

Package leaflet: Information for the user

Fultium-D3 800 IU Capsules

Colecalciferol (Vitamin D3)

Read all of this leaflet carefully before you start taking this medicine, because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if feel worse after 2 weeks.

What is in this leaflet:

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

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

Fultium-D3 contains vitamin D3 which regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.

Fultium-D3 is used to treat and prevent vitamin D3 deficiency in adults and adolescents over 12 years. Certain people are at higher risk of vitamin D3 deficiency. This can include people who have limited exposure to sunshine including patients who are hospitalised, obese, have darker skin, difficulty digesting or absorbing vitamin D from food, e.g. inflammatory bowel disease or coeliac disease. Your doctor may prescribe Fultium-D3 as an adjunct to specific bone loss medication.

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

Do not take Fultium-D3:

- if you are allergic to colecalciferol or any of the other ingredients of this medicine (listed in section 6)
- if you have hypercalcaemia (increased levels of calcium in the blood) or hypercalciuria (increased levels of calcium in the urine)
- if you have hypervitaminosis D (increased levels of vitamin D in the blood)
- if you have kidney stones
- if you have nephrocalcinosis (increased levels of calcium in the kidneys)
- if you have serious kidney problems
- if you have sarcoidosis (a special type of connective tissue disease that affects the lungs, skin and joints)
- if you are under 12 years of age
- if you have pseudohypoparathyroidism (disturbed parathyroid hormone metabolism)
- if you are taking thiazide diuretics (to treat high blood pressure)
- if you are taking cardiac glycosides (to treat heart conditions) such as digoxin

If any of the above applies to you, talk to your doctor or pharmacist before taking Fultium-D3.

Warnings and precautions

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

- when using other drugs or food supplements containing vitamin D or food or milk enriched with vitamin D.
- if you are taking any other medicines, particularly medicines for the heart.

Children

This medicine is not recommended for use in children under 12 years of age.

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.

Other medicines and Fultium-D3

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, in particular any of the following:

- Cholestyramine (used to treat high cholesterol)
- Phenytoin or barbiturates (used to treat epilepsy)
- Laxatives which contain paraffin oil
- Thiazide diuretics (to treat high blood pressure)
- Glucocorticoids (to treat inflammation)
- Cardiac glycosides (to treat heart conditions), e.g. digoxin
- Actinomycin (chemotherapy)
- Imidazole (antifungal)
- Orlistat (weight loss aid).

Fultium-D3 with food and drink

See section 3 "How to take Fultium-D3".

Pregnancy, breast-feeding and fertility

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 has no known effects on ability to drive or use machines.

3. How to take Fultium-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 capsules should be swallowed whole with water. Fultium-D3 can be taken with or without food.

The recommended dose in adults and adolescents over 12 years is: 1 capsule every day.

Do not take more than 5 capsules in one day.

Use in children

Fultium-D3 800 IU capsules are not intended for use in children under 12 years of age. Other forms of this medicine maybe more suitable for children; ask your doctor or pharmacist.

If you take more Fultium-D3 than you should

If you have taken more of this medicine than directed, or if a child accidentally has taken this medicine, please contact your doctor or emergency unit for judgement of the risk and advice. The most common symptoms of overdose are: nausea, vomiting, excessive thirst, the production of large amounts of urine over 24 hours, constipation and dehydration, high levels of calcium in the blood (hypercalcaemia and hypercalciuria) shown by lab test.

If you forget to take Fultium-D3

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

If you stop taking Fultium-D3

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.



Stop taking Fultium-D3 and seek immediate medical help if you experience symptoms of serious allergic reactions, such as:

- swollen face, lips, tongue or throat
- difficulty swallowing
- hives and difficulty breathing

Uncommon (may affect up to 1 in 100 people):

Hypercalcaemia (increased levels of serum calcium) and hypercalciuria (increased levels of urine calcium).

Rare (may affect up to 1 in 1,000 people):
Itching, rash (Pruritus/urticaria).

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 Yellow Card Scheme at 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 Fultium-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 carton and blister after Exp. The expiry date refers to the last day of the month.

Do not store above 25°C. Keep the blister(s) in the outer carton to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

6. Contents of the pack and other information

What Fultium-D3 contains

- The active substance is colecalciferol (vitamin D3). Each capsule contains 800 IU colecalciferol equivalent to 20 micrograms vitamin D3.
- The other ingredients are as follows:
Capsule content: Maize oil-refined and Butylated hydroxytoluene (BHT) (E321)
Capsule shell: Gelatin, Glycerol, Brilliant Blue WS (E133) and 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 or 30 capsules.

Not all pack sized may be marketed.

Marketing Authorisation Holder

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Other formats

To request a copy of this leaflet in braille, large print or audio please call 01484 848164.

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