

Package leaflet: Information for the user

Sapvit-D3 14,400 IU/ml oral drops, solution colecalfiferol (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 Sapvit-D3 is and what it is used for
2. What you need to know before you take Sapvit-D3
3. How to take Sapvit-D3
4. Possible side effects
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1. What Sapvit-D3 is and what it is used for

Sapvit-D3 contains the active substance colecalciferol (vitamin D₃).

Sapvit-D3 is used:

- for prevention and treatment of vitamin D deficiency
- for treatment of rickets (a condition that affects bone development in children)
- as an adjunct to osteoporosis treatment of patients who are at risk of vitamin D deficiency

2. What you need to know before you take Sapvit-D3

Do not take Sapvit-D3:

- if you are allergic to colecalciferol or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from medical conditions that result in a high calcium level in the blood or increased calcium excretion in the urine (as with treatment with certain medicines [benzothiazine derivatives] or if you are bedridden)
- if you suffer or have a tendency to suffer from calcium-containing kidney stones
- if you suffer from an excess of vitamin D
- if you have severe arteriosclerosis (hardening of the arteries)
- if you suffer from severe kidney dysfunction

Warnings and precautions

Talk to your doctor or pharmacist before taking Sapvit-D3.

Special care when taking Sapvit-D3 is required,

- if you are being treated with certain heart drugs (cardiac glycosides) or thiazide-type diuretic drugs
- if you suffer from kidney dysfunction. Your doctor will monitor the calcium and phosphate levels in the blood in this case. The risk of soft tissue calcification has to be considered.
- in severe kidney dysfunction, colecalciferol is not utilized. Your doctor will possibly recommend another vitamin D supplement.

- if you suffer from sarcoidosis (Boeck's disease), there is a risk of increased formation of the active form of vitamin D.
- in case of reduced bone mass due to inactivity (e.g. bedrest) there is an increased risk of occurrence of elevated calcium levels in the blood.

During long-term use, your doctor will check the levels of calcium in your blood and urine regularly and monitor your kidney function. If necessary, your doctor may tell you to reduce the dose or stop the treatment.

Raised parathyroid hormone levels can enhance the vitamin D metabolism and this increases the vitamin D requirement.

Additional doses of vitamin D should only be taken under close medical supervision.

Children and adolescents

Avoid the use of other vitamin D-containing products, especially in infants. If in doubt, your doctor will decide about the additional use of vitamin-enriched foods or baby foods and vitamin D-containing medicines.

Other medicines and Sapvit-D3

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important if you are taking:

- Rifampicin or isoniazid (against tuberculosis)
- Certain heart medicines (cardiac glycosides): they may enhance their harmful effects by increasing the blood calcium levels (risk of arrhythmias). A strict medical supervision is required, possibly including electrocardiogram (ECG) examination and control of the calcium level in the blood.
- Thiazide diuretics: they increase the risk for the occurrence of elevated calcium levels in the blood, because these drugs reduce the urinary excretion of calcium. Your doctor will check your blood calcium levels regularly in this case.
- Medicines for the treatment of epilepsy (carbamazepine, phenobarbital, phenytoin, primidone) or certain hormones of the adrenal cortex (glucocorticoids, "cortisone"): they may increase your vitamin D requirement.
- Medicines to lower blood lipids (e.g. orlistat and cholestyramine): they may reduce the absorption of vitamin D through the intestines.
- Medicines containing magnesium (e.g. antacids): they should not be used during Sapvit-D3-therapy as this may lead to high levels of magnesium in the blood (hypermagnesaemia).
- Aluminium-containing pills (against heartburn)

Sapvit-D3 with food and drink

Caution is advised concerning vitamin-enriched food or infant formula.

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

If your doctor prescribes Sapvit-D3 when you are pregnant, be careful to keep strictly to the dose your doctor has prescribed, since overdose of vitamin D₃ may involve a risk of physical and mental retardation, as well as heart and eye diseases of your child.

Breast-feeding

Vitamin D and its metabolites pass into breast milk. Overdose in infants induced by nursing has not been observed. This fact, however, should be taken into account if the child receives additional vitamin D.

Driving and using machines

Sapvit-D3 has no or negligible influence on the ability to drive and use machines.

3. How to take Sapvit-D3

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

The dosage will be determined by your doctor. The dose depends on the condition for which you get Sapvit-D3. Therefore, always take the dose that has been prescribed individually for you, even if you know someone else who has been prescribed a much higher dose.

Unless otherwise prescribed by your doctor, the recommended dose is:

Prevention of vitamin D deficiency:

The usual daily dose is:

For newborns, infants and children from the second week of life to the age of 3 years: between 1-2 drops

For children aged 4 years and above and adolescents: between 1-3 drops

For adults aged 19 to 70 years: between 1-4 drops

For elderly people aged above 70 years: between 2-4 drops

Treatment of rickets

The total amount of required vitamin D depends on the severity of the disease.

In existing rickets, treatment is started with a preparation with a higher concentration of vitamin D for the initial treatment.

Subsequently, the usual dose is between 2 to 12 drops of Sapvit-D3 daily.

Treatment of vitamin D deficiency

The usual daily dose is:

For children and adolescents: 5 drops daily for 6 weeks, then between 1-3 drops daily

For adults aged 19 to 70 years and elderly people aged above 70 years: 15 drops daily for 8 weeks, then between 3-5 drops daily

Adjunct to osteoporosis treatment of patients who are at risk of vitamin D deficiency

The usual daily dose is:

For adults aged 19 years and above: between 2-4 drops daily or between 14-26 drops weekly.

