

Package leaflet: Information for the user

Stexerol-D₃ 1,000 IU Film-coated Tablets Stexerol-D₃ 25,000 IU Film-coated Tablets Colecalciferol (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 Stexerol-D₃ is and what it is used for
2. What you need to know before you take Stexerol-D₃
3. How to take Stexerol-D₃
4. Possible side effects
5. How to store Stexerol-D₃
6. Contents of the pack and other information

1. What Stexerol-D₃ is and what it is used for

Stexerol-D₃ contains vitamin D₃ which is essential for healthy bones. Vitamin D₃ belongs to a group of medicines called vitamin supplements which are used to correct and maintain levels of the vitamin in your body.

Vitamin D is produced naturally by your skin after exposure to the sun and is also found in some foods. When levels of vitamin D in the body are too low this can cause bones to become fragile.

Stexerol-D₃ is available in two strengths and is used in adults and adolescents over 12 years old to prevent and treat:

- very low levels of vitamin D (deficiency)

Stexerol-D₃ can also be used in combination with other medicines to treat certain bone conditions such as thinning of the bones (osteoporosis).

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

Do not take Stexerol-D₃:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Stexerol-D₃:

- if you have problems with your kidneys
- if you have sarcoidosis (inflammation that produces lumps of cells in various organs in the body). Your doctor will be able to tell you if you do
- if you are already taking other medicines or supplements containing vitamin D

Your doctor may wish to do blood or urine tests to monitor your treatment.

Children

This medicine should not be given to children under 12 years old.

Other medicines and Stexerol-D₃

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

Tell your doctor or pharmacist before taking Stexerol-D₃:

- if you are taking medicines from a group known as cardiac glycosides used to treat heart conditions (e.g. digoxin, digitalis).

The following medicines may decrease the effects of Stexerol-D₃:

- medicines used to treat epilepsy (e.g. phenytoin)
- medicines used to help you sleep (e.g. barbiturates)
- laxatives (e.g. paraffin oil)
- cholesterol lowering medicines (e.g. cholestyramine)
- steroids from a group known as glucocorticoids often used to treat allergies or asthma (e.g. hydrocortisone, prednisolone)

The following medicines may increase the effects of Stexerol-D₃

- a group of medicines called thiazide diuretics which are mainly used to treat high blood pressure (e.g. bendroflumethiazide)

Stexerol-D₃ with food and drink

You can take this medicine with or without food and drink.

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.

Driving and using machines

Stexerol-D₃ should not affect your ability to drive or operate machines.

Stexerol-D₃ Film-coated Tablets contain Sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per 1,000 or 25,000 IU tablet, that is to say essentially 'sodium-free'.

3. How to take Stexerol-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.

Dose for treatment of Vitamin D deficiency

The dose needed to treat vitamin D deficiency will depend on how low your vitamin D levels are. Your doctor will advise you on the strength and number of tablets to take and how often you should take them – usually up to 75,000 IU for adolescents or up to 300,000 IU for adults, which may be spread over several weeks.

After this you may need to take regular doses to maintain your vitamin D levels.

Dose for prevention of deficiency, and maintenance after treatment of deficiency

The recommended dose is 1,000 IU a day, in some cases higher doses may be required. Your doctor will prescribe the correct dose for you.

Addition to specific therapy for osteoporosis:

Adults: 25,000 IU/month or 1,000 IU/day

The tablets can be swallowed whole, or crushed.

If you take more Stexerol-D₃ than you should

If you take one more tablet than you should it is unlikely that this will cause any harm. However, if you are concerned, contact your doctor or pharmacist.

If you take several more tablets than you should, seek medical advice immediately and if possible take the tablets, box and this leaflet with you.

Signs of overdose include:

- nausea, vomiting
- excessive passing of urine
- loss of appetite
- weakness
- apathy
- thirst
- constipation
- drowsiness
- dizziness

If you forget to take Stexerol-D₃

If you forget to take your medicine, take it as soon as possible and continue to take the tablets as normal. **Do not** take a double dose to make up for a forgotten dose.

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.

Serious side effects:

- Allergic reaction. The likelihood of this side effect happening to you is not known, however, **stop taking Stexerol-D₃ and seek immediate medical help** if you have any signs of serious allergic reaction such as a swollen face, lips, tongue or throat, difficulty swallowing or breathing
- Hypercalcaemia (too much calcium in your blood). This is an uncommon side effect of Stexerol-D₃ which can cause nausea, vomiting, excessive passing of urine, loss of appetite, weakness, apathy, thirst, constipation, drowsiness or dizziness. **Stop taking Stexerol-D₃ and seek immediate medical help if these symptoms occur.** Your doctor should monitor your blood calcium level during long-term treatment with Stexerol-D₃.

Other side effects:

Uncommon (may affect up to 1 in 100 people)

- hypercalciuria (too much calcium in your urine) which can cause increased frequency of urination, pain on urination, abdominal pain, bladder or kidney stones and urinary tract infections

Rare (may affect up to 1 in 1,000 people)

- itching
- skin rash

Frequency not known (frequency cannot be estimated from the available data)

- nausea, vomiting

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. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Stexerol-D₃

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 strip or bottle after EXP. The expiry date refers to the last day of that month.

- Do not store above 25°C
- Store in the original packaging in order to protect from light and moisture

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 Stexerol-D₃ contains

The active substance is vitamin D₃ as colecalciferol. Each tablet contains either 1,000 IU or 25,000 IU of colecalciferol which is equivalent to 25 or 625 micrograms of vitamin D₃.

The other ingredients are:

1,000 IU Tablet:

Tablet Core:

Microcrystalline cellulose
Croscarmellose sodium
Magnesium stearate
Modified maize starch
Colloidal anhydrous silica
Sucrose
Sodium ascorbate
Triglycerides, medium chain
Silicon dioxide, colloidal
all-rac- α -tocopherol

Film-coat:

Hypromellose
Talc
Macrogol 6000 (PEG)
Titanium dioxide (E171)
Yellow iron oxide (E172)
Red iron oxide (E172)

25,000 IU Tablet:

Tablet Core:

Modified maize starch
Sucrose
Mannitol
Croscarmellose sodium
Polacrillin potassium
Silicon dioxide, colloidal
Sodium ascorbate
Triglycerides, medium chain
Colloidal anhydrous silica
Magnesium stearate
all-rac- α -tocopherol

Film-coat:

Hypromellose
Talc
Macrogol 6000 (PEG)
Titanium dioxide (E171)
Yellow iron oxide (E172)
Red iron oxide (E172)

What Stexerol-D₃ looks like and the contents of the pack

Stexerol-D₃ 1,000 IU Film-coated tablets are orange, 8.5 mm long, oval shaped tablets.
Stexerol-D₃ 25,000 IU Film-coated tablets are orange, 14 mm long, capsule shaped tablets.

The 1,000 IU tablets are available in blister packs containing 28 tablets or in bottles containing 56 tablets.

The 25,000 IU tablets are available in blister packs containing 12 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Kyowa Kirin Limited
Galabank Business Park
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Tel.: 01896 664000
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Manufacturer

allphamed PHARBIL Arzneimittel GmbH
Hildebrandstr. 10-12
37081 Göttingen
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Other sources of information

If you have been prescribed Stexerol-D₃ Film-coated Tablets for the treatment or prevention of osteoporosis and would like further information you should speak to your doctor or pharmacist.

This leaflet was last revised in 11/2019.