

**PATIENT INFORMATION LEAFLET****BETTERYOU® DLUX1000 DAILY VITAMIN D ORAL SPRAY****SCHEDULING STATUS:** S0**BETTERYOU DLUX1000 DAILY VITAMIN D, 25 µg, Oral Spray**Cholecalciferol (Vitamin D<sub>3</sub>)

Sugar free

Complementary Medicine: Health Supplement: Vitamins

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority (SAHPRA) for its quality, safety or intended use.

**Read this entire leaflet carefully because it contains important information for you.**

BETTERYOU DLUX1000 DAILY VITAMIN D is available without a doctor's prescription for you to maintain your health. Nevertheless, you still need to use BETTERYOU DLUX1000 DAILY VITAMIN D carefully to get the best results from it.

- Keep this leaflet; you may need to read it again.
- Do not share BETTERYOU DLUX1000 DAILY VITAMIN D with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

**What is in this leaflet**

1. What BETTERYOU DLUX1000 DAILY VITAMIN D is and what it is used for
2. What you need to know before you take BETTERYOU DLUX1000 DAILY VITAMIN D
3. How to take BETTERYOU DLUX1000 DAILY VITAMIN D
4. Possible side effects
5. How to store BETTERYOU DLUX1000 DAILY VITAMIN D
6. Contents of the pack and other information

## **1. What BETTERYOU DLUX1000 DAILY VITAMIN D is and what it is used for**

BETTERYOU DLUX1000 DAILY VITAMIN D is a health supplement that contributes to the development and maintenance of strong bones and teeth, the maintenance of normal muscle function, and to the normal function of the immune system.

## **2. What you need to know before you take BETTERYOU DLUX1000 DAILY VITAMIN D**

### **Do NOT take BETTERYOU DLUX1000 DAILY VITAMIN D**

- If you are allergic (hypersensitive) to vitamin D<sub>3</sub> (cholecalciferol), or any of the other components of the formulation (see Section 6 *Contents of the pack and other information*).

### **Warnings and precautions**

Health supplements should not be used as a substitute for a healthy diet.

Excessive intake of BETTERYOU DLUX1000 DAILY VITAMIN D may lead to the development of high blood levels of calcium and phosphate. This may cause

calcifications in muscles, tendons, or joints as well as kidney, heart, and blood vessel damage. If you have previously been diagnosed with atherosclerosis (calcification of your arteries or blood vessels), hyperactive parathyroid glands, lymphoma, kidney disease, previous high blood levels of calcium, sarcoidosis, tuberculosis, or histoplasmosis, you may have to go for regular blood tests to monitor your blood calcium concentrations while you take BETTERYOU DLUX1000 DAILY VITAMIN D. Please discuss this with your treating doctor.

### **Other medicines and BETTERYOU DLUX1000 DAILY VITAMIN D**

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Before taking BETTERYOU DLUX1000 DAILY VITAMIN D, please discuss the use of the following medicines or substances with your doctor, pharmacist, or other healthcare professional:

- Calcipotriene for the treatment of psoriasis.
- Digoxin for heart failure or diltiazem or verapamil for abnormal heart rhythms or other heart problems.
- Diuretics or water tablets.
- Phosphate binders if you have kidney disease.

BETTERYOU DLUX1000 DAILY VITAMIN D may lower the blood levels of certain medicines, such as atorvastatin and lovastatin (for high cholesterol levels), clarithromycin (an antibiotic), ciclosporin (for suppression of the immune system), oestrogens, indinavir (for the treatment of HIV or AIDS), triazolam (a sedative), and

others. If you are taking any of these or other medicines and you feel that they are no longer effective, please inform your doctor or pharmacist.

Tell your doctor that you are taking BETTERYOU DLUX1000 DAILY VITAMIN D if you are scheduled to undergo blood tests. Supplementation with BETTERYOU DLUX1000 DAILY VITAMIN D may influence the results of certain blood tests.

### **BETTERYOU DLUX1000 DAILY VITAMIN D with food**

BETTERYOU DLUX1000 DAILY VITAMIN D can be taken without regard to meals (see **How to take BETTERYOU DLUX1000 DAILY VITAMIN D**).

### **Pregnancy and breastfeeding**

BETTERYOU DLUX1000 DAILY VITAMIN D at the recommended dosage of 1 spray daily is safe to use during pregnancy and while you are breastfeeding. Be careful when you combine (use more than one) health supplements during pregnancy or if you are breastfeeding and make sure that you do not exceed the tolerable upper intake level (UL) of 4 000 I.U. of vitamin D daily.

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before taking BETTERYOU DLUX1000 DAILY VITAMIN D.

### **Driving and using machines**

No specific studies have been conducted. Given its side-effect profile, it is unlikely that BETTERYOU DLUX1000 DAILY VITAMIN D will influence your ability to drive or use machines.

