

# Methylene Blue Injection

## 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 is Methylene Blue Injection being used?

Methylene Blue Injection contains the active ingredient methylene blue. Methylene Blue Injection helps with problems related to abnormal blood pigment levels, which can cause trouble in blood carrying oxygen effectively around the body.

For more information, see Section [1. Why is Methylene Blue Injection being used?](#) in the full CMI.

### 2. What should I know before Methylene Blue Injection is given?

You should not be given Methylene Blue Injection 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 you have any other medical conditions, take any other medicines, or are pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before Methylene Blue Injection is given?](#) in the full CMI.

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

Some medicines may interfere with Methylene Blue Injection 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 Methylene Blue Injection given?

- Methylene Blue Injection must only be given by a doctor or nurse.
- Your doctor will decide what dose of Methylene Blue Injection you will receive and for how long you will receive it.

More information can be found in Section [4. How is Methylene Blue Injection given?](#) in the full CMI.

### 5. What should I know while Methylene Blue Injection is being given?

<b>Things you should do</b>	<ul style="list-style-type: none"> <li>• Remind any doctor, dentist, or pharmacist you visit that you are using Methylene Blue Injection</li> <li>• Keep all of your doctor's appointments</li> <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 Methylene Blue Injection affects you</li> <li>• Methylene Blue Injection 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>• Methylene Blue 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 Methylene Blue Injection is being given?](#) in the full CMI.

### 6. Are there any side effects?

Methylene Blue Injection will cause a blue colour in your urine or bowel motions. Other common side effects include nausea, vomiting, diarrhoea, headaches, dizziness, redness or swelling at the injection site, change in the colour of your skin and/or saliva, increased sensitivity to the sun or light, dilated pupils and pain when passing urine. You may need urgent medical attention if you experience any of the following serious side effects: chest pain, fast or irregular heartbeat, problems with speaking, writing or reading, allergic reaction, low blood pressure, anaemia.

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.

# Methylene Blue Injection

Active ingredient: 50 mg/5 mL methylene blue

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Methylene Blue Injection. **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 Methylene Blue Injection.**

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

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

## 1. Why is Methylene Blue Injection being used?

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

**Methylene Blue Injection helps with problems related to abnormal blood pigment levels, which can cause trouble in blood carrying oxygen effectively around the body.**

**Methylene Blue Injection 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 Methylene Blue Injection is given?

### Warnings

**You should not be given Methylene Blue Injection if:**

- 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
- you have severe renal impairment

- you have an inherited condition called glucose-6-phosphate dehydrogenase deficiency
- you have cyanide poisoning
- you have chlorate poisoning

**Tell your doctor if you:**

- have any other allergies
- have any medical conditions, such as:
  - kidney problems
  - diabetes. Methylene Blue Injection 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 aniline poisoning

**Methylene Blue Injection is not recommended for long-term use.**

Tell your doctor if you have been given methylene blue before and for how long.

**The use of methylene blue in infants under 4 months of age is not recommended. Your doctor will discuss the 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 Methylene Blue Injection during pregnancy.

Tell your doctor if you are breastfeeding. Your doctor can discuss with you the risks and benefits involved.

### Light exposure

Methylene Blue Injection 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.

### 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 Methylene Blue Injection and affect how it works. These include:**

- serotonin reuptake inhibitors (SRIs): medicines used to treat depression, including Prozac, Zoloft and Aropax and others
- opioids: medicines used to treat pain, including tramadol, pethidine, and dextromethorphan
- dapsone – a medicine used to treat bacterial infections

These medicines may be affected by Methylene Blue Injection 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 Methylene Blue Injection.**

### 4. How is Methylene Blue Injection given?

#### How much is given

- Your doctor will decide how much Methylene Blue you will receive.
- This depends on your medical condition and other factors such as your weight.
- Sometimes only a single dose of Methylene Blue Injection is required.

#### When Methylene Blue Injection is given

- Your doctor will decide when and for how long you will receive Methylene Blue Injection.

#### How Methylene Blue Injection is given

- Methylene Blue Injection must only be given by a doctor or nurse.
- Methylene Blue Injection can be given in two ways depending upon what it is being used for. It can be given as an injection into a vein or by mouth.

#### If Methylene Blue Injection is missed

Methylene Blue Injection should be given 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 Methylene Blue Injection

As Methylene Blue Injection 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?](#)

**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 Methylene Blue Injection is being given?

#### 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 Methylene Blue Injection.**

**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 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 Methylene Blue Injection 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.

## Drinking alcohol

Tell your doctor if you drink alcohol.

## Looking after your medicine

- Methylene Blue 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.

## 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.

**Methylene Blue Injection will cause a blue colour in urine or bowel motions.**

### Common side effects

Common side effects	What to do
<b>Gastrointestinal and Urinary:</b> <ul style="list-style-type: none"> <li>• nausea, vomiting, diarrhoea</li> <li>• pain when passing urine</li> </ul> <b>Nervous System:</b> <ul style="list-style-type: none"> <li>• headaches, dizziness</li> <li>• mental confusion, anxiety, agitation</li> <li>• tremor</li> </ul> <b>Skin:</b> <ul style="list-style-type: none"> <li>• redness or swelling at the injection site</li> <li>• change in the colour of your skin, saliva, urine and/or faeces to blue or blue/green</li> </ul> <b>Eyes:</b> <ul style="list-style-type: none"> <li>• dilated pupils (increase in the size of the black part of the eyes)</li> </ul> <b>Taste:</b> <ul style="list-style-type: none"> <li>• taste disturbance or loss of taste</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

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

<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> <b>Heart:</b> <ul style="list-style-type: none"> <li>• chest pain</li> <li>• fast or irregular heartbeat</li> </ul> <b>General body:</b> <ul style="list-style-type: none"> <li>• stomach pain</li> <li>• pain at the injection site</li> <li>• high temperature</li> <li>• sweating more than normal</li> </ul> <b>Nervous system:</b> <ul style="list-style-type: none"> <li>• having problems with speaking, writing or reading</li> </ul>	
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**Tell your doctor or pharmacist if you notice anything else that may be 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.

### 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 Methylene Blue Injection contains

<b>Active ingredient (main ingredient)</b>	50 mg/ 5 mL methylene blue
<b>Other ingredients (inactive ingredients)</b>	Water for injections Hydrochloric acid and/or sodium hydroxide
<b>Potential allergens</b>	Not applicable

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

### What Methylene Blue Injection looks like

Methylene Blue Injection is a clear, blue solution in a clear glass vial sealed with a rubber stopper and aluminium seal with a plastic flip off cap. It is available in a 5 mL vial.

(AUST R 223583)

## **Who distributes Methylene Blue Injection**

Methylene Blue Injection is made in Australia by:

Phebra Pty Ltd

19 Orion Road

Lane Cove West, NSW 2066

Australia

Ph 1800 720 020

This leaflet was updated in September 2023.

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