## **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 NEOSYNEPHRINE?

NEOSYNEPHRINE contains the active ingredient phenylephrine hydrochloride. NEOSYNEPHRINE is used to help increase your blood pressure and slow down your heart, for example, during surgery or in states of shock. It does this by causing constriction (narrowing) of your blood vessels.

For more information, see Section <u>1. Why am I being treated with NEOSYNEPHRINE?</u> in the full CMI.

### 2. What should I know before treatment with NEOSYNEPHRINE?

Do not use if you have ever had an allergic reaction to phenylephrine hydrochloride, sodium metabisulfite 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 treatment with NEOSYNEPHRINE? in the full CMI.

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

Some medicines may interfere with NEOSYNEPHRINE 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 NEOSYNEPHRINE is given?

- NEOSYNEPHRINE must only be given by a doctor or nurse.
- It is given to you in three ways: as a slow injection or infusion (drip) into a vein, as a deep injection into a muscle or as an injection just under the skin.

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

### 5. What should I know during treatment with NEOSYNEPHRINE?

Things you should do	<ul> <li>Remind any doctor, dentist or pharmacist you visit that you are using NEOSYNEPHRINE.</li> <li>Your doctor will monitor your blood pressure closely while you are being given NEOSYNEPHRINE.</li> </ul>	
Driving or using machines	No data available.	
Drinking alcohol	Tell your doctor if you drink alcohol.	
Looking after your medicine	NEOSYNEPHRINE will be stored in the hospital, where the temperature stays below 25°C.	

For more information, see Section 5. What should I know while using NEOSYNEPHRINE? in the full CMI.

## 6. Are there any side effects?

Side-effects may include headache or irritability, restlessness, tingling in the hands or feet and changes to heart rate such as slowing down, or increasing heartbeat.

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.

## NEOSYNEPHRINE<sup>TM</sup> (nee-o-SIN-eh-frin)

Active ingredient(s): Phenylephrine Hydrochloride (Fen-nel-EF-reen Hi-dro-KLOR-ide)

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

This leaflet provides important information about using NEOSYNEPHRINE. 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 NEOSYNEPHRINE.

Where to find information in this leaflet:

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

# 1. Why am I being treated with NEOSYNEPHRINE?

**NEOSYNEPHRINE contains the active ingredient phenylephrine hydrochloride.** It belongs to a group of medicines called vasoconstrictors.

NEOSYNEPHRINE is used to help increase your blood pressure and slow down your heart, for example, during surgery or in states of shock. It does this by causing constriction (narrowing) of your blood vessels.

## 2. What should I know before treatment with NEOSYNEPHRINE?

#### Warnings

#### Do not use NEOSYNEPHRINE if:

- You are allergic to:
- phenylephrine hydrochloride.
- sodium metabisulfite.
- any of the ingredients listed at the end of this leaflet.
- You have very high blood pressure.
- You have a very fast heart beat (palpitations).

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.

## Check with your doctor if you:

- have any other medical conditions:
- thyroid disease.
- slow heart rate.
- other heart disease.
- severe arteriosclerosis (a disease of the arteries).

• take any medicines for any other condition.

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. Are there any side effects</u>?

## Pregnancy and breastfeeding

<u>Check with your doctor if you are pregnant or intend to become pregnant.</u>

Your doctor will discuss the risks and benefits of being given NEOSYNEPHRINE during pregnancy.

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

Your doctor will discuss the risks and benefits of being given NEOSYNEPHRINE when breast-feeding.

## 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 NEOSYNEPHRINE and affect how it works. These include:

- certain medicines to treat depression (such as monoamine oxidase inhibitors and tricyclic antidepressants).
- halothane anaesthetics (a type of medicine used to keep you asleep during an operation).
- certain medicines used to stimulate labour in pregnant women.

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

## 4. How is NEOSYNEPHRINE given?

#### How it is given

- NEOSYNEPHRINE must only be given by a doctor or nurse.
- NEOSYNEPHRINE can be given to you in three ways:
- as a slow injection or infusion (drip) into a vein,
- as a deep injection into a muscle or,
- as an injection just under the skin.
- Sometimes it is diluted before use and given with fluids into a vein.
- Your doctor will determine how you will be given this medicine. It may depend on why you need to use it.

#### How much to use

Your doctor will decide what dose and how long you will receive NEOSYNEPHRINE. The dose will be different, depending on how your doctor gives you NEOSYNEPHRINE and why you are being given it.

#### If you are given too much NEOSYNEPHRINE

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

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

Symptoms of overdose include sensation of fullness in the head, tingling in the hands or feet and irregular or fast heartbeat.

#### 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 during treatment with NEOSYNEPHRINE?

#### Things you should do

Your doctor will monitor your blood pressure closely while you are being given NEOSYNEPHRINE.

Remind any doctor, dentist or pharmacist you visit that you are being treated with NEOSYNEPHRINE, especially if you are about to be started on any new medicine.

#### Driving or using machines

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

#### **Drinking alcohol**

No information is available.

#### Looking after your medicine

NEOSYNEPHRINE will be stored in the pharmacy or kept on the hospital ward.

#### Getting rid of any unwanted medicine

If you no longer need to use this medicine or if it is out of date, the hospital will dispose of it safely.

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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

#### Side effects

Side effects	What to do
General: • headache • restlessness • excitability	Speak to your doctor if you have any of these less serious side effects and they worry you.
Heart rate and pulse related symptoms:	Call your doctor straight away, or go
<ul> <li>fast or irregular heartbeats (also called palpitations).</li> <li>very slow pulse</li> </ul>	straight to the Emergency Department at your nearest
Unusual sensations:	hospital if you
<ul><li>sensation of fullness in the head,</li><li>tingling in the hands or feet</li></ul>	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 <u>www.tga.gov.au/reporting-problems</u>. 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 NEOSYNEPHRINE contains

Active ingredient (main ingredient)	phenylephrine hydrochloride
Other ingredients (inactive ingredients)	<ul> <li>sodium metabisulfite</li> <li>sodium chloride</li> <li>sodium citrate dihydrate</li> <li>citric acid monohydrate</li> <li>water for injections</li> </ul>
Allergens	• contains sulfites

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

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

#### What NEOSYNEPHRINE looks like

NEOSYNEPHRINE is a clear, colourless, aqueous solution in glass ampoules presented in amber clamshells each containing 5 ampoules.

Five packs of 5 ampoules are shrink-wrapped to form packs of 25 ampoules (Aust R 15472).

#### Who distributes NEOSYNEPHRINE

Pfizer Australia Pty Ltd Sydney NSW Toll Free Number: 1800 675 229 www.pfizermedicalinformation.com.au

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