# EPHEDRINE-HAMELN INJECTION

# **Consumer Medicine Information (CMI) summary**

The <u>full CMI</u> 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 Ephedrine-hameln?

Ephedrine-hameln contains the active ingredient ephedrine hydrochloride. Ephedrine-hameln is used to treat low blood pressure which may occur during spinal anaesthesia.

For more information, see Section 1. Why am I being given Ephedrine-hameln? in the full CMI.

# 2. What should I know before I use Ephedrine-hameln?

Do not use Ephedrine-hameln if you have ever had an allergic reaction to ephedrine hydrochloride 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 given Ephedrine-hameln? in the full CMI.

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

Some medicines may interfere with Ephedrine-hameln 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 will I be given Ephedrine-hameln?

- Ephedrine-hameln is given as a slow injection into a vein; it must only be given by a doctor or nurse.
- Your doctor will decide what dose of Ephedrine-hameln you will be given and how long it will be given for.

More instructions can be found in Section 4. How do I be given Ephedrine-hameln? in the full CMI.

# 5. What should I know while using Ephedrine-hameln?

Things you should do	<ul> <li>Remind any doctor, nurse, dentist or pharmacist you visit that you have been given Ephedrine-hameln.</li> <li>Advise your doctor if you have or have had any medical conditions, or if you are breastfeeding or plan to become pregnant.</li> <li>Advise your doctor if you are taking any other medicines.</li> </ul>	
Things you should not do	Do not use Ephedrine-hameln if you have ever had an allergic reaction to ephedrine hydrochloride, or any of its ingredients.	
Driving or using machines	Be careful before you drive or use any machines or tools until you know how Ephedrine-hameln affects you.	
Drinking alcohol	Tell your doctor if you drink alcohol.	
Looking after your medicine	Ephedrine-hameln will be stored in the pharmacy or on the ward. Your doctor or pharmacist will dispose of any that might be left over.	

For more information, see Section 5. What should I know while being given Ephedrine-hameln? in the full CMI.

#### 6. Are there any 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.

Ephedrine-hameln v3.0 061124

# **EPHEDRINE-HAMELN INJECTION**

Active ingredient(s): ephedrine hydrochloride

# **Consumer Medicine Information (CMI)**

This leaflet provides important information about using Ephedrine-hameln. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being given Ephedrine-hameln.

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

- 1. Why am I being given Ephedrine-hameln?
- 2. What should I know before I am given Ephedrine-hameln?
- 3. What if I am taking other medicines?
- 4. How will I be given Ephedrine-hameln?
- 5. What should I know while being given Ephedrine-hameln?
- 6. Are there any side effects?
- 7. Product details

# 1. Why am I being given Ephedrinehameln?

Ephedrine-hameln contains the active ingredient ephedrine hydrochloride. It works by contracting the blood vessels in your limbs, so that more blood is available for your heart.

EP-hameln is used to treat the low blood pressure which may occur during spinal anaesthesia.

Your doctor may have prescribed this medicine for another reason. Ask your doctor if you have any questions about why it has been prescribed for you.

Ephedrine-hameln is available only with a doctor's prescription.

Ephedrine-hameln is not approved for use in children.

# 2. What should I know before I am given Ephedrine-hameln?

#### Warnings

#### Do not use Ephedrine-hameln if:

 you are allergic to ephedrine hydrochloride, or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to ephedrine may include:

- Shortness of breath, wheezing or difficulty in breathing
- swelling of the face, lips, tongue or other parts of

the body

- rash, itching or hives on the skin.
- you have, or have had any of the following medical conditions:
  - some heart problem such as ventricular fibrillation, tachyarrhythmias, coronary thrombosis and idiopathic hypertrophic subaortic stenosis)
  - pheochromocytoma (a rare tumour of the adrenal gland near the kidney)
  - closed angle glaucoma (a condition in which there is a build up of pressure in the eye)
  - · mood/thought disorders
  - using an antibiotic called linezolid
  - using general anaesthetic such as cyclopropane or halothane
  - using or have had use an antidepressant called monoamine oxidase inhibitors (MAO inhibitors) such as phenelzine or moclobemide within the last 14 days
- the packaging is torn or shows signs of tampering
- the expiry date on the pack has passed
  if you are given this medicine after the expiry date
  has passed, it may not work as well or it may make
  you feel sick

#### Check with your doctor:

- 1. if you have or have ever had any other health problems or medical conditions, including:
  - high or low blood pressure
  - prostate problems or difficulty in passing urine
  - mental health problems
  - thyroid problems
  - diabetes
  - heart problems such as angina (chest pain) and cardiac arrhythmia (irregular heart rate)

Your doctor may need to carefully monitor you.

#### 2. if you are an athlete or competing in sport

Ephedrine-hameln contains an active substance that may cause a positive reaction in antidoping tests.

If you have not told your doctor about any of the above, tell them before you are given Ephedrine-hameln.

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 <u>6</u>. Are there any side effects?

