

## **Package leaflet: Information for the patient**

### **Fultium 800 IU Capsules** cholecalciferol (vitamin D<sub>3</sub>)

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

#### **1. What Fultium is and what it is used for**

Fultium contains the active ingredient cholecalciferol (vitamin D<sub>3</sub>):

Vitamin D<sub>3</sub> regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.

Fultium is used to prevent and treat vitamin D<sub>3</sub> deficiency in adults and adolescents with an identified risk of vitamin D<sub>3</sub> deficiency.

Fultium can also be used as an adjunct to specific bone loss medication.

#### **2. What you need to know before you take Fultium**

##### **Do not take Fultium**

- 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 high blood levels of calcium (hypercalcaemia) or high urine levels of calcium (hypercalciuria)
- if you have kidney stones and/or nephrocalcinosis (renal calcification) or serious kidney problems.

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Fultium

- if you have kidney damage or disease. Your doctor will need to measure the levels of calcium in your blood or urine
- if you are being treated for heart disease
- if you have a tendency for the formation of calcium-containing kidney stones
- if your ability to move is severely restricted, as in these cases there is a risk of high blood levels of calcium (hypercalcaemia) or high urine levels of calcium (hypercalciuria)

- if you have sarcoidosis (an immune system disorder which may affect your liver, lungs, skin or lymph nodes)
- if you have pseudohypoparathyroidism (disorder that changes how the body reacts to the parathyroid hormone), as the vitamin D requirement may be reduced. Then there is a risk that you get too much vitamin D. Other medicines containing vitamin D may be more appropriate for you
- if you are already taking additional doses of calcium or vitamin D (e.g. medicines containing vitamin D and also if you are eating food or taking food supplements containing vitamin D). While you are taking Fultium your doctor will monitor your blood levels of calcium to make sure they are not too high.

### **Other medicines and Fultium**

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

In particular the following medicines may interact with Fultium

- 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.
- Medicinal products which speed-up urine excretion (thiazide diuretics, e.g. against high blood pressure). It may lead to high blood levels of calcium (hypercalcaemia) or high urine levels of calcium (hypercalciuria).
- 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.
- Antibiotics used to treat the bacterial infection called tuberculosis (such as rifampicin and isoniazid) as they may decrease the effect of vitamin D.
- Laxatives (such as paraffin oil), a cholesterol lowering drug called colestyramine or a weight reducing medicine called orlistat as they 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.

### **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.

You should not take this medicine during pregnancy without a confirmed vitamin D deficiency and your doctor finds it absolutely necessary for you.

Fultium can be used during breast-feeding when vitamin D deficiency has been confirmed. Vitamin D passes over to breast milk. This should be considered when giving additional vitamin D to the breast fed child.

### **Driving and using machines**

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

## **3. How to take Fultium**

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose is 1 capsule per day.

The daily dose shall not exceed 4000 IU (five capsules).

The capsules should be swallowed whole with water, preferably with food.

### **Use in children**

Fultium 800 IU Capsules are not suitable for children under 12 years.

### **If you take more Fultium 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**

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 medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

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

Side effects with Fultium 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 national reporting system listed in Appendix V](#).\* By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Fultium**

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

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 after “EXP”. The expiry date 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 Fultium 800 IU Capsules contain**

The active substance is cholecalciferol (vitamin D<sub>3</sub>).

1 capsule contains:

Cholecalciferol (vitamin D<sub>3</sub>, equivalent to 800 IU) 20 micrograms.

The other ingredients are:

Capsule Content:

- Maize oil, refined
- Butylated hydroxytoluene (BHT) (E321)

Capsule Shell:

- Gelatin (E441)
- Glycerol
- Brilliant Blue FCF (E133)
- Purified Water

### **What Fultium looks like and contents of the pack**

Fultium 800 IU Capsules are small (10.6 mm x 6.2 mm) translucent blue capsules which have no markings.

It is available in blister packs containing 7, 10, 14, 15, 20, 28, 30, 56, 60, or 90 capsules

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **The Marketing Authorisation Holder is:**

*<To be completed nationally>*

### **The Manufacturer is:**

Aenova Romania S.R.L.  
Carol I Street No. 20, Cornu  
Prahova 107180  
Romania

Swiss Caps GmbH  
Grassingerstrasse No.9  
83043 Bad Aibling,  
Germany

STADA Arzneimittel AG  
Stadastrasse 2 – 18  
61118 Bad Vilbel  
Germany

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

|              |                                                      |
|--------------|------------------------------------------------------|
| Denmark:     | Fultium                                              |
| Finland:     | Fultium 800 IU pehmeät kapselit                      |
| Netherlands: | Vitamine D <sub>3</sub> STADA 800 IE zachte capsules |
| Norway:      | Fultium 800 IU myke kapsler                          |
| Portugal:    | Fultium-D <sub>3</sub> 800 UI Cápsulas               |
| Sweden:      | Fultium 800 IE mjuka kapslar                         |

**This leaflet was last revised in 2025-05-07**