Package leaflet: Information for the patient

Fultium-D_3 250 IU/drop 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-D_3 is and what it is used for

Fultium-D_3 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-D_3 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-D_3 can also be used as an adjunct to specific bone loss medication

2. What you need to know before you take Fultium-D_3

Do not take Fultium-D_3
- 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 or serious kidney problems.

Warnings and precautions
Talk to your doctor or pharmacist before taking Fultium-D_3

- 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 sarcoidosis (an immune system disorder which may affect your liver, lungs, skin or lymph nodes)

- if you are already taking additional doses of calcium or vitamin D. While you are taking Fultium-D_3 your doctor will monitor your blood levels of calcium to make sure they are not too high.

Other medicines and Fultium-D_3
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-D_3
- 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.

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.

Higher doses than 4000 IU per day can be harmful.

Fultium-D_3 can be used during breast-feeding when vitamin D deficiency is 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-D_3 has no known effects on ability to drive or use machines.

3. How to take Fultium-D_3

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

The carton contains 1 bottle with a child-resistant cap with either an inserted dropper built-in or with a serperate, external dropper (in a protective plastic case).

For packs with an external (separate) dropper:
1. Press on the cap of the bottle and unscrew at the same time;
2. Remove the cap;
3. Take the dropper and unscrew the protective case;
4. Place the dropper into the bottle to draw up the contents;
5. Transfer the required number of drops onto a spoon;
6. Return the empty dropper to its protective case;
7. Screw the cap to close the bottle;
8. Return the bottle and dropper to the carton.

For packs with an inserted dropper:
The carton contains 1 bottle with a child-resistant cap with an inserted dropper built in.

1. Press on the cap of the bottle and unscrew simultaneously;
2. Remove the cap;
3. The bottle should be held vertically while dispensing drops onto a spoon.
4. Screw the cap to close the bottle.
5. Return the bottle with the inserted dropper built in to the carton.

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.

Only ever use the dropper provided with this medicine as the use of other droppers may not provide the correct dose.

Use in children
For the prevention of vitamin D deficiency in adolescents (aged 12 years to 18 years old) with an identified risk the recommended dose is 2-3 drops (500 IU - 750 IU) per day. For children below 12 years, recommended doses may not be feasible to administer with this drop strength.

For treatment of vitamin D deficiency the dosage is adjusted individually.
The daily dose should not exceed:
- 1000 IU (4 drops) for infants less than 1 year old
- 2000 IU (8 drops) for children 1-10 years old
- 4000 IU (16 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 2-3 drops (500 IU - 750 IU) per day.
For treatment of vitamin D deficiency the dosage is usually 3 drops (750 IU) per day, this amount can be adjusted individually by your doctor. The daily dose should not exceed 4,000 IU (16 drops).

If you take more Fultium-D_3 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-D_3
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-D_3 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 suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Healthcare professionals are asked to report any suspected adverse reactions via:

HPRA Pharmacovigilance
Earlsfort Terrace
IRL – Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail:medsafety@hpra.ie

5. How to store Fultium-D_3

Do not freeze.
Store bottle 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.
Opened bottle should be used within 5 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-D_3 250 IU/drop Oral Drops, solution contains
The active substance is cholecalciferol 10 000 IU/ml corresponding to 250 micrograms/ml vitamin D_3.
1 drop contains 250 IU cholecalciferol corresponding to 6.25 micrograms vitamin D_3.

The other ingredient is:
- Refined olive oil

What Fultium-D_3 looks like and contents of the pack
Fultium-D_3 250 IU/drop Oral Drops, solution is a pale yellow transparent oil. It is supplied in an amber glass bottle containing 10 ml oral solution (equivalent to 400 drops) with either an inserted dropper or with a separate glass dropper (in a protective plastic case).

Do not use this medicine if you notice the solution is cloudy.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is:

STADA Arzneimittel AG,
Stadastraße 2–18,
61118 Bad Vilbel
Germany

The Manufacturer is:
Mipharm S.p.A
Via B. Quaranta, 12
20141 Milano
Italy

Thornton and Ross Limited
Linthwaite
Huddersfield
West Yorkshire
HD7 5QH
United Kingdom

Distributed by:
Clonmel Healthcare Ltd.
Clonmel, Co. Tipperary, Ireland

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

Czech Republic:	Fultium D_3
Denmark:	Fultium
Finland:	Fultium 10 000 IU/ml tipat, liuos
Germany:	EUNOVA Vitamin D3 UNO 10.000 I.E./ml Tropfen zum Einnehmen, Lösung
Ireland:	Fultium-D_3 250 IU/drop Oral Drops, solution
Netherlands:	Vitamine D_3 STADA 10.000 IE/ml druppels voor oraal gebruik, oplossing
Norway:	Fultium 10000 IU/ml dråpemikstur
Poland:	Fultium-D_3, 10 000 IU, krople doustne, roztwór
Portugal:	Fultium-D_3 10 000 UI/ml Gotas orais, solução
Slovakia:	Fultium 10 000 IU/ml perorálne roztokové kvapky
Sweden:	Fultium 250 IE/droppe orala droppar, lösning

This leaflet was last revised in 02/2019