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Package Leaflet: Information for the user

Fultium-D₃ 800 IU Capsules
(Colecalciferol)

Read all of this leaflet carefully before you start taking this medicine.

- 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. **Do not pass it on to others.** It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Fultium-D₃ is and what it is taken for
2. Before you take Fultium-D₃
3. How to take Fultium-D₃
4. Possible side effects
5. How to store Fultium-D₃
6. Further information

1. What Fultium-D₃ is and what it is taken for

Fultium-D₃ are capsules. They contain the active ingredient:

- **Vitamin D₃** (800 IU colecalciferol equivalent to 20 micrograms Vitamin D₃)

Vitamin D is found in the diet and is also produced in the skin after exposure to the sun. Often vitamin D is given in combination with calcium. Fultium-D₃ is recommended for use when you have a normal intake of dietary calcium.

Fultium-D₃ may be prescribed by your doctor to treat or prevent vitamin D deficiency. Deficiency of vitamin D may occur when your diet or lifestyle does not provide you enough vitamin D or when your body requires more vitamin D (for instance when you are pregnant). Fultium-D₃ may also be prescribed for certain bone conditions, such as thinning of the bone (osteoporosis) when it will be given to you with other medicines.

2. Before you take Fultium-D₃

Do not take Fultium-D₃ if you

- are **allergic** (hypersensitive) to vitamin D or any of the other ingredients in the capsules (these are listed in section 6, Further information)
- have high levels of vitamin D in your blood (**hypervitaminosis D**)
- have high blood levels of calcium (**hypercalcaemia**) or high urine levels of calcium (**hypercalciuria**)
- have **kidney stones or serious kidney problems.**

Check with your doctor before taking Fultium-D₃ if

- you have **kidney damage or disease.** Your doctor may want to measure the levels of calcium in your blood or urine
- you are being treated for **heart disease**
- you have **sarcoidosis** (an immune system disorder which may affect your liver, lungs, skin or lymph nodes)
- you are already taking **additional doses of calcium or vitamin D.** Whilst you are taking Fultium-D₃ your doctor will monitor your blood levels of calcium to make sure they are not too high.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular the following medicines may interact with Fultium-D₃:

- **Heart medicines** (cardiac glycosides such as digoxin). Your doctor may monitor your heart with an electrocardiogram (ECG) and measure the levels of calcium in your blood
- Medicines to treat epilepsy (such as **phenytoin**) or medicines to make you sleep (**barbiturates** such as phenobarbitone) as these medicines can decrease the effect of vitamin D
- **Glucocorticoids** (steroid hormones such as hydrocortisone or prednisolone). These can decrease the effect of vitamin D.

- **Laxatives** (such as paraffin oil) or a cholesterol lowering drug called **colestyramine** may reduce the absorption of vitamin D
- **Actinomycin** (a medicine used to treat some forms of cancer) and **imidazole antifungals** (medicines such as clotrimazole and ketoconazole used to treat fungal diseases) as they may interfere with the metabolism of vitamin D.

Taking Fultium-D₃ with food and drink

You can take Fultium-D₃ with or without food and drink.

Pregnancy and breast-feeding

If you are pregnant or think you may be pregnant or you are breast-feeding you should talk to your doctor or pharmacist before you take Fultium-D₃.

Fultium-D₃ should be used during pregnancy and breast-feeding only if recommended by your doctor.

Driving and using machines

Fultium-D₃ should not affect your ability to drive or operate machinery.

3. How to take Fultium-D₃

Always take Fultium-D₃ exactly as your doctor has told you.

Dose

In severe vitamin D deficiency (for adults and the elderly)

Your doctor will usually prescribe you a dose of 1-4 capsules daily for up to 12 weeks. The amount will depend on how low your vitamin D levels are and how you respond to treatment. Your doctor will then tell you to take 1-2 capsules daily to maintain your vitamin D levels

In moderate vitamin D deficiency (for adults and the elderly) or to prevent vitamin D deficiency

Your doctor will usually prescribe 1-2 capsules daily.

In vitamin D deficiency in children over 12 years

Your doctor will usually prescribe you 1 capsule daily

In osteoporosis (you will also be taking other medicines for this)

Your doctor will usually prescribe 1 capsule daily

(continued overleaf)

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Use in pregnancy and breast-feeding

To treat vitamin D deficiency: Your doctor will usually prescribe 1 - 5 capsules daily for up to 12 weeks, followed by a long term maintenance dose.

Long term maintenance and to prevent vitamin D deficiency: Your doctor will usually prescribe 1 - 2 capsules daily.

You should check with your doctor or pharmacist if you are unsure.

The capsules should be **swallowed whole (not chewed) with water.**

Fultium-D₃ is **not suitable for children under 12 years.**

If you take more Fultium-D₃ than you should

If you accidentally take one capsule too many, nothing is likely to happen. If you accidentally take several capsules too many tell your doctor or get other medical advice immediately. If possible, take the capsules, the box and this leaflet with you to show the doctor. If you take too many capsules you may feel or be sick, become constipated or have stomach pains, weak muscles, tiredness, lack of appetite, kidney problems and in severe cases irregular heartbeats.

If you forget to take Fultium-D₃

If you forget to take your capsules, take them as soon as you can. **Do not take a double dose to make up for a forgotten dose.** After that, take the next capsule in accordance with the instructions given to you by your doctor.

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

4. Possible side effects

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

Side effects with Fultium-D₃ may include:

Uncommon side effects

(affecting less than 1 in 100 people)

- too much calcium in your blood (**hypercalcaemia**). You may feel or be sick, lose your appetite, have constipation, stomach ache, feel very thirsty, have muscle weakness, drowsiness or confusion.

- too much calcium in your urine (**hypercalciuria**)

Rare side effects

(affecting less than 1 in 1000 people)

- skin rash
- itching
- hives

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: 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 Fultium-D₃

Keep out of the sight and reach of children.

This medicinal product does not require any special temperature storage conditions. Store blister foil in the original container in order to protect from light.

Do not use Fultium-D₃ after the expiry date which is stated on the carton as "EXP". The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Fultium-D₃ contains

The active ingredient (which makes the medicine work) is colecalciferol. Each capsule contains 800 IU colecalciferol (equivalent to 20 micrograms Vitamin D₃).

The other ingredients are:

- Capsule content
- Maize oil, refined
- Butylated hydroxytoluene (BHT) (E321)
- Capsule Shell
- Gelatin
- Glycerol
- Brilliant Blue WS (E133)
- Purified Water

What Fultium-D₃ looks like and contents of the pack

Fultium-D₃ 800 IU Capsule is a blue coloured translucent soft gelatin capsule.

It is available in blister packs containing 28, 30, 56, 60 or 90 capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is:

Internis Pharmaceuticals Ltd.
Linthwaite Laboratories
Linthwaite
Huddersfield
West Yorkshire
HD7 5QH
United Kingdom

The Manufacturer is:

Thornton and Ross Limited
Linthwaite Laboratories
Linthwaite
Huddersfield
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United Kingdom

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

United Kingdom: Fultium-D₃ 800 IU Capsules

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