## **Neo-B12® Injection**

### **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 Neo-B12 Injection?

Neo-B12 Injection contains the active ingredient hydroxocobalamin. Neo-B12 Injection is a form of vitamin B12. Neo-B12 Injection is used for the prevention and treatment of anaemias associated with vitamin B12 deficiency. It is also used to treat diseases of nerves in the eyes.

For more information, see Section <u>1. Why am I being</u> treated with Neo-B12 Injection? in the full CMI.

# 2. What should I know before treatment with Neo-B12 Injection?

Do not use if you have ever had an allergic reaction to hydroxocobalamin, or any of the ingredients listed at the end of the CMI or cobalt.

Do not use if you have folate-deficient megaloblastic anaemia (a type of anaemia caused by the deficiency of another vitamin called folic acid).

Talk to your doctor if you have or have had any other medical conditions, such as a disease of the spinal cord.

Check with your doctor if you 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 Neo-B12 Injection?</u> in the full CMI.

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

Some medicines may interfere with Neo-B12 Injection 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 Neo-B12 Injection given?

- Neo-B12 Injection is given as an injection into a muscle. It must only be given by a nurse or doctor.
- Your doctor will decide what dose you will receive and how often you will receive it. This depends on your condition and other factors, such as your weight.

More instructions can be found in Section <u>4. How is Neo-B12 Injection given?</u> in the full CMI.

# 5. What should I know during treatment with Neo-B12 Injection?

| Things you should do        | <ul> <li>Tell any other doctors, dentists, and pharmacists who treat you that you are being given Neo-B12 Injection.</li> <li>If you become pregnant while being treated with Neo-B12 Injection, tell your doctor immediately.</li> </ul>  |
|-----------------------------|--|
| Driving or using machines   | <ul> <li>Be careful before you drive or use any machines or tools until you know how Neo-B12 Injection affects you.</li> </ul>   |
| Looking after your medicine | <ul> <li>Neo-B12 Injection is usually stored in the doctor's surgery or clinic, or at the pharmacy.</li> <li>If you need to store Neo-B12 Injection, keep it in the original pack until it is time for it to be given.</li> <li>Store below 25°C and in a cool dry place.</li> </ul> |

For more information, see Section <u>5. What should I know during treatment with Neo-B12 Injection?</u> in the full CMI.

### 6. Are there any side effects?

Less serious side effects include: diarrhoea, nausea, headache, vomiting, dizziness, acne, skin rash, itching pain or redness at the injection site, feeling hot or cold, fever, shivering, changes to the skin pigment, changes to colour of urine or faeces, general feeling of weakness or unwell, increased blood pressure or change in electrolytes.

Serious side effects include: signs of an allergic reaction (which 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), breathlessness (which may be very severe and usually worsens on lying down due to a build-up of fluid in the lungs), changes in heart rate (fast, slow or irregular), chest tightness or pain, swelling or pain in a body part (due to clots in the blood vessels). For more information, including what to do if you have any side effects, see Section <u>6</u>. Are there any side effects? in the full CMI.

## **Neo-B12 Injection**

**Active ingredient(s):** *hydroxocobalamin* (hye-drox-oh-koe-BAL-a-min)

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

This leaflet provides important information about using Neo-B12 Injection. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being treated with Neo-B12 Injection.

#### Where to find information in this leaflet:

- 1. Why am I being treated with Neo-B12 Injection?
- 2. What should I know before treatment with Neo-B12 Injection?
- 3. What if I am taking other medicines?
- 4. How is Neo-B12 Injection given?
- 5. What should I know during treatment with Neo-B12 Injection?
- 6. Are there any side effects?
- 7. Product details

# 1. Why am I being treated with Neo-B12 Injection?

Neo-B12 Injection contains the active ingredient hydroxocobalamin. Neo-B12 Injection is a form of vitamin B12. Neo-B12 Injection is used for the prevention and treatment of anaemias associated with vitamin B12 deficiency. It is also used to treat diseases of nerves in the eyes.

Your doctor may have prescribed it for another reason.

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

# 2. What should I know before treatment with Neo-B12 Injection?

### **Warnings**

# Do not use/ you must not be given Neo-B12 Injection:

- to treat megaloblastic anaemia of pregnancy (a type of anaemia usually caused by the deficiency of another vitamin called folic acid).
- If you are allergic to hydroxocobalamin, or any of the ingredients listed at the end of this leaflet.
- If you are allergic to cobalt.

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
- skin rash, itching or hives.

Always check the ingredients to make sure you can use this medicine.

