Package leaflet: Information for the user

Detremin 800 I.U./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 Detremin is and what it is used for

Detremin contains cholecalciferol (vitamin D_3). It is used to treat vitamin D deficiency or insufficiency, for example in the following conditions:

- bone fragility, together with calcium and other treatment
- secondary hyperparathyroidism (when low blood calcium levels lead to excessive secretion of parathyroid hormone, combined with enlargement of the parathyroid gland).

Detremin is also used as prophylaxis and treatment of vitamin D deficiency in persons with difficulties to absorb vitamin D.

2. What you need to know before you take Detremin

Do not take Detremin
- if you are allergic to vitamin D_3 or any of the other ingredients of this medicine (listed in section 6)
- if you have hypercalcemia (too high levels of calcium in the blood)
- if you have hypervitaminosis D (too high levels of vitamin D in the blood).

Do not take Detremin together with calcium if you have severely impaired renal function.

Warnings and precautions
Do not take more Detremin than your doctor has prescribed, since overdosage may occur. Do not at the same time take other vitamin D containing products other than your doctor has prescribed.

Talk to your doctor, pharmacist or nurse before taking Detremin:
- if you have had kidney stones
- if you have impaired renal function
- if you have renal calcification (calcification of the kidney)
- if you have sarcoidosis (an illness with the formation of inflammatory nodules, mostly affecting the lungs) or other chronic inflammation leading to the formation of nodules.

- If you have a disease that increases the risk of elevated levels of calcium in the blood such as thyrotoxicosis (excess of thyroid hormone) or certain malignancies.
- If you have increased phosphate concentration in the blood, your doctor may prescribe a phosphate binder together with Detremin. Ask your doctor for advice.

Other medicines and Detremin
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is especially important if your are taking:

- Phenytoin (against epilepsy), barbiturates (sleeping-pills or tranquillizers)
- Rifampicin or isoniazid (against tuberculosis)
- Cardiac glycosides (against heart disease), for example digoxin
- Thiazide diuretics (e.g. hydrochlorthiazide and bendroflumethiazide, medicines against high blood pressure)
- Aluminium-containing medicines (against heartburn)
- Other vitamin D containing products
- Glucocorticoids (against inflammation)
- HAART (treatment against HIV)
- Lithium (antipsychotic medication)
- Laxatives
- Orlistat (against weight loss)
- Cholestyramin (against high cholesterol)

Detremin with food and drink
Detremin can be taken independently of meals. You can also mix the drops with food or drink to facilitate intake.

Pregnancy, breast-feeding and fertility
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.

Detremin can be used during pregnancy, in case of a vitamin D deficiency.

Detremin can be used during breast-feeding. Vitamin D and its metabolites pass into breast milk. Ask your doctor or midwife if you have any questions regarding this.

There are no data on the effect of Detremin on fertility. However, normal levels of vitamin D are not expected to have any adverse effects on fertility.

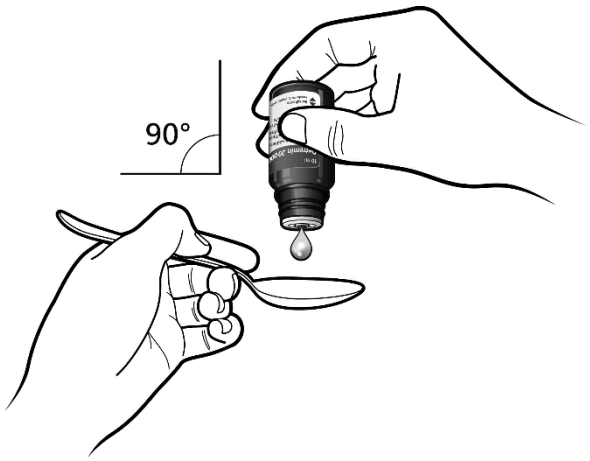
Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed. Detremin has no known side effects which are likely to affect the ability to drive and use machines.

3. How to take Detremin

Always take Detremin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The dose depends on the condition for which you get Detremin and your level of vitamin D in the blood. Therefore, always take the dose that has been prescribed individually for you, even if you know someone else who has been prescribed a much higher dose. The usual dose is between 1 drop and 5 drops daily or between 7 drops and 35 drops weekly. In case you have difficulties absorbing vitamin D, you may need to be prescribed a higher dose, up to 12 drops daily or 84 drops per week. Follow the instructions from your doctor.

Detremin can be taken independently of meals. The bottle should be slowly turned upside down to allow air to enter the bottle,see the figure below:



It may take several seconds to the first drop. The following drops will come slightly faster. The drops are preferably taken with a spoon. Make sure to ingest the entire dose.

If you take Detremin during a long time, your doctor may want to take blood samples regularly to ensure that the treatment is optimal for you.

If you take more Detremin than you should
If you have taken more Detremin than you should, tell your doctor. If you have taken a massive overdose you should seek medical help immediately; hospital treatment may be necessary.

If you forget to take Detremin

Leave out the missed dose and go back to the regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

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

The following symptoms have been seen after intake of products containing vitamin D_3: too high levels of calcium in the blood and urine, constipation, formation of gas, nausea, abdominal pain, diarrhoea and hypersensitivity reactions such as itching, rash or 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.
[To be completed nationally]

5. How to store Detremin

- Keep the dropper container in the outer carton in order to protect from light.
- Keep this medicine out of the sight and reach of children.
- The content of the bottle should be used within 6 months after first opening.
- Do not use Detremin after the expiry date which is stated on the carton and the bottle, after EXP. The expiry date refers to the last day of that month.
- Do not use Detremin if you notice turbidity.

Do not throw away any medicines via wastewater. 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 Detremin contains

- The active substance is cholecalciferol (vitamin D_3). 1 ml solution (approximately 25 drops) contains 0.5 mg cholecalciferol, equivalent to 20,000 I.U. vitamin D_3.
- 1 drop contains 20 microgram cholecalciferol, which corresponds to 800 IU vitamin D_3.
- The other ingredients are medium chain triglycerides.

What Detremin looks like and contents of the pack

Detremin is a clear, weakly yellowish, viscous solution. Each box contains one dropper container of brown glass with a colourless dropper and a white screw cap. The bottle contains 3.6 ml solution (90 drops of 800 IU vitamin D_3) or 10 ml solution (250 drops of 800 IU vitamin D_3).

Marketing Authorisation Holder and Manufacturer

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Manufacturer:
NextPharma SAS, Limay, France

This medicinal product is authorized in the Member States of the EEA under the following names:
Denmark, Finland, Norway, Sweden: Detremin

This leaflet was last approved in 2024-02-12