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Package Leaflet: Information for the user

Fultium-D₃ Drops (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 Drops is an oral solution. It contains the active ingredient:

- **Vitamin D₃** (2740 IU/ml Colecalciferol equivalent to 68.5 micrograms/ml 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 drops (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 Drops. Fultium-D₃ Drops 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.

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.

Dose

Use in children and adolescents

Infants aged 0 up to 2 years old

To treat vitamin D deficiency: Your doctor will usually prescribe 6 – 15 drops 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 3 – 15 drops daily

Children aged 2 years to 11 years old

To treat vitamin D deficiency: Your doctor will usually prescribe 6 – 30 drops 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 6 – 15 drops daily.

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(continued overleaf)



Adolescents aged 12 years to 18 years old

To treat vitamin D deficiency: Your doctor will usually prescribe 6 – 60 drops 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 6 – 24 drops daily.

In infants, children and adolescents the drops can be mixed with a small amount of children's foods, yogurt, milk, cheese or other dairy products. The drops must not be mixed into a bottle of milk or container of soft foods in case the child does not consume the whole portion, and so does not then receive the full dose.

Use in adults and the elderly

To treat vitamin D deficiency: Your doctor will usually prescribe 12 – 60 drops 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 12 – 24 drops daily.

In osteoporosis (you will also be taking other medicines for this): Your doctor will usually prescribe 12 drops daily.

Use in pregnancy and breast-feeding

To treat vitamin D deficiency: Your doctor will usually prescribe 6 – 60 drops 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 6 – 30 drops daily.

In adults, the drops can be mixed with a small amount of cold or lukewarm food immediately before taking. You should check with your doctor or pharmacist if you are unsure.

Doses of 800 IU and above can also be administered using Fultium-D₃ soft capsules.

If you take more Fultium-D₃ 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-D₃

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 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.

Store below 25°C.

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.

Opened bottle should be used within 6 months. 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. 1 ml oral drops solution (41 drops) contains 2740 IU colecalciferol (equivalent to 68.5 micrograms Vitamin D₃).

The other ingredient is:

Medium-chain triglycerides (from coconut oil and palm kernel oil)

What Fultium-D₃ looks like and contents of the pack

Fultium-D₃ Drops is a clear, colourless to slightly yellow oil. It is supplied in a 25 ml brown glass bottle with an integral vertical dropper.

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

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is:

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

The Manufacturer is:

UNIMEDIC AB
Box 91, SE-864 21 Mattfors
Sweden

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