUE may cause serotonin syndrome, which can be potentially life-threatening
- Dapsone - a medicine used to treat bacterial infections

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

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

## **4. How do I use PROVEBLUE?**

### **How much is given**

- Your doctor will decide what dose of PROVEBLUE you will receive
- This depends on your medical condition and other factors such as your weight
- Sometimes only a single dose of PROVEBLUE is required

### **When PROVEBLUE is given**

- Your doctor will decide when and for how long you will receive PROVEBLUE

### **How PROVEBLUE is given**

- PROVEBLUE must only be given by a doctor or nurse

- PROVEBLUE can be given in two ways depending upon what it is being used for. It can be given:
  - As an injection into a vein either diluted or undiluted, or
  - By mouth after dilution

## **If you forget to use PROVEBLUE**

PROVEBLUE should be given when you are told to by your doctor or nurse. If you miss the appointment for your dose, speak with your doctor or nurse.

## **If you are given too much PROVEBLUE**

As PROVEBLUE is always given to you in a hospital under the supervision of a doctor, it is unlikely that you will receive an overdose.

Symptoms of an overdose are the same as side effects but may be more severe. The symptoms of a side effect are listed under section [6. Are there any side effects?](#)

If you think that you have been given too much PROVEBLUE, you may need urgent medical attention.

### **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.**

## **5. What should I know while using PROVEBLUE?**

### **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 PROVEBLUE.**

Remind any doctor, dentist or pharmacist you visit that you are using PROVEBLUE.

**If you are about to have any blood tests, tell your doctor that you have been 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.

**Get up slowly if you feel light-headed, dizzy or faint when getting out of bed or standing up.** 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.

### **Call your doctor straight away if you:**

- Become pregnant while being given this medicine

- Notice the PROVEBLUE solution is discoloured, cloudy, or contains solids or particles. The solution is normally a clear, blue liquid
- Notice that when mixed with another solution, PROVEBLUE becomes discoloured, cloudy, or has visible solids or particles. The doctor or nurse will check to ensure the medicine is not past its expiry date and has not been tampered with.

## **Light exposure**

- PROVEBLUE can cause a photosensitivity reaction in the skin (sunburn-like reaction) when exposed to strong light sources, such as lights in operating rooms
- Protective measures against light exposure should be taken

## **Driving or using machines**

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

PROVEBLUE may cause dizziness in some people. If you feel dizzy do not drive, operate machinery or do anything else that could be dangerous.

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

## Looking after your medicine

- PROVEBLUE Injection will be stored in the surgery, pharmacy or ward of a hospital
- The injection is kept in a cool, dry place where the temperature is below 25°C

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 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.

**PROVEBLUE will cause a blue colour in urine or bowel motions.**

## Less serious side effects

Less serious side effects	What to do
<p data-bbox="204 432 671 533"><b>Gastrointestinal and Urinary:</b></p> <ul data-bbox="204 568 770 745" style="list-style-type: none"><li data-bbox="204 568 627 674">● nausea, vomiting, diarrhoea</li><li data-bbox="204 696 770 745">● pain when passing urine</li></ul> <p data-bbox="204 768 596 817"><b>Nervous System:</b></p> <ul data-bbox="204 853 751 1211" style="list-style-type: none"><li data-bbox="204 853 711 902">● headaches, dizziness</li><li data-bbox="204 925 627 1025">● mental confusion, anxiety, agitation</li><li data-bbox="204 1048 389 1097">● tremor</li><li data-bbox="204 1120 751 1211">● tingling or numbness of the hands or feet</li></ul> <p data-bbox="204 1238 320 1288"><b>Skin:</b></p> <ul data-bbox="204 1323 759 1794" style="list-style-type: none"><li data-bbox="204 1323 719 1424">● redness or swelling at the injection site</li><li data-bbox="204 1447 759 1671">● change in the colour of your skin, saliva, urine and/or faeces to blue or blue/green</li><li data-bbox="204 1693 735 1794">● increased sensitivity to the sun or light</li></ul> <p data-bbox="204 1821 331 1870"><b>Eyes:</b></p>	<p data-bbox="817 432 1374 656"><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● dilated pupils (increase in the size of the black part of the eyes)</li> </ul> <p><b>Taste:</b></p> <ul style="list-style-type: none"> <li>● taste disturbance or loss of taste</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Low blood pressure:</b></p> <ul style="list-style-type: none"> <li>● loss of consciousness</li> <li>● sever fatigue</li> <li>● feeling lightheaded</li> <li>● buzzing or ringing in the ear</li> <li>● blurring or loss of vision</li> </ul> <p><b>Anaemia:</b></p> <ul style="list-style-type: none"> <li>● tiredness and shortness of breath when exercising</li> <li>● dizziness</li> <li>● pale appearance</li> </ul> <p><b>Allergic reaction:</b></p> <ul style="list-style-type: none"> <li>● shortness of breath</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 serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● wheezing or difficulty breathing</li> <li>● swelling of the face, lips, tongue or other parts of the body</li> <li>● rash</li> <li>● itching or hives on the skin</li> </ul> <p><b>Heart:</b></p> <ul style="list-style-type: none"> <li>● chest pain</li> <li>● fast or irregular heartbeat</li> </ul> <p><b>General Body:</b></p> <ul style="list-style-type: none"> <li>● stomach pain</li> <li>● pain at the injection site</li> <li>● pain in extremities</li> <li>● high temperature</li> <li>● sweating more than normal</li> </ul> <p><b>Skin and Eyes:</b></p> <ul style="list-style-type: none"> <li>● yellow colouring to the skin and/or eyes; also called jaundice (this has only been reported in infants)</li> </ul> <p><b>Nervous System:</b></p>	

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• having problems with speaking, writing or reading</li> </ul>	

**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.

Some of these side effects (for example, changes in blood pressure) can only be found when your doctor does tests from time to time to check your progress.

## **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 PROVEBLUE contains

<b>Active ingredient (main ingredient)</b>	Methylene blue
<b>Other ingredients (inactive ingredients)</b>	Water for injections
<b>Potential allergens</b>	Not Applicable

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

## What PROVEBLUE looks like

PROVEBLUE is a clear, dark blue solution in a clear glass ampoule. It is available in a pack of 5 ampoules (Aust R 224639).

## Who distributes PROVEBLUE

PROVEBLUE is sponsored in Australia and New Zealand for Provepharm SAS by:

Clinect Pty Ltd

120 - 132 Atlantic Drive

Keysborough VIC 3173

Australia

Free Call Australia:

1800 899 005

Free Call New Zealand:

0800 138 803

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