OSTELIN SPECIALIST RANGE VITAMIN D 7000IU (WEEKLY)

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Ostelin Specialist Range Vitamin D 7000IU?

Ostelin Specialist Range Vitamin D 7000IU contains the active ingredient Colecalciferol. Ostelin Specialist Range Vitamin D 7000IU is a supplement that is used for the treatment of vitamin D deficiency in adults and adolescents as directed by your medical practitioner or pharmacist, and the prevention of vitamin D deficiency in high risk individuals under the supervision of a medical practitioner.

For more information, see Section <u>1. Why am I using</u> Ostelin Specialist Range Vitamin D 7000IU? in the full CMI.

2. What should I know before I use Ostelin Specialist Range Vitamin D 7000IU?

Do not use if you have ever had an allergic reaction to Ostelin Specialist Range Vitamin D 7000IU or any of the ingredients listed at the end of the CMI. Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. Do not give to children under 12 years old.

For more information, see Section <u>2. What should I know</u> before I use Ostelin Specialist Range Vitamin D 7000IU? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ostelin Specialist Range Vitamin D 7000IU and affect how it works. A list of these medicines is in Section <u>3. What if I am</u> <u>taking other medicines?</u> in the full CMI.

4. How do I use Ostelin Specialist Range Vitamin D 7000IU?

- Swallow the whole capsule with a glass of water.
- The usual dose is one capsule once a week. Take the capsule on the same day each week.

More instructions can be found in Section <u>4. How do I</u> <u>use Ostelin Specialist Range Vitamin D 7000IU?</u> in the full CMI.

5. What should I know while using Ostelin Specialist Range Vitamin D 7000IU?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Ostelin Specialist Range Vitamin D 7000IU.
Things you should not do	 Do not give your supplement to anyone else, even if they have the same condition as you.
Driving or using machines	 Not applicable
Drinking alcohol	 Not applicable
Looking after your medicine	 Keep your capsules in the blister pack until it is time to take them. Keep in a cool, dry place where the temperature stays below 25°C.

 Do not refrigerate. Do not freeze. Protect from light.

For more information, see Section <u>5. What should I know</u> while using Ostelin Specialist Range Vitamin D 7000IU? in the full CMI.

6. Are there any side effects?

Too much vitamin D may lead to an electrolyte imbalance in your body and you may suffer from constipation, nausea, thirst, sweating, vertigo, anorexia, somnolence, abdominal pain, vomiting, headache, aching muscles or bone or frequent urinating. Other side effects are high levels of calcium in the blood or urine. For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

Ostelin Specialist Range Vitamin D 7000IU

Active ingredient(s): Colecalciferol

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ostelin Specialist Range Vitamin D 7000IU. 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 Ostelin Specialist Range Vitamin D 7000IU.

Where to find information in this leaflet:

1. Why am I using Ostelin Specialist Range Vitamin D 7000IU?

2. What should I know before I use Ostelin Specialist Range Vitamin D 7000IU?

3. What if I am taking other medicines?

4. How do I use Ostelin Specialist Range Vitamin D 7000IU?

5. What should I know while using Ostelin Specialist Range Vitamin D 7000IU?

6. Are there any side effects?

7. Product details

1. Why am I using Ostelin Specialist Range Vitamin D 7000IU?

Ostelin Specialist Range Vitamin D 7000IU contains the active ingredient Colecalciferol (a naturally occurring form of vitamin D). Ostelin Specialist Range Vitamin D 7000IU is a supplement.

Ostelin Specialist Range Vitamin D 7000IU is used for the treatment of vitamin D deficiency in adults and adolescents as directed by your medical practitioner or pharmacist, and the prevention of vitamin D deficiency in high risk individuals under the supervision of a medical practitioner.

Vitamin D is required for optimal calcium and phosphorous absorption in the body, which are vital for the development and maintenance of strong bones and the maintenance of muscle function. The body can only absorb calcium properly if it has enough vitamin D.

Vitamin D is primarily produced in the skin, as a result of direct exposure to sunlight. Very few foods contain vitamin D.

Ostelin Specialist Range Vitamin D 7000IU has been given as you have too little vitamin D.

This deficiency may lead to your body not being able to effectively absorb calcium which may lead to poor bone health. It may also lead to muscle weakness which may contribute to falls in the elderly. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

2. What should I know before I use Ostelin Specialist Range Vitamin D 7000IU?

Warnings

Do not use Ostelin Specialist Range Vitamin D 7000IU 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.
- you have a condition where you have too much calcium in your blood (hypercalcaemia).
- you have a diseases/condition, which leads to high levels of calcium in your blood (e.g. kidney problems, some cancers, high levels of parathyroid hormone, prolonged bed rest).
- you have hypervitaminosis D, a condition when you take too much vitamin D.

Check with your doctor or pharmacist if you:

- have any other medical conditions
- have a condition in which you have too much calcium in your blood (hypercalcemia)

- have a condition in which your urine contains unusually large amounts of calcium (hypercalciuria)
- have leukaemia, lymphoma, sarcoidosis
- have any condition that makes it hard for the body to absorb vitamin D
- have kidney problems, including kidney stones or heart disease
- take other medicines, including multivitamins which may contain vitamin D
- take any medicines for any other condition

Do not give to children under 12 years old.

