

OSTEVIT-D® ONE -A-WEEK

Active ingredient(s): Colecalciferol 175mcg equivalent to Vitamin D3 7000IU

Consumer Medicine Information (CMI)

This leaflet provides important information about using OsteVit-D One-A-Week capsules. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using OsteVit-D One-A-Week capsules.**

1. Why am I using OsteVit-D One-A-Week Capsules?

OsteVit-D One-A-Week capsules contain the active ingredient colecalciferol. Colecalciferol is another name for vitamin D3.

OsteVit-D One-A-Week is used as directed by your medical practitioner or pharmacist, for (a) treatment of vitamin D deficiency in adults and adolescents and (b) for the prevention of vitamin D deficiency in high-risk individuals.

Vitamin D3 is a fat-soluble vitamin that helps your body absorb calcium and phosphorus, for strong, healthy bones and teeth. A diet with not enough calcium can lead to osteoporosis later in life. Adequate vitamin D and calcium is needed to help build strong bones and assist in the prevention of osteoporosis. Ostevit-D One-A-Week is not a source of calcium.

It is unlikely that adequate vitamin D levels can be achieved through the diet.

The main source of vitamin D is from the sun, however deficiency is common, and it should not be assumed that Australians get enough vitamin D from the sun.

People who may be at risk of being deficient are the elderly (particularly those in residential care), people with skin conditions where avoidance of sunlight is advised, those with dark skin (particularly if veiled), and those with malabsorption.

2. What should I know before I use OsteVit-D One -A-Week Capsules?

Warnings

Do not use Ostevit-D One-A-Week capsules if:

- you are allergic to colecalciferol, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- your doctor has told you that you have high calcium (hypercalcaemia) and / or vitamin D levels (hypervitaminosis) in your blood.

Check with your doctor or pharmacist if you:

- have any other medical conditions, kidney disease, kidney stones, heart disease, long-standing high calcium levels in the blood, any condition that makes it hard for your body to absorb nutrients from food (malabsorption)
- have leukaemia, lymphoma, sarcoidosis.
- take any medicines for any other condition
- Take other medicines, including OTC and health food preparations that contain vitamin D

Do not give to children under the age of 12 years.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows sign of tampering.

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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Vitamin D3 is a therapeutic good which is exempted from pregnancy classification by TGA.

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

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

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.

In particular, you should tell your doctor or pharmacist if you are using:

- Thiazides (medications used for high blood pressure and fluid build-up).
- Medicines used to treat seizures such as carbamazepine, phenobarbital, phenytoin and primidone.
- Calcium or phosphate supplements
- Orlistat (weight loss medicine)
- Antacids (medicines used to treat indigestion eg Gaviscon, mylanta)
- Bile acid sequestrants (eg cholestyramine, colestipol)
- Isoniazid

Some medicines may interfere with OsteVit-D One-A-Week capsules and affect how it works.

You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist will advise you.

Medicines that may increase the effect of OsteVit D One-A-Week include

- There is an increased risk of hypercalcaemia with thiazide diuretics, calcium or phosphate supplements.

Medicines that may reduce the effect of OsteVit D One a Week include:

- Orlistat (weight loss medicine)
- Cholestyramine (bile acid sequestrants)
- Colestipol (bile acid sequestrants)
- Antacids (medicines used to treat indigestion eg Gaviscon, mylanta)
- Calcium and phosphate supplements (may impair absorption of vitamin D)
- Anticonvulsants, cimetidine and thiazides may increase the catabolism of vitamin D through P450 interactions.
- Isoniazid may reduce the effectiveness of colecalciferol.
- Concomitant treatment with rifampicin, phenytoin or barbiturates can decrease the effect of colecalciferol due to metabolism activation.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affects OsteVit-D One-A-Week capsules.

4. How do I use OsteVit-D One-A-Week Capsules?

How much to take / use

- Adults and adolescents over 12 years of age: one capsule once weekly as directed by your medical practitioner or pharmacist.
- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.

When to take / use OsteVit-D One-A-Week capsules

- OsteVit-D One-A-Week capsules should be taken with or without a meal.
- Take your medicine on the same day each week.
- Continue taking your medicine for as long as your pharmacist or doctor tells you.

If you use too much OsteVit-D One-A-Week capsules

If you think that you have used too much Ostevit-D One-A-Week capsules, you may need urgent medical attention.

Excessive intake of Vitamin D leads to the development of hypercalcaemia and its associated effects including hypercalciuria, hyperphosphataemia, ectopic calcification, and renal and cardiovascular damage.

Symptoms of overdose may include anorexia, lassitude, nausea and vomiting, bone pain, weight loss, diarrhoea, polyuria, nocturia, sweating, headache, thirst, somnolence, constipation, muscle weakness, apathy, proteinuria, depression, vague aches, stiffness, anaemia, hypertension, cardiac arrhythmias, urinary tract infections and vertigo.

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 while using OsteVit-D One-A-Week Capsules

Things you should do

- If you become pregnant while taking this medicine, tell your doctor immediately.
- If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests. Your medical practitioner should monitor your urine and serum calcium, vitamin D and parathyroid hormone levels while you are taking Ostevit-D One -A-Week in order to assess your response to treatment.

Remind any doctor, dentist or pharmacist you visit that you are using OsteVit-D One-A-Week capsules.

Things you should not do

- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not take more than the recommended dose unless your pharmacist or doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how OsteVit-D One-A-Week capsules affects you.

Looking after your medicine

- Keep your capsules in the pack until it is time to take it.

- Keep your medicine in a cool dry place where the temperature stays below 25°C. Protect from light after opening.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it 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.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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.

Adverse Event	Frequency Category	
	Uncommon (affecting $\geq 1/1000$ and < 1 in 100 people)	Rare (affecting $\geq 1/10,000$ and $< 1/1000$ people)
Metabolism and nutrition disorders	Hypercalcaemia Hypercalciuria	
Skin and Subcutaneous disorders		Pruritus Rash Urticaria

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 www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available behind-the-counter without a doctor's prescription.

What OsteVit-D One-A-Week Capsules contains

Active ingredient (main ingredient)	Colecalciferol 175mcg
Other ingredients (inactive ingredients)	Soya oil Gelatin Glycerol Fractionated coconut oil Opacode monogramming ink S-1-1-17823 Black Purified water

Do not take this medicine if you are allergic to any of these ingredients.

What OsteVit-D One-A-Week capsules looks like

OsteVit-D One-A-Week is a pale-yellow transparent oil filled soft gelatin capsule with '7000' printed in black ink. (Aust R 256292).

Who distributes OsteVit-D One-A-Week capsules

Key Pharmaceuticals Pty Ltd
MQX4, 1 Giffnock Avenue
Macquarie Park NSW 2113

This leaflet was revised in July 2024.