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.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using *neffy* ?

neffy contains the active ingredient adrenaline (epinephrine). *neffy* is used for the emergency treatment of severe allergic reactions, including anaphylaxis.
For more information, see Section 1. Why am I using *neffy*? in the full CMI.

2. What should I know before I use *neffy*?

neffy is a life-saving treatment in the emergency management of severe allergic reactions. Therefore, it should not be withheld from anyone who is considered to need it.
Talk to your doctor or pharmacist 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 *neffy*? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with *neffy* 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 *neffy* ?

- **Use *neffy* at the first signs or symptoms of a severe allergic reaction (anaphylaxis).**
- *neffy* is a nasal spray that contains one dose of adrenaline for use in adults or children 4 years and older who weigh 15 kg or more.
- Seek further medical attention immediately after using *neffy*. Although you have received adrenaline from *neffy*, you may need more medical treatment.
- If symptoms do not start to improve after 5 minutes, use a new *neffy* nasal spray, to give a second dose ideally in the same nostril as the first dose.

More instructions can be found in Section 4. How do I use *neffy*? in the full CMI.

5. What should I know while using *neffy* ?

Things you should do	• Carefully follow-all instructions for use. • It is recommended to always carry two doses of *neffy* with you or have it close at all times in the event of an allergic emergency.
Things you should not do	• **Do not test, prime or pre-spray *neffy* before use**; each *neffy* nasal spray has only one dose. • Do not give *neffy* to children under 4 years old and who weigh less than 15 kg.
Driving or using machines	• Do not drive or use machines if you are having an anaphylactic reaction.
Drinking alcohol	• Alcohol may increase the side effects of adrenaline.
Looking after your medicine	• **Store below 25°C.** If accidentally frozen allow the *neffy* nasal spray to thaw for at least one hour Freezing does not affect the shelf life of the product.

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

6. Are there any side effects?

Tell your doctor or pharmacist if you experience any of the following common side effects: Anxiety, headache, tremor, fast uneven or noticeable heart-beat, nasal discomfort, throat irritation, runny nose, nose pain, or nasal congestion.

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.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

neffy®

Active ingredient: *adrenaline (epinephrine)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using *neffy* . **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 *neffy*.**

Where to find information in this leaflet:

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

1. WHY AM I USING *neffy*?

***neffy* contains the active ingredient adrenaline (epinephrine).**

***neffy* is used in adults and children 4 years and older with a body weight of 15 kg or more for the emergency treatment of severe allergic reactions, including anaphylaxis (sudden, severe and sometimes life-threatening allergic reactions).**

***neffy* is intended for immediate self-administration by a person (or given to a person by a caregiver or medical professional) with a history or recognised risk of a severe allergic reaction that can lead to anaphylaxis.**

The active substance in *neffy*, adrenaline (epinephrine), is a naturally occurring hormone released by the body in response to stress. It works directly on the cardiovascular system (heart and blood circulation) and respiratory system (lungs) to stop the possible fatal effects of a severe allergic reaction that can lead to anaphylaxis. In acute allergic reactions it improves blood pressure, heart function and breathing, and reduces tissue swelling.

***neffy* is for the emergency treatment of anaphylaxis but you must seek emergency medical assistance immediately after using *neffy* for close monitoring and in the event further treatment is required (see Section 2 Signs of anaphylaxis and using *neffy*).**

2. What should I know before I use *neffy*?

Warnings

Do not use *neffy* if:

- *neffy* is a life-saving treatment in the emergency management of severe allergic reactions. Therefore, it should not be withheld from anyone who is considered to need it.

Check with your doctor or pharmacist if you:

- have any other medical conditions, or
- have nasal issues, nasal polyps, or a history of nasal injury or surgery, or
- 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 6. Are there any side effects?

Pregnancy and breastfeeding

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

There is limited experience of the use of adrenaline during pregnancy. **If you are pregnant, do not hesitate to use *neffy* in an emergency, since you and your baby's lives may be in danger.** Discuss this with your doctor if you are pregnant.

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

It is expected that the amount of *neffy* that is passed through breastfeeding is very low. **For the emergency treatment of anaphylaxis, *neffy* should be used in breastfeeding women in the same manner as for non-breastfeeding patients.**

Signs of anaphylaxis and using *neffy*

You, or anyone who may need to give *neffy* to you, should be carefully instructed on how and when to correctly use *neffy* (see the Instructions for Use in Section 4 How do I use *neffy*?).

Signs of an allergic reaction include:

- swelling of lips, face or eyes
- hives or welts

- tingling mouth
- abdominal pain or vomiting

These signs may progress very quickly to a severe allergic reaction, including anaphylaxis, or they may not occur at all before anaphylaxis begins.

Signs that signal the onset of severe allergic reactions, including anaphylaxis, may occur within minutes of exposure to the allergen and include:

- difficult or noisy breathing
- swelling of tongue
- swelling or tightness in throat
- wheeze or persistent cough
- difficulty talking or hoarse voice
- persistent dizziness or collapse
- becoming pale and floppy in young children

Use *neffy* at the first signs of a severe allergic reaction.