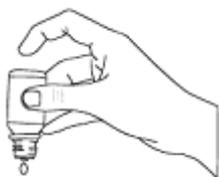
Method of administration

Sapvit-D3 drops are taken directly orally. The best way is to drip them straight into the mouth or, if necessary, administer with a spoon and some liquid.

Please talk to your doctor or pharmacist if you have the impression that the effect of Sapvit-D3 is too strong or too weak.

Instruction for handling

For withdrawal, hold the bottle vertically and gently tap the bottom of the bottle with your finger until the first drop appears.



If you take more Sapvit-D3 than you should

In case of overdose with Sapvit-D3 drops you should contact a doctor.

Symptoms of overdose may include: headache, loss of appetite, weakness, weight loss, disorders of the gastrointestinal tract (feeling sick, vomiting, constipation), growth disorders, increased urine volume, increased fluid intake, signs of paralysis, feebleness, increased blood pressure and in severe cases irregular heart beat.

The doctor decides on the severity of poisoning and determines the required treatment.

If you forget to take Sapvit-D3

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

If you stop taking Sapvit-D3

No withdrawal symptoms are known.

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.

Vitamin D can cause the following undesirable effects, especially in overdose:

Metabolism and nutrition disorders:

Too high calcium levels in blood and urine (hypercalcaemia, hypercalciuria).

Gastrointestinal disorders:

Constipation, bloating, feeling sick, stomach-ache, diarrhoea.

Frequency of the occurrence of the above mentioned side effects is not known (cannot be estimated from the available data).

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 Yellow Card Scheme at:

<http://www.mhra.gov.uk/yellowcard>. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sapvit-D3

- Do not store above 30°C.
- Keep the bottle in the outer carton in order to protect from light.
- 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 label and carton after EXP . The expiry date refers to the last day of that month.
- After opening the container, use Sapvit-D3 oral drops within 10 months. Residues have to be discarded. Do not store above 25°C after first opening.
- Do not use this medicine if you notice the following: turbidity or discolouration of the solution.

After opening the container, use Sapvit-D3 oral drops within 10 months. Any unused product should be disposed of thereafter. Do not store above 25°C after first opening.

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 protect the environment.

6. Contents of the pack and other information

What Sapvit-D3 contains

- The active substance is: Colecalciferol (vitamin D₃).
1 ml (= 36 drops) contains:
14,400 IU (360 µg) colecalciferol (vitamin D₃)
1 drop = 400 IU (10 µg) colecalciferol (vitamin D₃)
- The other ingredient is:
Medium-chain triglycerides

What Sapvit-D3 looks like and contents of the pack

Sapvit-D3 are clear, colourless to slightly yellowish oral drops (oily solution) and are available in brown glass bottles containing 12.5 ml each (corresponding to 450 drops) or 25 ml (corresponding to 900 drops) with dropper applicator and screw cap with tamper evident ring made of polyethylene.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Fresenius Kabi Austria GmbH
Hafnerstraße 36
8055 Graz
Austria

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email: info-atgr@fresenius-kabi.com

Manufacturer:

Fresenius Kabi Austria GmbH,
Estermannstrasse 17,
4020 Linz,
Austria

Distributor:

Stirling Anglian Pharmaceuticals Ltd,
Hillington Park Innovation Centre,
1 Ainslie Road, Hillington Park,
Glasgow G52 4RU
United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	Colecalciferol Fresenius 14.400 I.E./ml Tropfen zum Einnehmen, Lösung
Belgium:	Kabivit-D3 14400 IE/ml, druppels voor oraal gebruik, oplossing Kabivit-D3 14400 UI/ml, solution buvable en gouttes Kabivit-D3 14400 IE/ml, Tropfen zum Einnehmen, Lösung
Bulgaria:	Олеовит D3 14 400 IU/ml перорални капки, разтвор
Cyprus:	KabiVit 14.400 IU/ml, πόσιμο διάλυμα
Czech Republic:	Olvit D3 14400 IU/ml perorální kapky, roztok
Estonia:	Colecalciferol Fresenius
Finland:	Oleo D3 14 400 IU/ml tipat, liuos
Greece:	KabiVit 14.400 IU/ml
Hungary:	Vitamin D3 Fresenius Kabi 14000 NE/ml belsőleges oldatos cseppek
Ireland:	Sapvit-D3 400 IU/drop Oral Drops, Solution
Lithuania:	Colecalciferol Fresenius 14400 TV/ml geriamieji lašai (tirpalas)

Malta: KabiVit 14.400 IU/ml oral drops, solution
Norway: KabiVit
Poland: OIVit D₃
Portugal: Colecalciferol Kabi
Romania: Vitamina D3 Fresenius Kabi 14 400 UI/ml picături orale, soluție
Slovakia: Olvit D3, 14 400 IU/ml perorálne roztokové kvapky
Slovenia: Oleovit D3 14400 i.e./ml peroralne kapljice, raztopina
Spain: Vitamina D3 Fresenius Kabi 14.400 IU/ml solución oral
Sweden: Oleo D3 14 400 IE/ml orala droppar, lösning
United Kingdom (Northern Ireland): Sapvit-D3 14,400 IU/ml Oral Drops, Solution

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