### Check with your doctor if you:

- have or have had any other medical conditions, especially the following:
  - a disease of the spinal cord
  - folate-deficient megaloblastic anaemia (a type of anaemia caused by the deficiency of another vitamin called folic acid)
- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you are given Neo-B12 Injection.

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.

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

Your doctor can discuss with you the possible risks and benefits involved.

## 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 Neo-B12 Injection and affect how it works. These include:

- chloramphenicol, a medicine used to treat infections
- the contraceptive pill (birth control pill)
- folic acid.

These medicines may be affected by hydroxocobalamin, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Neo-B12 Injection.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while being treated with Neo-B12 Injection.

### 4. How is Neo-B12 Injection given?

### How is it given

- Neo-B12 Injection is given as an injection into a muscle.
- It must only be given by a nurse or doctor.

### How much is given

 Your doctor will decide what dose you will receive and how often you will receive it. This depends on your condition and other factors such as your weight.

### If you receive too much (Overdose)

As Neo-B12 Injection 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 the side effects listed under Section <u>6. Are there any side effects</u>? but are usually of a more severe nature.

If you experience severe side effects or if you think that you have been given too much Neo-B12 Injection, you may need urgent medical attention.

#### 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 Neo-B12 Injection?

### Things you should do

- Tell any other doctors, dentists, and pharmacists who treat you that you are being given Neo-B12 Injection.
- If you are to be started on any new medicine, remind your doctor and pharmacist that you are being given Neo-B12 Injection.
- If you become pregnant while you are being treated with Neo-B12 Injection, tell your doctor immediately.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are being given Neo-B12 Injection. It may affect other medicines used during surgery.
- If you are about to have any blood tests, tell your doctor that you are being given Neo-B12 Injection.
   It may interfere with the results of some tests.
- Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the

medicine is working and to prevent any unwanted side effects.

### **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how Neo-B12 Injection affects you.

### Looking after your medicine

- Neo-B12 Injection is usually stored in the doctor's surgery or clinic, or at the pharmacy.
- If you need to store Neo-B12 Injection, keep it in the original pack until it is time for it to be given.

Store below 25°C. Store in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

### Getting rid of any unwanted medicine

Neo-B12 Injection should not be given to you if the packaging is torn or shows signs of tampering.

If your doctor tells you to stop using Neo-B12 Injection or it is out of date, take any ampoules that are left over to a pharmacy for safe disposal.

## 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  | What to do  |
|--|---|
| <ul><li>diarrhoea</li><li>nausea</li><li>headache</li><li>vomiting</li></ul>   | Speak to your doctor if you have any of these common side effects and they worry you. |
| <ul> <li>dizziness</li> <li>acne</li> <li>skin rash or discolouration</li> <li>itching</li> <li>pain or redness at the injection site</li> <li>feeling hot or cold, fever, shivering</li> <li>general feeling of weakness or unwell</li> <li>change in urine or</li> </ul> | These side effects are usually mild.  |
| weakness or unwell   |   |

| Less serious side effects   | What to do  |
|---|---|
| <ul> <li>increased blood<br/>pressure and change in<br/>electrolytes</li> </ul>   |   |
| Serious side effects  | What to do  |
| <ul> <li>signs of an allergic reaction, including:         <ul> <li>shortness of breath</li> <li>wheezing or difficulty breathing</li> <li>swelling of the face, lips, tongue or other parts of the body</li> <li>rash, itching or hives on the skin.</li> </ul> </li> <li>breathlessness, which may be severe and usually worsens on lying down (due to a build-up of fluid in the lungs)</li> <li>changes in heart rate (fast, slow or irregular)</li> <li>chest tightness or pain</li> <li>swelling or pain in a body part (due to clots in</li> </ul> | 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.  You may need urgent medical attention or hospitalisation.  These side effects are rare. |
| body part (due to clots in the blood vessels).  |   |

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 <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. 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

### What Neo-B12 Injection contains

| Active ingredient (main ingredient) | Hydroxocobalamin (as chloride) |
|-------------------------------------|--------------------------------|
| Other ingredients                   | sodium chloride                |
| (inactive ingredients)              | acetic acid                    |
|                                     | water for injections           |

Do not use this medicine if you are allergic to any of these ingredients. This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

### What Neo-B12 Injection looks like

Neo-B12 Injection is a clear, dark red solution in a glass ampoule. It is available in packs of 3 ampoules.

 1000 micrograms/1 mL ampoules x 3 (AUST R 121709)

### **Who distributes Neo-B12 Injection**

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedinfo.com.au

This leaflet was prepared in June 2022.