

## **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 may contain 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 to 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 the 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:**

- have an allergy (hypersensitivity) to calcium, colecalciferol or any of the other ingredients of Osteofos D3 (see "Important information about some of the ingredients" section below and Section 6)
- are inactive and have high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria)
- have calcium deposits in the tissues of your body
- have serious kidney problems
- have kidney stones or calcium stones in general
- have abnormally high levels of vitamin D.
- are pregnant or breast feeding
- if you are less than 12 year of age

#### **Take special care with 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
- 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
- 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

#### **Taking other medicines**

Please tell your doctor if you are taking or have recently taken any other medicines (including medicines obtained without a prescription), especially:

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.

#### **Taking Osteofos D3 with food and drink**

Take Osteofos D3 preferably with your evening meal.

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.

#### **Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine.

Do not use Osteofos D3 if you are pregnant or breastfeeding.

#### **Children**

Osteofos D3 is not recommended for children under 12 years old.

## Driving and using machines

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

## Important information about some of the ingredients of Osteofos D3

Osteofos D3 contains the colouring agent sunset yellow (E 110) which may cause allergic reactions.

Osteofos D3 contains 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.

## 3. HOW TO TAKE OSTEOFOS D3

Always take Osteofos D3 exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Take 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, you should never take a double dose in the same day to make up for forgotten sachets.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Osteofos D3 can cause side effects, although not everybody gets them.

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

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

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:

- skin allergy
- 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto: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 out of the sight and reach of children.

Store Osteofos D3 in the original package. Do not store above 25°C.

Do not use Osteofos D3 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 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 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, sunset yellow FCF (E110), lemon flavouring, saccharin sodium, anhydrous citric acid, microcrystalline cellulose and carmellose sodium, monopalmitate sucrose, silica colloidal anhydrous and mannitol (see Section 2 'Important information about some of the ingredients of Osteofos D3').

### 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 30 sachets.

### Product procured within the EU, repackaged and distributed by the Parallel Product Authorisation

**Holder:** PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

### Manufacturer

A. Menarini Manufacturing Logistics and Services s.r.l., Via Sette Santi, 3, Florence, Italy or Sigmar Italia S.p.A., via Sombreno, 11, Almé (BG), Italy.

### Parallel Product Authorisation Number

PPA 465/278/1

Osteofos D3 is a registered trademark of Menarini International Operations Luxembourg S.A

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

United Kingdom	<i>Osteofos D3</i>
Austria	<i>Osteofos</i>
Denmark	<i>Osteofos D3</i>
Finland	<i>Osteofos D3</i>
Germany	<i>Osteofos D3</i>
Greece	<i>Caldesil</i>
Luxembourg	<i>Osteofos D3</i>
Ireland	<i>Osteofos D3</i>
Spain	<i>Metafisol</i>
Sweden	<i>Osteofos D3</i>

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