

Package leaflet: Information for the user

Divifarm 2000 IU film-coated tablets

cholecalciferol (Vitamin D₃)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <invented name> is and what it is used for
2. What you need to know before you take <invented name>
3. How to take <invented name>
4. Possible side effects
5. How to store <invented name>
6. Contents of the pack and other information

1. What <invented name> is and what it is used for

<invented name> contains vitamin D₃ which regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.

<invented name> is used to treat vitamin D₃ deficiency in adults and adolescents aged 12 years and older.

2. What you need to know before you take <invented name>

Do not take <invented name>:

- if you are allergic to cholecalciferol or any of the other ingredients of this medicine (listed in section 6).
- if you have hypercalcaemia (increased levels of calcium in the blood) or hypercalciuria (increased levels of calcium in the urine).
- if you have hypervitaminosis D (increased levels of vitamin D in the blood).
- if you have kidney stones.

If any of the above applies to you, talk to your doctor or pharmacist before taking <invented name>.

Warnings and precautions

Talk to your doctor or pharmacist before using <invented name>:

- if you suffer from sarcoidosis (a special type of connective tissue disease that affects the lungs, skin and joints).
- when using other products containing vitamin D.
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- if you have kidney problems or have had kidney stones.

Other medicines and <invented name>

Tell your doctor if you are taking, have recently taken or might take any other medicines.

- Cholestyramine (used to treat high cholesterol).
- Phenytoin or barbiturates (used to treat epilepsy).
- Laxatives which contain paraffin oil.
- Thiazide diuretics (to treat high blood pressure).
- Glucocorticoids (to treat inflammation).
- Cardiac glycosides (to treat heart conditions), e.g. digoxin.
- Orlistat (for weight loss, reduces the amount of fat your body absorbs).

<invented name> with food and drink

<invented name> can be taken with food.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

You should not take this medicine during pregnancy without a confirmed vitamin D deficiency and your doctor finds it necessary for you.

Breast-feeding

<invented name> can be used during breastfeeding. Vitamin D passes over into breast milk. This should be considered when giving additional vitamin D to the breast-fed child.

Driving and using machines

<invented name> has no known effects on ability to drive or use machines.

<invented name> contains sucrose and lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking <invented name>.

<invented name> contains sodium

<invented name> contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take <invented name>

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 1 tablet every day. The daily dose in adults and adolescents should not exceed 4000 IU (two tablets per day).

The tablets can be swallowed whole or crushed.

Use in children

<invented name> is not suitable for use in children under 12 years due to lack of study data.

If you take more <invented name> than you should

If you have taken more of this medicine than directed, or if a child accidentally has taken this medicine, please contact your doctor or emergency unit for judgement of the risk and advice.

If you forget to take <invented name>

Do not take a double dose to make up for a forgotten dose.

If you stop taking <invented name>

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking <invented name> and seek immediate medicinal help if you experience symptoms of serious allergic reactions, such as:

- swollen face, lips, tongue or throat
- difficult to swallow
- hives and difficulty breathing

Uncommon (may affect up to 1 in 100 people): Too much calcium in your blood (hypercalcaemia). Too much calcium in your urine (hypercalciuria).

Rare (may affect up to 1 in 1,000 people): Pruritus, rash and urticaria.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <invented name>

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of the month.

Do not store above 25°C. Keep the blister in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information**What <invented name> contains**

- The active substance is cholecalciferol (Vitamin D₃)
 - each <invented name> 2000 IU Film-coated Tablet contains 50 microgram cholecalciferol corresponding to 2000 IU vitamin D₃.
- The other ingredients:
 - Tablet core: lactose (as lactose monohydrate), powdered cellulose (E460 (ii)), modified food starch, maize starch, croscarmellose sodium (E468), sucrose, colloidal anhydrous silica (E551), magnesium stearate (E470b), sodium ascorbate (E301), medium chain triglycerides, All-rac-alpha-tocopherol (E307).
 - Coating: polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol, talc (E553b), quinoline yellow aluminum lake (E104), yellow iron oxide (E172).

See also section 2.

What <invented name> looks like and contents of the pack

<invented name> 2000 IU Film-coated Tablet is a yellow coloured, round, 9 mm diameter biconvex film-coated tablets, embossed 'S' on one side.

Pack sizes: 90 and 100 film-coated tablets in opaque PVC/PVdC-Alu blisters and box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer**Marketing Authorisation Holder**

<To be completed nationally>

Manufacturer

<To be completed nationally>

This leaflet was last revised in

2025-06-12

Other sources of information

Detailed information on this medicine is available on the web site of {MA/Agency}