If you have asthma, you may be at increased risk of a severe anaphylactic reaction.

neffy can be used even if you have a cold or a congested nose.

You must make sure you understand the reason *neffy* has been prescribed for you. You should be confident that you know exactly how and when to use *neffy*.

Avoidance of known allergens is most important in preventing severe allergic reactions.

If you are at risk of a severe allergic reaction, you should ideally keep two *neffy* nasal sprays with you.

Use *neffy* with caution if:

neffy is a life-saving medicine for the emergency treatment of severe allergic reactions and it should not be withheld from anyone who is considered to need it. However, some people may have an increased risk of developing side effects.

You may have a greater risk of developing side effects with *neffy* if you have:

- heart or circulation problems
- glaucoma
- severe kidney impairment
- prostatic adenoma (an enlarged prostate which pushes against the urethra and the bladder, blocking the flow of urine)
- hypercalcaemia (high blood calcium levels)
- hypokalaemia (low blood potassium levels)
- Parkinson's disease
- hyperthyroidism (an overactive thyroid gland)
- hypertension (high blood pressure)
- diabetes

You may also have a greater risk of developing side effects with *neffy* if you are:

- elderly
- pregnant (see Section 2 Pregnancy and breastfeeding).

Talk to your doctor if any of the above conditions apply to you, or if you are not sure.

Children and adolescents

Do not give this medicine to children under 4 years old and weighing less than 15 kg. The safety and efficacy of this medicinal product has not been studied in children under 4 years old and below 15 kg body weight.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

It is especially important to tell your doctor or pharmacist if you take any of the following medicines:

- Medicines to treat abnormal or irregular heartbeats (arrhythmias) such as cardiac glycosides.
- Medicines to treat depression such as tricyclic antidepressants or monoamine oxidase inhibitors (MAO inhibitors).
- Medicines for the treatment of Parkinson's disease such as catechol-O-methyl transferase inhibitors (COMT inhibitors).
- Medicines for heart disease including alpha blockers (such as phentolamine) and beta blockers (such as propranolol).
- Medicines for thyroid disease such as levothyroxine.
- Medicines that make you breathe more easily; used for asthma (theophylline).
- Medicines used in labour (oxytocin).
- Certain antihistamines used to treat allergies (diphenhydramine, chlorpheniramine).
- Medicines that act on the nervous system (anticholinergics) (e.g. atropine, cyclopentolate, homatropine, hyoscine).

Patients with diabetes should carefully monitor their glucose levels after they use *neffy*, as adrenaline can reduce the amount of insulin made by the body, thus increasing the blood glucose level.

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

4. How do I use *neffy*?

Always use *neffy* exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

When to carry *neffy*

You should always carry *neffy* with you or have it close at all times in the event of a severe allergic reaction. It is recommended to always carry two *neffy* nasal sprays in the event a second dose is needed.

How much to use

- The recommended dosage for patients weighing 15 kg to less than 30 kg is one spray of *neffy* 1 mg administered into one nostril.
- The recommended dosage for patients weighing 30 kg or greater is one spray of *neffy* 2 mg administered into one nostril.
- If symptoms do not start to improve after 5 minutes of the initial dose of *neffy*, use a new *neffy* nasal spray to give a second dose, ideally in the same nostril as the first dose.

When to use *neffy*

- Use *neffy* at the first signs of a severe allergic reaction (see Section 2 Signs of anaphylaxis and using *neffy*).

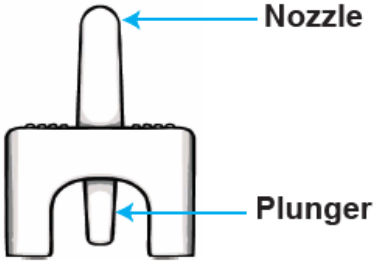
How to use *neffy*

- *neffy* must be given nasally (in the nose) only. Do not spray *neffy* into the eyes or mouth.
- *neffy* is a ready-to-use, single-dose, nasal spray that delivers its entire contents (1 mg or 2 mg) when sprayed.
- **Do not** press the plunger before inserting the *neffy* nasal spray into a nostril, otherwise the single dose will be lost prior to use.
  The Instructions for Use must be carefully followed to make sure you use *neffy* correctly.

Instructions for Use for *neffy* single-dose nasal spray

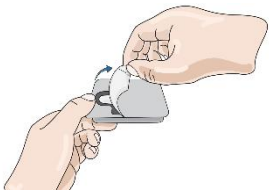
Before you need to use it, fully familiarise yourself with *neffy*, including when and how it should be used.

***neffy* nasal spray**



Follow these instructions **only** when you are ready to use *neffy*.

Remove *neffy* nasal spray from the packaging.



Pull open the packaging to remove the *neffy* nasal spray.

1. **Hold *neffy* nasal spray as shown.**

Hold *neffy* nasal spray with your thumb on the bottom of the plunger and one finger on either side of the nozzle.