It is not always possible to predict to what extent BETTERYOU DLUX1000 DAILY VITAMIN D may interfere with your daily activities. Please ensure that you do not engage in the above activities until you are aware of the measure to which BETTERYOU DLUX1000 DAILY VITAMIN D affects you.

### **3. How to take BETTERYOU DLUX1000 DAILY VITAMIN D**

*Adults and children over 1 year:*

Always take BETTERYOU DLUX1000 DAILY VITAMIN D exactly as described in this leaflet or as your doctor, pharmacist, or healthcare provider has told you. Check with your doctor, pharmacist, or healthcare provider if you are not sure.

Use 1 spray per day. Shake the bottle well before each use.

Initial use: Press the pump 3 times to prime the spray mechanism.

Press the pump once to carefully spray the contents onto the inside of the cheek and hold for a few seconds. Replace the cap after use.

BETTERYOU DLUX1000 DAILY VITAMIN D can be used without regard to meals.

Once opened, use within 6 months.

Do NOT exceed the recommended maximum dose of 1 spray per day.

You can continue with BETTERYOU DLUX1000 DAILY VITAMIN D supplementation for as long as you derive benefit from it.

Health supplements should not replace a healthy diet.

**If you take more BETTERYOU DLUX1000 DAILY VITAMIN D than you should**

Symptoms of overdose include nausea and vomiting, loose stools, frequent urination, sweating, headache, and thirst. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

### **If you forget to take BETTERYOU DLUX1000 DAILY VITAMIN D**

If you forget to take BETTERYOU DLUX1000 DAILY VITAMIN D, take the next dose as soon as you remember. If it is the next day, skip the missed dose and continue with the usual dose of 1 spray per day. Do NOT take a double dose to make up for forgotten individual doses.

### **4. Possible side effects**

BETTERYOU DLUX1000 DAILY VITAMIN D can have side effects.

Not all side effects for BETTERYOU DLUX1000 DAILY VITAMIN D are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BETTERYOU DLUX1000 DAILY VITAMIN D, please consult your healthcare provider for advice.

It is important not to exceed the recommended dose. BETTERYOU DLUX1000 DAILY VITAMIN D is usually well tolerated when used in the prescribed dosage.

Stop taking BETTERYOU DLUX1000 DAILY VITAMIN D and report to your doctor or nearest hospital emergency centre immediately if you develop the following side effects:

- Those for which the frequency is not known:
  - Hypersensitivity or allergic reaction that may present with a skin rash,

itching, fever, difficulty breathing, swelling of the face, lips, or throat, or tightness of the chest.

Please report the following side effects to your doctor if they continue or become bothersome:

- Those for which the frequency is not known:
  - Dry mouth

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the **“6.04 Adverse Drug Reaction Reporting Form”** found online under SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of BETTERYOU DLUX1000 DAILY VITAMIN D. In addition, side effects can also be reported to Natroceutics by email at [info@natroceutics.com](mailto:info@natroceutics.com).

### 5. How to store BETTERYOU DLUX1000 DAILY VITAMIN D

Store at or below 25 °C.

Keep in the outer carton until required for use. Once opened, use within 6 months.

Protect from direct sunlight.

Do not use after the expiry date stated on the bottle and carton.

Do not dispose of unused BETTERYOU DLUX1000 DAILY VITAMIN D in drains or sewerage systems (e.g. toilets). Return all unused supplements to your pharmacist.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

## **6. Contents of the pack and other information**

### **What BETTERYOU DLUX1000 DAILY VITAMIN D contains**

Each daily dose (1 spray) of BETTERYOU DLUX1000 DAILY VITAMIN D contains:

|                                           |                    |
|-------------------------------------------|--------------------|
| Cholecalciferol (vitamin D <sub>3</sub> ) | 1 000 I.U. (25 µg) |
|-------------------------------------------|--------------------|

BETTERYOU DLUX1000 DAILY VITAMIN D is sugar free.

Preservative: potassium sorbate 0,2 % w/v

Other ingredients are acacia gum (emulsifier), citric acid (acidity regulator), natural peppermint oil (flavouring), sunflower lecithin (emulsifier), water, and xylitol (diluent).

### **What BETTERYOU DLUX1000 DAILY VITAMIN D looks like and contents of the pack**

Outer carton containing white opaque HDPE spray bottle with clear cap. Each bottle contains a clear solution.

Pack size: 15 ml

### **HOLDER OF CERTIFICATE OF REGISTRATION**

NATROCEUTICS (PTY) LTD

The Hudson, 1st Floor

30 Hudson Street

De Waterkant

Cape Town

8001

South Africa

**This leaflet was last revised in**

July 2023.

**Registration/Application number**

To be allocated by the Authority upon registration.

**Access to the corresponding Professional Information**

Please contact [info@natroceutics.com](mailto:info@natroceutics.com).