

OSTEOFOS D3 1200 mg/ 800 I.U. powder for oral suspension

Calcium and Colecalciferol

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 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 OSTEOFOS D3 is and what it is used for
2. What you need to know before you take OSTEOFOS D3
3. How to take OSTEOFOS D3
4. Possible side effects
5. How to store OSTEOFOS D3
6. Contents of the pack and other information

1. What OSTEOFOS D3 is and what it is used for

OSTEOFOS D3 is a calcium and vitamin D3 supplement for the treatment of certain bone conditions in adults and elderly.

Both calcium and vitamin D are found in the diet and vitamin D is also produced in the skin following exposure to the sun.

A lack of vitamin D and calcium may lead to reduced bone density and bone fractures. OSTEOFOS D3 may be taken to make up for this deficiency of calcium and vitamin D.

2. What you need to know before you take OSTEOFOS D3

Do not take OSTEOFOS D3:

- if you are allergic to calcium, colecalciferol or any of the other ingredients of this medicine (listed in section 6)
- if you are inactive and have high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria)
- if you have calcium deposits in the tissues of your body
- if you have serious kidney problems
- if you have kidney stones or calcium stones in general
- if you have abnormally high levels of vitamin D.
- if you are pregnant or breast feeding
- if you are less than 18 years of age

Warning and precautions

Talk to your doctor before taking OSTEOFOS D3:

- if you have kidney problems, or a tendency to form urinary stones. Your doctor will check your blood and urine calcium levels to make sure they do not get too high

- if you are currently being treated for heart problems. You will be closely supervised by your doctor if you take cardiac glycosides (e.g. digitalis), since their effect may be enhanced by taking OSTEOFOS D3
- if you suffer from sarcoidosis (an immune system disorder of inflamed lesions of liver, lung, skin or lymph nodes). Your doctor will monitor your blood and urine calcium levels, which may increase due to a possible increased vitamin D activity.

Children

Do not give this medicine to children under 18 years of age because the safety and efficacy of OSTEOFOS D3 have not been established in children.

Other medicines and OSTEOFOS D3

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

In particular you should tell your doctor if you are taking:

Medicines that decrease the absorption or effect of OSTEOFOS D3:

- colestyramine (used to treat high blood cholesterol levels), steroids (such as cortisone), mineral oils (such as paraffin oil used as a laxative or stool softener): these medicines may decrease the absorption of the vitamin D3
- phenytoin and barbiturates (e.g. phenobarbital), which are used to treat epilepsy: they may decrease the activity of vitamin D3
- some diuretics (water pills e.g. furosemide and ethacrynic acid), antacids (used for indigestion) that contain aluminium salts and thyroid hormones: these medicines can decrease the absorption of calcium and increase its elimination in the stools or urine

Medicines that increase the absorption or effect of OSTEOFOS D3:

- some other diuretics (of the thiazide kind, e.g. hydrochlorothiazide) can decrease the elimination of calcium in the urine and thus cause too high calcium levels in the blood
- antibiotic drugs, such as penicillin, neomycin and chloramphenicol can increase the absorption of calcium: your doctor may tell you to check your blood calcium during prolonged treatment with OSTEOFOS D3 and any of these drugs

Medicines whose absorption is decreased by OSTEOFOS D3:

- tetracycline antibiotics: when taking these leave at least three hours before taking OSTEOFOS D3. Do not take them at the same time
- bisphosphonates (medicines used to treat or prevent osteoporosis) and sodium fluoride: when taking these leave at least three hours before taking OSTEOFOS D3

Medicines whose effect is increased by OSTEOFOS D3:

- digitoxin (e.g. Lanoxin) or other cardiac glycosides used to treat heart disorders: calcium may increase their effect on the heart

Tell your doctor and ask for his/her advice before taking any other product containing vitamin D or its derivatives while taking OSTEOFOS D3.

