

# PROVEBLUE®

50 mg/10 mL

methylene blue injection

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## Consumer Medicine Information

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### What is in this leaflet

This leaflet answers some common questions about PROVEBLUE. 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 PROVEBLUE against the benefits they expect it will have for you.

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

**Keep this leaflet in a safe place.**

You may need to read it again.

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### What PROVEBLUE is used for

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

This medicine belongs to a group of medicines called dyes.

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.

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.

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

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### Before you are given PROVEBLUE

#### ***When you must not be given it***

- if your blood disorder has been caused by cyanide
- if your blood disorder has been caused by chlorate poisoning

**You should not be given PROVEBLUE if you have an allergy to:**

- any medicine containing methylene blue
- any other dyes

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 have glucose-6-phosphate dehydrogenase deficiency.**

This is an inherited condition.

**You should not be given this medicine if you have or have had severe kidney problems.**

**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.

**You should not be given PROVEBLUE if the solution is discoloured, cloudy, turbid, or a precipitate is present.**

The solution is normally a clear, blue liquid.

**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.**

The doctor or nurse will check to ensure the medicine is not past its expiry date and has not been tampered with.

**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 kidney problems.**

**Tell your doctor if you have been given PROVEBLUE before and for how long.**

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

Your doctor can discuss with you the risks and benefits involved.

**Tell your doctor if you are a diabetic.**

PROVEBLUE may need to be diluted with glucose solution. The amount of glucose may affect your blood glucose levels.

**Tell your doctor if you have aniline poisoning.**

**If you have not told your doctor about any of the above, tell them before you are given PROVEBLUE.**

### ***Taking other medicines***

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

Some medicines and PROVEBLUE may interfere with each other. 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
- 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.

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

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## **How PROVEBLUE is given**

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**PROVEBLUE must only be given by a doctor or nurse.**

### ***How it is given***

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
- by mouth after dilution

### ***How much is given***

Your doctor will decide what dose of PROVEBLUE you will receive and how long you will receive it.

This depends on your medical condition and other factors such as your weight.

Sometimes only a single dose of PROVEBLUE is required.

### ***If you are given too much (overdose)***

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 Side effects below.

**If you notice any symptoms of an overdose immediately contact your doctor or go to the Emergency Department at the nearest hospital.**

**Contact the Poisons Information Centre on 13 11 26 for further advice on overdose management.**

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## **While you are being given PROVEBLUE**

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### ***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 PROVEBLUE.**

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

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

**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.

### ***Things to be careful of***

**Be careful driving or operating machinery until you know how PROVEBLUE affects you.**

This medicine may cause dizziness in some people. If you feel dizzy 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.

**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.**

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## Side effects

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**Tell your doctor or nurse as soon as possible if you do not feel well while you are being given PROVEBLUE.**

This medicine helps most people but it may have unwanted side effects in a few people. 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.**

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

**Tell your doctor or nurse if you notice any of the following and they worry you:**

- nausea, vomiting, diarrhoea
- headaches, dizziness
- mental confusion, anxiety, agitation
- tremor
- redness or swelling at the injection site
- change in the colour of your skin, saliva, urine and/or faeces to blue or blue/green
- dilated pupils (increase in the size of the black part of the eyes)
- pain when passing urine
- tingling or numbness of the hands or feet
- taste disturbance or loss of taste
- increased sensitivity to the sun or light

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

- stomach pain

- chest pain
- fast or irregular heartbeat
- pain at the injection site
- pain in extremities
- high temperature
- sweating more than normal
- low blood pressure signs of which may include loss of consciousness, severe fatigue, feeling lightheaded, buzzing or ringing in the ear and blurring or loss of vision
- signs of anaemia such as tiredness and shortness of breath when exercising and/or dizziness or pale appearance
- rash or hives
- yellow colouring to the skin and/or eyes; also called jaundice (this has only been reported in infants)
- having problems with speaking, writing or reading
- allergic reaction signs of which 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

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

**Tell your doctor or nurse if you notice anything 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, changes in blood pressure) can only be found when your doctor does tests from time to time to check your progress.

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## After being given PROVEBLUE

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### Storage

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.

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## Product description

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### *What it looks like*

PROVEBLUE is a clear, dark blue solution in a clear glass ampoule.

It is available in a pack of 5 ampoules.

### *Ingredients*

#### **Active ingredients:**

The active substance is methylene blue. One 10 mL ampoule contains 50 mg methylene blue.

#### **Inactive ingredients:**

Water for injections

### *Sponsor*

PROVEBLUE is sponsored in Australia for Provepharm SAS by:

Clinect Pty Ltd

120 - 132 Atlantic Drive

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Australia

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### *Date of Preparation*

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