Package leaflet: Information for the patient

Fultium 2 740 IU/ml Oral Drops, solution
cholecalciferol (vitamin D_3)

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

Fultium contains the active ingredient cholecalciferol (vitamin D_3):

Vitamin D_3 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_3 deficiency in adults, adolescents and children with an identified risk of vitamin D_3 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.

Turn the bottle upside down and shake gently to get the first drop, the bottle should be held vertically while dispensing drops.

The drops should be dispensed onto a spoon before taking. The drops can be mixed with a small amount of cold or lukewarm food immediately before taking. The whole portion should be consumed.

Where higher doses are required, higher strength products may be more appropriate to deliver the dose.

Use in children
For prevention of vitamin D deficiency in children (0 up to 11 years old) with an identified risk the recommended dose is 6 drops (400 IU) per day.
For prevention in adolescents (12 years to 18 years old) with an identified risk the recommended dose is 6-12 drops (400 IU - 800 IU) per day.
For treatment of vitamin D deficiency the dosage is adjusted individually.
The daily dose should not exceed:
- 1000 IU (15 drops) for infants less than 1 year old
- 2000 IU (30 drops) for children 1-10 years old
- 4000 IU (60 drops) for adolescents 11 years and older.

Use in adults
Recommended dose for prevention of vitamin D deficiency and as an adjunct to specific bone loss medication (osteoporosis) is 6-12 drops (400 IU - 800 IU) per day.
For treatment of vitamin D deficiency the dosage is usually 12 drops (800 IU) per day, this amount can be adjusted individually by your doctor.
The daily dose should not exceed 4,000 IU (60 drops).

If you take more Fultium than you should
If you accidentally take one drop too many, nothing is likely to happen. If you accidentally take several drops too many tell your doctor or get other medical advice immediately. If possible, take the bottle, the box and this leaflet with you to show the doctor. If you take too many drops 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 drops, 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 dose 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 medicine does not require any special storage conditions..

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.
Opened bottle should be used within 6 months.

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 2 740 IU/ml Oral Drops, solution contains
The active substance is cholecalciferol (vitamin D_3).

1 ml oral solution contains:
Cholecalciferol (vitamin D_3, equivalent to 2 740 IU) 68.5 micrograms.

1 drop contains:
Cholecalciferol (vitamin D_3, equivalent to 67 IU) 1.67 micrograms.

The other ingredient is:
- Medium-chain triglycerides (from coconut oil and palm kernel oil)

What Fultium looks like and contents of the pack
Fultium 2 740 IU/ml Oral Drops, solution is a clear colourless to slightly yellow oil. Do not use this medicine if you notice the solution is cloudy.
It is supplied in a brown glass bottle with an integral vertical dropper.

Each pack contains 1 bottle containing 25 ml oral solution (equivalent to 1025 drops).

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is:
<To be completed nationally>

The Manufacturer is:

UNIMEDIC AB
Storjordenvägen 2
86421 Matfors
Sweden

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 2740 IU/ml tipat, liuos
Ireland:	Fultium-D_3 67 IU/drop Oral Drops, solution
Norway:	Fultium 2740 IU/ml dråpemikstur
Sweden:	Fultium 67 IE/droppe orala droppar, lösning

This leaflet was last revised in 2022-01-20**.**