

Consumer Medicine Information**1. What is in the leaflet?**

This leaflet answers some common questions about NanoCelle® D3.

It does not contain all 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 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 is used for

NanoCelle® D3 is used to assist in the management of vitamin D deficiency. Vitamin D3 is a fat-soluble vitamin that is synthesised in the body naturally from sun exposure but also obtained from dietary sources such as fatty fish, egg yolk and beef liver.

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 D3 plays a significant role in:

- Preventing bone density loss
- Healthy immune function
- Healthy nervous system function
- Healthy cardiovascular function
- Healthy kidney function

What is colecalciferol?

Colecalciferol is a form of vitamin D3 and is the active ingredient in NanoCelle® D3. It is also known as vitamin D or D3.

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

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

NanoCelle® D3 is not addictive.

3. Before you take NanoCelle® D3

Do not take NanoCelle® D3 if:

1. **You have had an allergic reaction to NanoCelle® D3, Colecalciferol or any other ingredient in NanoCelle® D3 Spray (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 to children under 4 years of age.**

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

Before you take NanoCelle® D3, 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 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
 - Malabsorption syndrome
 - 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, from a pharmacy, supermarket or health food store.

Some medicines may interfere with NanoCelle® D3. These include:

- Steroid medications such as prednisone
- Weight loss medication Orlistat
- Cholesterol lowering medications such as Cholestyramine
- Seizure medications such as Phenobarbital and Dilantin

These medicines may be affected by NanoCelle® D3 or may affect its efficacy. 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 have more information on medicines to be careful with or avoid while taking NanoCelle® D3.

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

If you have not told your health professional about any of the above, tell them before you start taking NanoCelle® D3.

4. How to take NanoCelle® D3

1. **Follow all directions given to you by your health professional carefully.**
2. **Take NanoCelle® D3 exactly as your health professional has prescribed.**
This may differ from the information contained in this leaflet.
3. **How much NanoCelle® D3 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® D3 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

NanoCelle® D3 should be sprayed directly on the inside of the cheek.

Consult with your health professional if you are unsure.

5. When to take NanoCelle® D3

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

6. How long to take NanoCelle® D3

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

7. If you forget to take NanoCelle® D3

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 (overdose)

Visit your health professional as soon as possible. Tell your health professional how much NanoCelle® D3 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

Things you MUST do:

1. **If you become pregnant while taking NanoCelle® D3 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.**
3. **If you are planning to have surgery, including dental surgery, tell your health professional that you are taking NanoCelle® D3.**
4. **Always follow your health professional's instructions carefully.**
5. **Do not give NanoCelle® D3 to children under 4 years of age.**

Things you MUST NOT do:

1. Do not spray NanoCelle® D3 into your eyes. Do not spray NanoCelle® D3 onto skin that is cut or bleeding.
2. Do not heat NanoCelle® D3 or add into hot foods.
3. Do not expose NanoCelle® D3 to extreme heat conditions for extended periods of time.

Things to be careful of:

NanoCelle® D3 contains vitamin D3, which is a fat-soluble vitamin. Some weight loss medicines can bind to vitamin D3 and make treatment unsuccessful.

6. Side Effects

NanoCelle® D3 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, tell your health professional. These symptoms may be from an allergic reaction:

- Difficulty breathing
- Swelling of the face and 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 is ceased.

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

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

7. After taking NanoCelle® D3

Storage

Keep NanoCelle® D3 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 in a cool, dry place. Store below 25°C. Do not freeze the product.

Do not store NanoCelle® D3 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 from direct sunlight.

Keep out of reach of children.

8. Product description

What NanoCelle® D3 looks like:

NanoCelle® D3 is a peppermint-flavoured, clear liquid emulsion. NanoCelle® D3 is packaged in a 30 mL plastic spray bottle with a 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 (1000 IU)

Excipient ingredients:

Water - purified
PEG-40 hydrogenated castor oil
Glycerol
Maize oil
Citric acid
Potassium sorbate
Steviol glycosides
Peppermint oil

NanoCelle® D3 is suitable for vegetarians and vegans.

NanoCelle® D3 is dairy and gluten free.

9. Manufacturer

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

NanoCelle® D3 is supplied in Australia by:
Medlab Pty Limited™
A division of Medlab Pty Limited™

Unit 5 11 Lord St
Botany NSW 2019
Toll free: 1300 369 570

NanoCelle® D3 is supplied in Northern America by:

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

Australian Listing Number
AUST L 232096

This leaflet was prepared in November 2014

Version 4.0

Medlab Pty Limited™