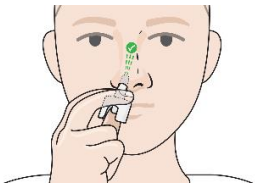
! **Do not pull or push on the plunger until ready to give the dose.**

! **Do not test or pre-spray (prime); each *neffy* nasal spray has only one dose.**

2. **Place the nozzle of the nasal spray into a nostril until fingers touch the nose. For smaller noses place nozzle into nostril and aim for fingers to touch the nose.**

Keep the nozzle pointed toward the forehead.
Do not angle the nozzle to the inner or outer walls of the nose.

3. **Press plunger up firmly until it sprays into the nostril.**



Do not angle the nozzle of the nasal spray to the inner or outer walls of the nose.

Seek immediate medical attention after use.

- Seek emergency medical assistance immediately after using *neffy* for close monitoring and in the event further treatment is required.
- In Australia, telephone 000 or in New Zealand, telephone 111 and let them know that you have used *neffy*.

Monitor patient symptoms

If symptoms do not start to improve after 5 minutes, use a new *neffy* nasal spray to give a second dose, ideally in the same nostril as the first.

If you use too much *neffy*

If you think that you have used too much *neffy* you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 764 766 (0800 POISON) in NZ)**,** 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.

Overdose may cause a sudden increase in blood pressure (with symptoms including headache or dizziness), bleeding in brain tissue, palpitations (forceful heartbeats that may be rapid or irregular), reduced blood flow and accumulation of fluid in the lungs (causing symptoms including difficulty breathing). You will need to be monitored. You may need urgent medical attention.

5. What should I know while using *neffy*?

Things you should do

- Always carry *neffy* with you or have it close at all times in the event of a severe allergic reaction.
- Carry two *neffy* nasal sprays in case a second dose is needed.
- Tell your friends and family that you carry *neffy* with you.
- Be confident that you know exactly how and when to use *neffy*.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- Remind any doctor, dentist or pharmacist that you visit that you are using *neffy*.

Things you should not do

- **Do not** press the plunger, test, or pre-spray (prime) *neffy* before inserting the nozzle into a nostril, otherwise the single dose will be lost prior to use.
- **Do not** spray *neffy* into the eyes or mouth.
- **Do not** give *neffy* to children under 4 years old and weighing less than 15 kg.

Driving or using machines

Do not drive or use machines if you are having a severe allergic reaction.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.
Alcohol may increase the side effects of adrenaline.

Looking after your medicine

Keep *neffy* in a place where the temperature stays below 25° C.

Do not freeze. If accidentally frozen, the *neffy* nasal spray will not function. Allow the *neffy* nasal spray to thaw for at least one hour; do not use if the contents are still frozen or not completely thawed. Freezing does not affect the shelf life of the product.

Do not use this medicine after the expiry date which is stated on the *neffy* nasal spray label after EXP. The expiry date refers to the last day of that month.

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

Keep this medicine out of sight and reach of children who are not the intended user.

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.

Less serious side effects

Less serious side effects	What to do
• Nasal discomfort • Runny nose • Nose pain • Nasal congestion • Dry nose or throat • Throat irritation • Headache • Feeling of over excitement, nervousness, or anxiety • Shakiness • Tingling sensation • Fast, uneven or noticeable heart beat	**Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.**

Serious side effects

The following side effects have been reported following the administration of adrenaline in general and are not specifically linked to administration of *neffy*.

Serious side effects	What to do
Heart/cardiovascular system • Severe irregular heartbeat and heart attack • Sudden increase in blood pressure which may cause bleeding into the brain Nervous system • disorientation and impaired memory. Respiratory system • Lung problems •	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.

neffy may contain trace amounts of sodium metabisulphite which may cause severe allergic reactions (hypersensitivity) in some patients. Sensitivity to sodium metabisulphite should not deter use of *neffy* for treatment of serious allergic reactions including anaphylaxis.

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.

7. Product details

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

What *neffy* contains

Active ingredient (main ingredient)	adrenaline (epinephrine)
Other ingredients (inactive ingredients)	• sodium chloride • dodecyl-beta-D-maltoside • disodium edetate • benzalkonium chloride • sodium metabisulphite • hydrochloric acid • sodium hydroxide • water for injections.
Potential allergens	Sulfites

If you are allergic to any of these ingredients talk to your doctor about using *neffy*.

What *neffy* looks like

neffy nasal spray solution is filled into a glass vial and closed with stopper. The vial is enclosed in a white plastic holder (see the *neffy* nasal spray diagram in Section 4 above) which forms part of the single-dose nasal spray. You cannot see the liquid in the vial.

Each dose of *neffy* nasal spray delivers either 1 mg or 2 mg adrenaline (epinephrine) in 100 microlitres (µL) of solution.

neffy 1 mg nasal spray (AUST R 469945)

neffy 2 mg nasal spray (AUST R 470025)

neffy is available in packs containing 2 single-dose nasal sprays.

Who distributes *neffy*

Seqirus Pty Ltd
ABN 26 160 735 035
655 Elizabeth Street
Melbourne, Vic, 3000
Australia

Telephone: 1800 642 865
www.cslseqirus.com.au

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