

NEO-SYNEPHRINE™

(nee-o-SIN-eh-frin)

Phenylephrine Hydrochloride 1% Injection (Fen-nel-EF-reen Hi-dro-KLOR-ide)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NEO-SYNEPHRINE™.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks associated with giving you NEO-SYNEPHRINE™ against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor, pharmacist or nurse.

Keep this leaflet while you are being given NEO-SYNEPHRINE™. You may need to read it again.

What NEO-SYNEPHRINE™ is used for

NEO-SYNEPHRINE™ 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.

It belongs to a group of medicines called vasoconstrictors.

Ask your doctor if you have any questions about why NEO-SYNEPHRINE™ has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

Before you are given NEO-SYNEPHRINE™

When you must not be given it

You must not be given NEO-SYNEPHRINE™ if you are allergic to:

- phenylephrine
- sodium metabisulfite
- any of the ingredients listed at the end of this leaflet.

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.

You must not be given NEO-SYNEPHRINE™ if you have:

- very high blood pressure.
- a very fast heart beat (palpitations)

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- thyroid disease
- slow heart rate

- other heart disease
- severe arteriosclerosis (a disease of the arteries)

Tell your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the risks and benefits of being given NEO-SYNEPHRINE™ during pregnancy.

Tell your doctor if you are breast-feeding or plan to breast-feed.

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

If you have not told your doctor or nurse about any of the above, tell them before you are given NEO-SYNEPHRINE™.

Taking other medicines

Tell your doctor if you are taking other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and NEO-SYNEPHRINE™ may interfere with each other. These include:

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

These medicines may be affected by NEO-SYNEPHRINE™ or affect how well it works. You may need different amounts of your

medicines, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid, while using NEO-SYNEPHRINE™.

How NEO-SYNEPHRINE™ is given

How it is given

NEO-SYNEPHRINE™ 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 this drug.

NEO-SYNEPHRINE™ must only be given by a doctor or nurse.

How much is given

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

If you take too much (overdose)

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

Immediately tell your doctor or nurse if you think that you or anyone else has taken or been given too much NEO-SYNEPHRINE™.

If you are not in a hospital, telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand) 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 NEO-SYNEPHRINE™. Do this even if there are no signs of discomfort or poisoning.

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 heart beat.

While you are being given NEO-SYNEPHRINE™

Things you must do

Your doctor will monitor your blood pressure closely while you are being given NEO-SYNEPHRINE™.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given NEO-SYNEPHRINE™.

Tell any other doctors, dentists, and pharmacists who treat you that you are being given this medicine.

Things to be careful of

Be careful driving or operating machinery until you know how NEO-SYNEPHRINE™ affects you.

Make sure you know how you react to NEO-SYNEPHRINE™ before you drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given or after receiving NEO-SYNEPHRINE™.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Tell your doctor if you notice any of the following and they worry you:

- headache
- restlessness
- excitability.

These are mild side effects.

Tell your doctor immediately if you notice any of the following:

- fast or irregular heart beats (also called palpitations).
- very slow pulse
- sensation of fullness in the head,
- tingling in the hands or feet

These are very serious side effects. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor if you notice any other effects.

Other side effects not listed above may also occur in some patients.

After receiving NEO-SYNEPHRINE™

Storage

NEO-SYNEPHRINE™ should only be given to you in hospital. It will be stored in a cool dry place away from the light, where the temperature stays below 25°C.

The ampoules should not be taken out of the box until just before they are to be used. This is because the medicine is affected by light.

This is not all the information available on NEO-SYNEPHRINE™. If you have any more questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was prepared in May 2017.

Product Description

What it looks like

NEO-SYNEPHRINE™ 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.

Ingredients

Each 1 mL of NEO-SYNEPHRINE™ contains 10 mg of phenylephrine hydrochloride as the active ingredient.

It also contains:

- sodium metabisulfite
- sodium chloride
- sodium citrate dihydrate
- citric acid monohydrate
- water for injections

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

Sponsor

Australian Sponsor:

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10mg/mL ampoule AUST R 15472