OSTEOFOS D3 with food and drink

Tell your doctor if you usually eat food that contains oxalic acid (e.g. spinach and rhubarb), phosphates (especially from food additives) or phytinic acid (whole cereals), since these may reduce the absorption of calcium contained in OSTEOFOS D3.

Tell your doctor and ask for his/her advice before taking foodstuffs which may be fortified with vitamin D. *See also section 3 how to take OSTEOFOS D3.*

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.

OSTEOFOS D3 should not be used during pregnancy or when breast-feeding.

Driving and using machines

OSTEOFOS D3 has no influence on your ability to drive or use machines.

OSTEOFOS D3 contains the colouring agent sunset yellow (E 110), sucrose, sodium and propylene glycol (E 1520).

Sunset yellow (E 110): may cause allergic reactions.

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.

Sodium: this medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

Propylene glycol: this medicine contains 640 mg propylene glycol (E 1520) in each dosage unit which is equivalent to 9.14 mg / 1 kg.

3. How to take OSTEOFOS D3

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 sachet of OSTEOFOS D3 once a day, preferably during the evening meal. Pour the contents of the sachet into a glass of non-carbonated water. Stir with a spoon to obtain a pleasant-tasting suspension. Drink the suspension immediately after mixing.

If you take more OSTEOFOS D3 than you should

Contact your doctor or go to the nearest hospital emergency department if you or someone near you has taken too much OSTEOFOS D3. Remember to take with you any remaining sachets and the box or this leaflet so that doctors know what has been taken.

If you forget to take OSTEOFOS D3

If you forget to take OSTEOFOS D3, take it as soon as you remember. In any case, do not take a double dose to make up for a forgotten sachet.

4. Possible side effects

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

Serious side effects

Stop taking OSTEOFOS D3 and contact a doctor immediately if you experience any of the following symptoms:

- swelling of face, lips and throat
- sudden difficulty breathing
- severe itching and/or rash (hives)
- skin allergy.

Other side effects

Tell your doctor promptly if you experience the following side effects, which may indicate that calcium levels in your blood or urine are too high:

- anorexia, nausea (feeling sick), vomiting, headache, weakness, apathy and drowsiness;
- thirst, dehydration, passing water frequently throughout the day or night, abdominal pain, lack of bowel movement, irregular heart beat.

In addition, the following side effects may occur with the use of OSTEOFOS D3:

- constipation
- diarrhoea
- nausea (feeling sick) or vomiting
- stomach ache.

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 HPRÁ Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store OSTEOFOS D3

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

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the sachet and carton. The expiry date [“EXP”] refers to the last day of that month.

Do not throw away any medicine 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 OSTEOFOS D3 contains

The **active** substances are: calcium and colecalciferol.

Each sachet contains calcium 1200 mg (as calcium phosphate) and colecalciferol (vitamin D3) 20 micrograms (equivalent to 800 I.U).

The **other** ingredients are: propylene glycol (E1520), sunset yellow FCF (E110), lemon flavouring (containing: natural flavourings, maltodextrin, gum arabic), saccharin sodium, anhydrous citric acid, microcrystalline cellulose and carmellose sodium, monopalmitate sucrose, silica colloidal anhydrous, mannitol, α -tocopherol, edible fats, gelatin, sucrose and maize starch (see Section 2).

What OSTEOFOS D3 looks like and contents of the pack

OSTEOFOS D3 sachets contain white or slightly orange, granular powder for oral suspension. The obtained suspension is an orange opaque liquid containing white granules.

The sachets are packaged in cardboard boxes containing 2, 30 or 60 sachets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Menarini International Operations Luxembourg S.A.,

1, Avenue de la Gare
L-1611 Luxembourg

Manufacturer:

Sigmar Italia S.p.A.
Via Sombreno, 11
Almé 24011-BG-Italy

or

A. Menarini Manufacturing Logistics and Services s.r.l.
Via Sette Santi, 3
Florence-Italy

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

Ireland OSTEOFOS D3

This leaflet was last revised in 12/2020.