#### Pregnancy and breastfeeding

Your doctor will discuss the risks and benefits of using Ephedrine-hameln during pregnancy.

Your doctor will discuss the risks and benefits of using Ephedrine-hameln when breast-feeding. Ephedrine-hameln is not recommended for use if you are breastfeeding.

# 3. What if I am taking other medicines?

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may interfere with Ephedrine-hameln. These include:

- Medicines used to treat heart failure (e.g. digoxin).
- Alpha blockers or beta blockers (used to treat high blood pressure, e.g. prazosin, propranolol or methyldopa)
- Medicines used to manage depression or mental health disorders such as monoamine oxidase (MAO) inhibitors (e.g. phenelzine or moclobemide), tricyclic antidepressants (e.g. dothiepin or amitriptyline) and noradrenergic - serotoninergic antidepressants (e.g. venlafaxine, milnacipran)
- Medicines used in the treatment of migraine such as ergotamine and derivatives
- Reserpine (used in the treatment of blood pressure or mental disorders)
- Guanethidine used to lower blood pressure
- Theophylline (a medicine used to treat asthma)
- Acetazolamide, dichlorphenamide, sodium bicarbonate, sodium citrate (medicines that make urine less acidic i.e. alkaline)
- Linezolid (an antibiotic)
- Medicines used to treat epilepsy such as phenytoin
- Medicines used to treat ADHD such as methylphenidate
- Medicines found commonly in over the counter cold and flu preparations such as pseudoephedrine and phenylephrine
- Atropine (medicine used in heart problems or bowel problems)
- Medicine used in general anaesthetics such as cyclopropane and halothane
- Clonidine (medicine used to treat high blood pressure)
- Dexamethasone, a corticosteroid
- Sibutramine, an appetite suppressant
- Doxapram, a medicine that assists with breathing

These medicines may be affected by Ephedrine-hameln, or may affect how well it works.

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

Your doctor or pharmacist has more information on medicines to be careful with or avoid while being given Ephedrine-hameln .

If you are not sure whether you should be given ephedrine, talk to your doctor or pharmacist.

#### 4. How will I be given Ephedrine-hameln?

Ephedrine-hameln is given as a slow injection into a vein. Ephedrine-hameln must only be given by a doctor or nurse.

#### How much will be given

- Your doctor will decide what dose of Ephedrinehameln you will receive and how long you will receive it for. This depends on your medical condition and other factors, such as your weight.
- Sometimes only a single dose of is required.

#### If you are given too much Ephedrine-hameln

As Ephedrine-hameln is given to you under the supervision of a doctor, it is unlikely that you will receive an overdose. However, if you experience severe side effects tell your doctor immediately.

Immediately telephone your doctor or the Poisons Information Centre (In Australia, call 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Ephedrine-hameln.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose include the side effects listed in the "Side Effects" section (see below) but are usually of a more severe nature. They include severe nausea or vomiting, severe high or low blood pressure, severe breathing difficulties, dizziness or lightheadedness and convulsion.

# 5. What should I know while being given Ephedrine-hameln?

#### Things you should do

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given Ephedrine-hameln.

Remind any doctor, dentist or pharmacist you visit that you have been given Ephedrine-hameln.

#### **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how Ephedrine-hameln affects you.

#### **Drinking alcohol**

Tell your doctor if you drink alcohol.

#### How your medicine will be stored

Ephedrine-hameln will be stored in the pharmacy or on the ward.

#### Getting rid of any unwanted medicine

Your doctor or pharmacist will dispose of any Ephedrinehameln that may be left over.

# 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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

# While being given Ephedrine-hameln

Side effects	What to do
<ul> <li>headache</li> <li>dry nose, mouth or throat</li> <li>fever or sweating</li> <li>nausea, vomiting or stomach pain</li> <li>mood or mental changes, such as depression, nervousness,</li> <li>anxiety, confusion, fear or irritability</li> <li>difficult or painful urination</li> <li>chest pain</li> <li>breathing difficulties</li> <li>irregular, fast or slow heartbeat</li> <li>muscle weakness</li> <li>problems sleeping</li> <li>dizziness, light headedness, feeling weak</li> <li>eye pain, blurred vision</li> <li>loss of appetite</li> <li>increased saliva</li> <li>addiction</li> </ul>	Tell your doctor or nurse immediately if you notice any of these side effects.

# Tell your doctor or nurse 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 <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

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

#### What Ephedrine-hameln contains

Active ingredient	Ephedrine hydrochloride
(main ingredient)	
Other ingredients	Water for Injection
(inactive ingredients)	

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

#### What Ephedrine-hameln looks like

Ephedrine-hameln is a clear, colourless solution

#### Who distributes Ephedrine-hameln

Ephedrine-hameln is supplied by:

hameln pharma Pty Ltd Level 3, 302 Burwood Rd, Hawthorn, Victoria 3122, Australia

mail@hameIn-pharma.com.au

#### **Australian Registration Numbers**

30 mg/1 mL: AUST R 337996

#### **Date of Preparation**

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