NORADRENALINE (NOREPINEPHRINE) (AS ACID TARTRATE MONOHYDRATE)

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 am I using Noradrenaline Medsurge?

Noradrenaline (Norepinephrine) Medsurge contains the active ingredient noradrenaline (norepinephrine) acid tartrate monohydrate.

Noradrenaline (Norepinephrine) concentrated injection is only given by a doctor or nurse in an emergency situation, 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 drug, severe reaction to a blood transfusion, allergic reactions.

Noradrenaline concentrated injection is used to restore blood pressure back to normal. This medicine 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor, however, may have prescribed Noradrenaline concentrated injection for another purpose.

There is no evidence that Noradrenaline concentrated injection is addictive.

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

For more information, see Section 1. Why am I using Noradrenaline Medsurge? in the full CMI.

2. What should I know before I use Noradrenaline Medsurge?

Do not use if you have ever had an allergic reaction to Noradrenaline acid tartrate monohydrate 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 use Noradrenaline Medsurge? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Noradrenaline Medsurge 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 Noradrenaline Medsurge?

- Your doctor will decide what dose you will receive. This depends on your condition and how you respond to Noradrenaline concentrated injection. Often, the dose is adjusted according to how the medicine is affecting your blood pressure.
- Noradrenaline concentrated solution is diluted and given slowly as an infusion (a drip) into a large vein. It will usually be given to you by a doctor.

More instructions can be found in Section <u>4. How do I use Noradrenaline Medsurge?</u> in the full CMI.

5. What shou	ld I know while using Noradrenaline Medsurge?
Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Noradrenaline Medsurge concentrated solution. Noradrenaline (norepinephrine) should be used only in conjunction with appropriate blood volume replacement. When infusing noradrenaline (norepinephrine), the blood pressure and rate of flow should be checked frequently to avoid hypertension.
Things you should not do	• The noradrenaline (norepinephrine) infusion should be gradually decreased since abrupt withdrawal can result in acute hypotension.
Driving or using machines	• The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration. Patients should refrain from driving or using machines until they know that the medicinal product does not negatively affect these abilities.
Looking after	Store below 25°C, protect from light.
your medicine	 This product contains no antimicrobial preservative, to reduce microbiological hazard, use as soon as practicable after preparation. If storage is necessary, hold at 2 to 8 °C for not more than 24 hours. Noradrenaline (norepinephrine) is for single use in one patient only. Discard any residue, Discoloured solutions or those containing a precipitate should not be used. Avoid contact with iron salts, alkalis or oxidising agents. Keep out of reach of children

For more information, see Section 5. What should I know while using [insert medicine]? in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Noradrenaline Medsurge. For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

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Consumer Medicine Information (CMI)

This leaflet provides important information about using Noradrenaline Medsurge. 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 Noradrenaline Medsurge.

Where to find information in this leaflet:

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

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Noradrenaline concentrated injection is only given by a doctor or nurse in an emergency, 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 drug, severe reaction to a blood transfusion, allergic reactions.

Noradrenaline concentrated injection is used to restore blood pressure back to normal. This medicine belongs to a group of medicines called sympathomimetic amines. It works by making the heartbeat 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor, however, may have prescribed Noradrenaline concentrated injection for another purpose.

There is no evidence that Noradrenaline concentrated injection is addictive.

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

2. I know before I use Noradrenaline Medsurge?

Warnings

- Tell your doctor or pharmacist if you have low blood pressure due to low blood volume, blood clots in certain vessels.
- Tell your doctor or pharmacist if you have asthma.

Do not use Noradrenaline Medsurge if:

- you are allergic to Noradrenaline acid tartrate monohydrate or any of the ingredients listed at the end of this leaflet.
- any other similar medicines such as adrenaline, phenylephrine, pseudoephedrine.

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.

Noradrenaline (norepinephrine) should not be given to patients who are hypotensive from hypovolaemia except as an emergency measure to maintain coronary and cerebral artery perfusion until blood volume replacement therapy can be completed. Noradrenaline (norepinephrine) is continuously administered to maintain blood pressure in the absence of blood volume replacement, the following occur: severe peripheral and visceral vasoconstriction, decreased renal perfusion and urine output, poor systemic blood flow despite "normal" blood pressure, tissue hypoxia and lactate acidosis. Noradrenaline (norepinephrine) should not be given to patients with mesenteric or peripheral vascular thrombosis (because of the risk of increasing ischaemia and extending the area of infarction) unless, in the opinion of the attending physician, the administration of Noradrenaline (norepinephrine) is necessary as a lifesaving procedure. The use of Noradrenaline (norepinephrine) during cyclopropane and halothane anaesthesia is generally considered contraindicated because of the risk of producing ventricular tachycardia or fibrillation. The same type of cardiac arrthymias may result from the use of Noradrenaline (norepinephrine) in patients with profound hypoxia or hypercarbia.

Check with your doctor if you:

Have or have had any of the following medical conditions:

- · heart problems
- high or low blood pressure
- diabetes
- kidney or liver problems
- In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Noradrenaline (norepinephrine) infusion solutions should not be administered into the veins in the leg in elderly patients.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and

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how to monitor for them. For 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.

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 Noradrenaline Medsurge and affect how it works.

- Some medicines and Noradrenaline concentrated injection may interfere with each other. These include:
- antidepressants including moclobemide, imipramine and amytriptilline
- guanethidine.

These medicines may increase the effects of Noradrenaline concentrated injection. You may need different amounts of this medicine, 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 Noradrenaline Medsurge.

4. How do I use Noradrenaline Medsurge?

How much to take / use

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

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

If you use too much Noradrenaline Medsurge

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

Symptoms of an overdose may include extreme drowsiness, confusion, dizziness, weakness or becoming unconscious. If you think that you have used too much Noradrenaline Medsurge, you may need urgent medical attention.

You should immediately:

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Noradrenaline Medsurge.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Noradrenaline Medsurge?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using Noradrenaline Medsurge concentrated solution. Noradrenaline (norepinephrine) should be used only in conjunction with appropriate blood volume replacement. When infusing noradrenaline (norepinephrine), the blood pressure and rate of flow should be checked frequently to avoid hypertension

Things you should not do

The noradrenaline (norepinephrine) infusion should be gradually decreased since abrupt withdrawal can result in acute hypotension.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Noradrenaline Medsurge affects you.

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration. Patients should refrain from driving or using machines until they know that the medicinal product does not negatively affect these abilities.

Looking after your medicine

- Store below 25°C, protect from light.
- This product contains no antimicrobial preservative, to reduce microbiological hazard, use as soon as practicable after preparation. If storage is necessary, hold at 2 to 8 °C for not more than 24 hours.
- Noradrenaline (norepinephrine) is for single use in one patient only. Discard any residue, Discoloured solutions or those containing a precipitate should not be used. Avoid contact with iron salts, alkalis or oxidising agents.
- Keep out of reach of children

Follow the instructions in the carton on how to take care of your medicine properly.

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.

Less serious side effects

Less serious side effects	What to do
anxiety	If you are over
 headache 	If you are over 65 years of age you may have
dizziness	you may have
	an increased

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chance of
getting side
effects.
Speak to your
doctor if you
have any of
these less
serious side
effects and
they worry you.

Serious side effects

Serious side effects		What to do
•	skin and tissue damage close to	Call your doctor
	the site of injection	straight away,
•	difficulty breathing and	or go straight
	shortness of breath	to the
•	low or irregular heart-beat	Emergency
•	tingling or numbness in the feet	Department at
•	coldness, numbness or	your nearest
	discolouration of your limbs.	hospital if you
		notice any of
		these serious
		side effects.

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 taking any of your medicines.

7. Product details

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

What Noradrenaline Medsurge contains

Active ingredient	Noradrenaline Medsurge (1	
(main ingredient)	mg/mL) (1:1000) contains 2	
	mg/mL of Noradrenaline acid	
	tartrate monohydrate	
	(equivalent to 1 mg/mL	
	Noradrenaline base)	
Other ingredients	sodium chloride	
(inactive ingredients)	hydrochloric acid	
	water for injections.	
Potential allergens	This medicine does not contain	
	lactose, sucrose, gluten,	
	tartrazine or other azo dyes.	

The solution contains no antimicrobial preservatives or chemical stabilisers.

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

What Noradrenaline Medsurge looks like

Noradrenaline Medsurge concentrated injection solution for intravenous infusion (1 mg/mL) is a sterile clear, colourless or yellowish solution.

Noradrenaline Medsurge concentrated injection is available as a single use glass ampoule with following pack size Noradrenaline Medsurge 1 mg/1 mL in pack of 10 x 1 mL (AUST R 349474)

Noradrenaline Medsurge 2 mg/2 mL in pack of 10 x 2 mL (AUST R 349471)

Noradrenaline Medsurge 4 mg/4 mL in pack of 10 x 4 mL (AUST R 349480)

Noradrenaline Medsurge 5 mg/5 mL in pack of 10 x 5 mL (AUST R 349475)

Noradrenaline Medsurge 8 mg/8 mL in pack of 10 x 8 mL (AUST R 349473)

Noradrenaline Medsurge 10 mg/10 mL in pack of 10 x 10 mL. (AUST R 349472)

Not all presentations and pack sizes are marketed.

Who distributes Noradrenaline Medsurge

Medsurge Pharma Limited PO Box 331054 Takapuna Auckland 0622

Telephone: 0800 788 261

Marketed and distributed by Medsurge Healthcare Pty Ltd.

Tel: 1300 788 261 www.medsurgehc.com

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