Do not take this supplement after the expiry date printed on the pack or if the packaging is torn or shows signs 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 <u>6. Are there any side effects?</u>

Pregnancy and breastfeeding

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.

Your pharmacist or doctor may advise you to take Ostelin Specialist Range Vitamin D 7000IU during pregnancy or breastfeeding.

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.

Some medicines may interfere with Ostelin Specialist Range Vitamin D 7000IU and affect how it works.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while talking this medicine.

Tell your pharmacist if you are taking any other medicines including:

- Medicines used to treat seizures such as carbamazepine, phenobarbital, phenytoin and primidone
- Orlistat (weight loss medicine)
- Antacids (medicines used to treat indigestion, e.g. Gaviscon, Mylanta)
- Medicines to remove bile, such as cholestyramine and colestipol
- Fluid tablets (diuretics) such as hydrochlorothiazide
- Blood pressure tablets
- Isoniazid
- Corticosteroids
- Ketaconazole

Medicines that may <u>increase</u> the effect of Ostelin Specialist Range Vitamin D 7000IU include:

- Calcium and phosphate supplements. There is an increased risk of hypercalcaemia if colecalciferol is given with calcium and phosphate. Calcium concentrations should be monitored in those situations.
- Concomitant use of other vitamin D containing medicines.

Medicines that may <u>reduce</u> the effect of Ostelin Specialist Range Vitamin D 7000IU include:

- Thiazide diuretics (medications used for high blood pressure and fluid build-up). Thiazide diuretics reduce the urinary excretion of calcium. Serum calcium should be regularly monitored during concomitant use of thiazide diuretics.
- Corticosteroids. Systemic corticosteroids reduce calcium absorption. Moreover, the effect of vitamin D may be decreased.
- Rifampicin, isoniazid or some anti-epileptic medicines. Concomitant treatment with rifampicin, phenytoin, carbamazepine or barbiturates can decrease the effect of vitamin D3 because of metabolic activation.
- Simultaneous treatment with ion exchange resins such as cholestyramine may reduce the gastrointestinal absorption of vitamin D. Therefore, separate the time each medicine is taken by a time interval as long as possible.

Additional vitamin D supplements may be considered on an individual basis.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Ostelin Specialist Range Vitamin D 7000IU.

4. How do I use Ostelin Specialist Range Vitamin D 7000IU?

Take Ostelin Specialist Range Vitamin D 7000IU as instructed by your pharmacist or doctor.

How much to take / use

- The usual dose is one capsule once a week.
- Swallow the whole capsule with a glass of water.

When to take / use Ostelin Specialist Range Vitamin D 7000IU

- Take the capsule on the same day each week.
- Continue taking this supplement for as long as your doctor or pharmacist tells you to.

If you use too much Ostelin Specialist Range Vitamin D 7000IU

If you think that you have used too much Ostelin Specialist Range Vitamin D 7000IU, you may need urgent medical attention. You may suffer from constipation, nausea, abdominal pain, vomiting, headache, aching muscles or bone, fatigue, thirst, sweating, vertigo, anorexia, somnolence or frequent urinating.

Overdose can lead to high levels of vitamin D and calcium in the blood (symptoms may include anorexia, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, renal function can be impaired early stage (polyuria, polydipsia, nocturia), chronic overdose may cause blood vessel and soft tissue calcification).

In cases of high blood levels of vitamin D weakness, fatigue, muscle pain, polydipsia, polyuria, decreased appetite have been reported.

Other symptoms of overdose include lassitude, bone pain, weight loss, diarrhoea, sweating, headache, somnolence, 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 Ostelin Specialist Range Vitamin D 7000IU?

Things you should do

 Remind any doctor, dentist or pharmacist you visit that you are using Ostelin Specialist Range Vitamin D 7000IU.

Things you should not do

• Do not give your supplement to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Ostelin Specialist Range Vitamin D 7000IU affects you.

Looking after your medicine

- Keep your capsules in the blister pack until it is time to take them.
- Keep in a cool, dry place where the temperature stays below 25°C.
- Do not refrigerate.
- Do not freeze.
- Protect from light.

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.

Less serious side effects

Less serious side effects	What to do
Too much vitamin D may lead to an electrolyte imbalance in your body and you may suffer from	Speak to your doctor or pharmacist if you have any of these less serious

Less serious side effects	What to do
constipation, nausea, thirst, sweating, vertigo, anorexia, somnolence, abdominal pain, vomiting, headache, aching muscles or bone, or frequent urinating.	side effects and they worry you.
High levels of calcium in the blood or urine.	

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 <u>www.tga.gov.au/reporting-problems</u>. 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, following a discussion with a pharmacist.

What Ostelin Specialist Range Vitamin D 7000IU contains

Active ingredient (main ingredient)	colecalciferol (175mcg)
Other ingredients (inactive ingredients)	 dl-alpha tocopherol Soya oil Gelatin Allura red AC Patent blue V Glycerol Purified water Ink-white opacode

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

What Ostelin Specialist Range Vitamin D 7000IU looks like

Ostelin Specialist Range Vitamin D 7000IU is supplied in pack sizes of 24 and 48. (AUST R 280039).

Who distributes Ostelin Specialist Range Vitamin D 7000IU

Sanofi Consumer Healthcare

87 Yarraman Place,

Virginia, Queensland 4014

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