

NanoCelle® D3+K2

Contains Micellized Vitamin D3 & Vitamin K2

Consumer Medicine Information

1. What is in the leaflet?

This leaflet answers some common questions about NanoCelle® D3+K2.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking NanoCelle® D3+K2 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® D3+K2 is used for

NanoCelle® D3+K2 is used to assist in the management of Vitamin D deficiency. Vitamins D3 and K2 are required for healthy mineralization and a normal bone metabolism.

Vitamin D3 aids in dietary calcium and phosphorus absorption, important for maintaining healthy bone mineral density. Vitamin D3 is used to treat and prevent bone disorders such as rickets and osteomalacia. The vitamin D receptor (VDR) is located on body cells, including immune cells, and is responsible for activating gene

expression and therefore cellular function. Vitamin D3 affects the transcription of more than 900 genes.

Vitamin K is vital for bone and cardiovascular health. Vitamin K2 is the most biologically active form of Vitamin K.

Your health professional may have prescribed NanoCelle® D3+K2 for another reason.

Ask your health professional if you have any questions concerning why NanoCelle® D3+K2 has been prescribed for you.

NanoCelle® D3+K2 is not addictive.

3. Before you take NanoCelle® D3+K2

Do not take NanoCelle® D3+K2 if:

- 1. You have had an allergic reaction to NanoCelle® D3+K2, colecalciferol, 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 bottle and/or carton has passed.**

If you take this medicine after the expiry date has passed, the efficacy of the medicine may be reduced.
- 4. Do not give NanoCelle® D3+K2 to children under 4 years of age.**

If you are not sure if you should start taking NanoCelle® D3+K2 contact your health professional.

Before you start to take it, you must 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® D3+K2, 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:**

- Hypercalcaemia
- Hypervitaminosis D
- Thrombophilia (hypercoagulable states)
- Bleeding disorders (Haemophilia, von Willebrands disease)
- Malabsorption
- Kidney Disease
- Liver Disease

- 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.

Anticoagulant medications interact with Vitamin K. Vitamin K is used by the body to help

blood clot. Warfarin (Coumadin) is used to slow blood clotting. By helping the blood clot, vitamin K might decrease the effectiveness of warfarin (Coumadin).

Tell your health professional if you are taking any of the following:

- Warfarin (Coumadin)

Your doctor or pharmacist will advise you.

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® D3+K2.

4. How to take NanoCelle® D3+K2

1. Follow all directions given to you by your health professional carefully.

2. Take NanoCelle® D3+K2 exactly as your health professional has prescribed.

This may differ from the information contained in this leaflet.

3. How much NanoCelle® D3+K2 should be taken?

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

Your health professional will tell you how much NanoCelle® D3+K2 to take each day. This depends on the condition being treated and whether any other medicines are being used.

4. How to take NanoCelle® D3+K2

NanoCelle® D3+K2 should be sprayed directly on the inside of the cheek (buccal).

Consult your health professional if you are unsure.

5. When to take NanoCelle® D3+K2

You can take NanoCelle® D3+K2 anytime of the day, unless otherwise advised by your health professional.

6. How long to take NanoCelle® D3+K2

Take NanoCelle® D3+K2 as long as your health professional prescribes.

7. If you forget to take NanoCelle® D3+K2

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.

8. If you have taken too much NanoCelle® D3+K2 (overdose)

Visit your health professional as soon as possible. Tell them how much NanoCelle® D3+K2 you took and when so they can determine what action is best for your health. Please visit your health professional if there are signs of discomfort.

5. While you are taking NanoCelle® D3+K2

Things you MUST do:

1. If you become pregnant while taking, NanoCelle® D3+K2 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® D3+K2.

3. If you are planning to have surgery, including dental surgery, tell your health

professional that you are taking NanoCelle® D3+K2.

4. Always follow your health professional's instructions carefully.

5. Do not give NanoCelle® D3+K2 to children under 4 years of age.

Things you MUST NOT do:

1. Do not spray NanoCelle® D3+K2 into your eyes. Do not spray NanoCelle® D3+K2 onto skin that is cut or bleeding.

2. Do not expose NanoCelle® D3+K2 to extreme heat conditions for extended periods of time.

Things to be careful of:

NanoCelle® D3+K2 contains Vitamin D3, which is a fat-soluble vitamin. Some weight loss medicines can bind to Vitamin D3 and make treatment unsuccessful. Vitamin K is a fat-soluble vitamin that plays a key role in blood clotting, preventing excessive bleeding.

You should discuss this with your health professional if you are taking anticoagulant medications.

6. Side Effects

NanoCelle® D3+K2 has a low risk of side effects when taken as directed.

If you experience any of the following symptoms after taking a dose of NanoCelle® D3+K2, tell your healthcare professional immediately. These symptoms may be from an allergic reaction:

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

These side effects are usually mild and dose related. They usually

disappear in a few days after the use of NanoCelle® D3+K2 is ceased.

Tell your health professional if you notice anything else that is making you feel unwell while taking NanoCelle® D3+K2.

If you have questions, please ask your health professional.

7. After taking NanoCelle® D3+K2

Storage

Keep NanoCelle® D3+K2 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® D3+K2 in a cool, dry place where the temperature stays below 25°C. Do not refrigerate or freeze this product.

Do not store NanoCelle® D3+K2, 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® D3+K2 from direct sunlight.

Keep out of reach of children.

8. Product description

What NanoCelle® D3+K2 looks like:

NanoCelle® D3+K2 is a peppermint-flavoured, clear liquid. NanoCelle® D3+K2 is packaged in a 30 mL opaque 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 D3 (as colecalciferol) 25 micrograms (1000IU)

Vitamin K2 (as menaquinone-7) 45 micrograms

Excipient ingredients:

Water- purified

PEG-40 hydrogenated castor oil

Glycerol

Olive oil

Maize oil

Citric acid

Potassium sorbate

Steviol glycosides

Peppermint oil

NanoCelle® D3+K2 is suitable for vegetarians and vegans.

NanoCelle® D3+K2 is dairy and gluten free.

9. Manufacturer

NanoCelle® D3+K2 is manufactured in Canada by Factors Laboratories Ltd.

NanoCelle® D3+K2 is supplied in Australia by:

A division of Medlab Pty Limited™
Unit 5 11 Lord St
Botany NSW 2019
Toll free: 1300 369 570

NanoCelle® D3+K2 is supplied in Northern America by:

A division of InMed Technologies™
Suite 400, 29883 Santa Margarita Pkwy
Rancho Santa Margarita CA 92688
Toll free 1800 921 1710

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