LEVOPHED™ 1:1000

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 being treated with LEVOPHED?

LEVOPHED contains the active ingredient noradrenaline (norepinephrine). LEVOPHED is used by a doctor in an emergency to restore blood pressure back to normal.

For more information, see Section 1. Why am I being treated with LEVOPHED? in the full CMI.

2. What should I know before treatment with LEVOPHED?

Do not start treatment if you have ever had an allergic reaction to LEVOPHED 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 <u>2. What should I know before treatment with LEVOPHED?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LEVOPHED 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 LEVOPHED given?

Your doctor will decide what dose you will receive. This depends on your condition and how you respond to LEVOPHED. Often, the dose is adjusted according to how the medicine is affecting your blood pressure.

More instructions can be found in Section <u>4. How is</u> <u>LEVOPHED given?</u> in the full CMI.

5. What should I know during and after treatment with LEVOPHED?

Things you should do Remind any doctor, nurse, dentist or pharmacist who is treating you that you have been given or are being given LEVOPHED.

Driving or using machines

 Do not drive or use any machines or tools until you know how LEVOPHED affects you.

For more information, see Section <u>5. What should I know</u> during and after treatment with LEVOPHED? in the full CMI.

6. Are there any side effects?

Side effects include: skin and tissue damage close to the site of injection, anxiety, headache, dizziness, low or irregular heart-beat, tingling or numbness in the feet, and, coldness, numbness or discolouration of your limbs.

Serious side effects include: allergic reaction symptoms (shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, mouth, throat or tongue or other parts of the body and, rash, itching or hives on the skin), Very high blood pressure symptoms (headache, dizziness, sensitivity to light, chest pain, slow heart-beat, sweating and pale skin, vomiting, and trouble breathing and shortness of breath).

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

LEVOPHED™ 1:1000

Active ingredient(s): noradrenaline (norepinephrine) acid tartrate monohydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using LEVOPHED. 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 LEVOPHED.

Where to find information in this leaflet:

- 1. Why am I being treated with LEVOPHED?
- 2. What should I know before treatment with LEVOPHED?
- 3. What if I am taking other medicines?
- 4. How is LEVOPHED given?
- 5. What should I know during and after treatment with LEVOPHED?
- 6. Are there any side effects?
- 7. Product details

1. Why am I being treated with LEVOPHED?

LEVOPHED contains the active ingredient noradrenaline (norepinephrine).

LEVOPHED belongs to a group of medicines called sympathomimetic amines.

It works by making the heart beat more forcefully and constricting blood vessels. This results in a higher blood pressure and greater blood flow to the heart and other organs of the body.

LEVOPHED is used to restore blood pressure back to normal. LEVOPHED is only given by a doctor in emergency situations, usually in hospital, as a result of serious conditions which cause a dramatic drop in blood pressure.

Such conditions could be:

- a heart attack
- infection in the blood
- severe reaction to a medicine
- severe reaction to a blood transfusion
- allergic reactions

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.

There is no evidence that LEVOPHED is addictive.

2. What should I know before treatment with LEVOPHED?

Warnings

You must not be given LEVOPHED if:

1. you are allergic to:

- noradrenaline (norepinephrine), or any of the ingredients listed at the end of this leaflet.
- any other similar medicines such as adrenaline (epinephrine), phenylephrine, pseudoephedrine.
- sodium metabisulfite or sulfites.
 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.
 Always check the ingredients to make sure you can use this medicine.

2. you have:

- low blood pressure due to low blood volume
- blood clots in certain vessels.
 If given in these cases, it can further reduce blood supply to important organs.

Check with your doctor if you:

- have allergies to any other medicines and/or substances, such as foods, preservatives or dyes.
- have or have had any other medical conditions, especially the following:
 - asthma
 - heart problems
 - diabetes
 - high blood pressure
 - an overactive thyroid gland
- take any medicines for any other condition.

If you have not told your doctor about any of the above, tell them before you start receiving LEVOPHED.

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

Check with your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the possible risks and benefits of you being given LEVOPHED during pregnancy.

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

Your doctor will discuss the possible risks and benefits of using LEVOPHED during breast-feeding. It is not known whether LEVOPHED passes into breast milk.

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 LEVOPHED and affect how it works.

Medicines that may <u>increase</u> the effect of LEVOPHED include:

- antidepressants including moclobemide, imipramine and amitriptyline.
- guanethidine

You may need different amounts of LEVOPHED, or you may need to take different medicines. Your doctor or pharmacist will advise you.

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

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

4. How is LEVOPHED given?

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and how you respond to LEVOPHED. Often, the dose is adjusted according to how the medicine is affecting your blood pressure.

How LEVOPHED is given

LEVOPHED is diluted and given slowly as an infusion (a drip) into a large vein. It will usually be given to you by a doctor.

How long LEVOPHED is given for

This medicine is given until blood pressure and blood circulation to all organs is back to normal and remains normal even when the medicine is no longer given.

If you are given too much LEVOPHED

As LEVOPHED is given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive too much.

Symptoms of an overdose may include:

- headache
- dizziness
- sensitivity to light
- chest pain

- slow heart-beat
- sweating and pale skin
- vomiting
- trouble breathing and shortness of breath.

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

You should immediately:

- contact your doctor, or
- phone the Poisons Information Centre (by calling 13 11 26), 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 during and after treatment with LEVOPHED?

Things you should do

Remind any doctor, nurse, dentist or pharmacist who is treating you that you have been given or are being given LEVOPHED.

Driving or using machines

Do not drive or use any machines or tools until you know how LEVOPHED affects you.

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.

If you are over 65 years of age you may have an increased chance of getting side effects.

Side effects

Side effects	What to do
Administration site conditions	Speak to your doctor if you have any of these side effects.
 skin and tissue damage close to the site of injection Nervous system 	
anxietyheadachedizzinessHeart related issues	
 low or irregular heart- beat 	

Side effects	What to do
Blood flow related issues	
tingling or numbness in the feet	
 coldness, numbness or discolouration of your limbs 	

Serious side effects

Serious side effects	What to do
Allergic reaction symptoms • shortness of breath • wheezing or difficulty breathing • swelling of the face, lips, mouth, throat or tongue or other parts of the body • rash, itching or hives on the skin. Very high blood pressure symptoms • headache • dizziness	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.

Serious side effects	What to do
sensitivity to light	
• chest pain	
slow heart-beat	
 sweating and pale skin 	
vomiting	
 trouble breathing and shortness of breath 	

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. 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 treatment with any of your medicines.

7. Product details

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

What LEVOPHED contains

Active ingredient (main ingredient)	noradrenaline (norepinephrine) acid tartrate monohydrate
Other ingredients	sodium chloride
(inactive ingredients)	sodium metabisulfite
	water for injections

Each 4mL vial contains 4mg of noradrenaline (norepinephrine).

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

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

What LEVOPHED looks like

LEVOPHED is a clear liquid in a glass vial (Aust R 183622).

It is available in packs of 10 vials.

How is LEVOPHED stored

LEVOPHED injection will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light. Store below 25°C. Do not freeze.

Who distributes LEVOPHED

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free number: 1800 675 229

www.pfizermedinfo.com.au

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