

Consumer Medicine Information

1. What is in the leaflet?

This leaflet answers some common questions about NanoCelle® Activated B12.

It does not contain all of the available information. It does not take the place of talking to your health professional.

All medicines and supplements have risks and benefits. Your doctor has weighed the risks of you taking NanoCelle® Activated B12 against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your health professional.

Keep this leaflet with the medicine.

You may need to read it again.

2. What NanoCelle® Activated B12 is used for

NanoCelle® Activated B12 is used to assist in the management of dietary Vitamin B12 deficiency. Vitamin B12 is a water-soluble vitamin that is found almost exclusively in poultry, seafood, milk, cheese and eggs. Vegetarians, vegans, the elderly and people with poor intestinal absorption may require Vitamin B12 supplementation.

Vitamin B12 plays a significant role in:

- Methylation pathways
- DNA synthesis
- A healthy nervous system
- Mitochondrial energy production
- Synthesis of myelin and so healthy myelin/nerve function
- Conversion of homocysteine to methionine
- Red blood cell production

What is Mecobalamin (Synonym: Co-methylcobalamin)?

Mecobalamin is the biologically active form of vitamin B12.

Your health professional may have prescribed NanoCelle® Activated B12 for another reason.

Ask your health professional if you have any questions concerning why NanoCelle® Activated B12 has been prescribed for you.

NanoCelle® Activated B12 is not addictive.

3. Before you take NanoCelle® Activated B12

Do not take NanoCelle® Activated B12 if:

- 1. You have had an allergic reaction to NanoCelle® Activated B12, other Vitamin B12 supplements, Vitamin E or any ingredient (listed in section 8).**
- 2. The packaging is torn, missing or shows signs of tampering.**
- 3. The expiry date (EXP) printed on the carton and/or bottle has passed.**

If you take this medicine after the expiry date has passed, the efficacy may be reduced.

If you are not sure you should start taking NanoCelle® Activated B12 contact your health professional.

Before you take NanoCelle® Activated B12, tell your doctor if:

- 1. You have any allergies to any other medicines, foods, preservatives, dyes or additives.**

If you experience any allergic reaction or other side effects after consuming NanoCelle® Activated B12 you should discontinue use and consult with your health professional.

- 2. You are pregnant or planning to become pregnant.**

- 3. You are breastfeeding or planning to breastfeed.**

- 4. You have or have had any other health problems or issues including:**

- Liver disease (cirrhosis or hepatitis)
- Myeloproliferative disorders (polycythaemia vera and chronic myelocytic leukaemia)

- 5. You drink large amounts of alcohol.**

- 6. You are taking other medicines.**

Tell your health professional if you are taking any other medicines, including any that you get without a prescription.

Some medicines may interfere with NanoCelle® Activated B12. These include:

- Colchicine
- Metformin
- Extended-release potassium products
- Antibiotics
- Anti-seizure medications
- H2 blockers
- Proton pump inhibitors

Some medicines may be affected by NanoCelle® Activated B12 or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your health professional has more information on medicines to be careful with or avoid while taking NanoCelle® Activated B12.

Ask your health professional if you are not sure about the above list of medicines.

If you have not told your health professional about any of the above, tell them before you start taking NanoCelle® Activated B12.

4. How to take NanoCelle® Activated B12

- 1. Follow all directions given to you by your health professional carefully.**
- 2. Take NanoCelle® Activated B12 exactly as your health professional has prescribed.**

This may differ from the information contained in this leaflet.

- 3. How much NanoCelle® Activated B12 should be taken?**

The adult dose is 300 microlitres (2 sprays) once daily, sprayed on the inside of the cheek (buccal).

Your health professional will tell you how much NanoCelle® Activated B12 to take each day. This depends on the

condition being treated and whether any other medicines are being used.

- 4. How to take NanoCelle® Activated B12**

NanoCelle® Activated B12 should be sprayed directly on the inside of the cheek.

Consult your health professional if you are unsure.

- 5. How long to take NanoCelle® Activated B12**

Take NanoCelle® Activated B12 as long as your health professional prescribes.

- 6. If you forget to take NanoCelle® Activated B12**

Do not try to make up for missed doses by taking an extra dose. This may increase the chance of getting an unwanted side effect.

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

If you are unsure of what to do, check with your health professional.

- 7. If you have taken too much NanoCelle® Activated B12 (overdose)**

Visit your health professional as soon as possible. Tell them how much NanoCelle® Activated B12 you took and when so they can determine what action is best for your health. Please visit your health professional if there are any signs of discomfort.

5. While you are taking NanoCelle® Activated B12

Things you MUST do:

- 1. If you become pregnant while taking NanoCelle® Activated B12 tell your health professional immediately.**
- 2. If you are about to start taking a new medicine, tell your health professional that you are taking NanoCelle® Activated B12.**
- 3. If you are planning to have surgery, including dental surgery, tell your health professional that you are taking NanoCelle® Activated B12.**
- 4. Always follow your health professional or pharmacist's instructions carefully.**

Things you MUST NOT do:

1. Do not spray NanoCelle® Activated B12 into your eyes. Do not spray NanoCelle® Activated B12 onto skin that is cut or bleeding.
2. Do not heat NanoCelle® Activated B12 or add to hot food.
3. Do not expose NanoCelle® Activated B12 to extreme heat conditions for extended periods of time.

6. Side Effects

NanoCelle® Activated B12 has a low risk of side effects when taken as directed. Excess vitamin B12 is excreted from the body via urine.

If you experience any of the following symptoms after taking a dose of NanoCelle®

Activated B12, tell your health professional. These symptoms may be from an allergic reaction:

- Skin rash
- Swelling of the face and/or throat
- Difficulty breathing
- Itching of the skin

These side effects are usually mild and dose related. They usually disappear in a few days after the use of NanoCelle® Activated B12 is ceased.

Tell your health professional if you notice anything else that is making you feel unwell while taking NanoCelle® Activated B12.

If you have any questions, please ask your health professional.

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7. After taking NanoCelle® Activated B12

Storage

Keep NanoCelle® Activated B12 in its original bottle until it is time to take it. If you take the liquid out of the bottle it may not keep well.

Keep NanoCelle® Activated B12 in a cool, dry place. Store below 25°C. Do not freeze the product.

Do not store NanoCelle® Activated B12, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy the medicine.

Protect NanoCelle® Activated B12 from direct sunlight.

Keep out of reach of children.

8. Product description

What NanoCelle® Activated B12 looks like:

NanoCelle® Activated B12 is a peppermint-flavoured liquid. NanoCelle® Activated B12 is packaged in a 30 mL plastic spray bottle with a clear plastic cap.

Each bottle is packed in a recyclable cardboard box with a safety seal.

Each 30 mL spray bottle contains 100 doses (200 sprays).

Ingredients:

Active Ingredients PER 300 microlitres (2 SPRAYS):

Vitamin B12 (as Methylcobalamin)1000 micrograms

Excipient ingredients:

Water- purified

PEG-40 hydrogenated castor oil

Glycerol

D-alpha-tocopherol

Sunflower oil

Citric acid

Potassium sorbate

Steviol glycosides

Peppermint oil

NanoCelle® Activated B12 is suitable for vegetarians and vegans.

NanoCelle® Activated B12 is dairy and gluten free.

9. Manufacturer

NanoCelle® Activated B12 is manufactured in Canada by Factors Laboratories Ltd.

It is supplied in Australia by: