

PACKAGE LEAFLET: INFORMATION FOR THE USER

Detremin 25000 I.U. soft capsules

cholecalciferol (vitamin D₃)

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, pharmacist or nurse. 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
2. What you need to know before you take Detremin
3. How to take Detremin
4. Possible side effects
5. How to store Detremin
6. Contents of the pack and other information

1. What Detremin is and what it is used for

Detremins contains cholecalciferol (vitamin D₃).

Detremin is used to treat vitamin D deficiency or vitamin D insufficiency, in adults and adolescents (children ≥ 12 years). It is also used as supportive treatment for a specific treatment for osteoporosis in combination with calcium.

2. What you need to know before you take Detremin

Do not take Detremin

- if you are allergic to vitamin D₃ 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 this medicine together with calcium if you have severely impaired renal function.

Warnings and precautions

Do not take more Detremin than your doctor has prescribed, since over dosage may occur. Do not combine Detremin with other vitamin D products other than the one your doctor has prescribed.

Talk to your doctor, pharmacist or nurse before taking Detremin:

- if you have had or have had kidney stones
- if you have impaired renal function
- if you have calcification of the kidneys (calcification of the kidney)
- if you have sarcoidosis (an illness with the formation of inflammatory nodules, mostly affecting the lungs) or another chronic inflammatory diseases leading to the formation of nodules.
- If you have a disease that increase 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.

Children

This medicine is not recommended for use in children under 12 years of age.

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 you are taking:

- Phenytoin (against epilepsy) or barbiturates (tranquilizer)
- Rifampicin or isoniazid (against tuberculosis)
- Cardiac glycosides (against heart disease), for example digoxin
- Thiazide diuretics (medicine 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

See section 3 “How to take Detremin”.

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 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.

Excipients

This medicine contains 8 milligram sorbitol in each capsule.

3. How to take Detremin

Always take this medicine exactly as your doctor or pharmacists have told you. Check with your doctor or pharmacists if you're 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. Follow the instructions from your doctor.

Treatment of vitamin D deficiency or vitamin D insufficiency:

The recommended dose for vitamin D deficiency is 1-2 capsules every month during 3-6 months.

The recommended dose for vitamin D insufficiency is 1 capsule every month.

As supportive treatment for a specific treatment for osteoporosis in combination with calcium.

The recommended dose when used as supportive treatment for osteoporosis in combination with calcium is 1 capsule per month.

Detremin can be taken independently of meals.

When you take Detremin, your doctor may want to take blood samples 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, contact 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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

The following symptoms, of which the frequency is unknown, have been seen after intake of products containing vitamin D₃:

- too high levels of calcium in the blood and urine
- constipation, formation of gas, nausea, abdominal pain, diarrhoea
- 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 this medicine out of the sight and reach of children.

Do not store above 25°C.

Keep the blister in the outer carton in order to protect from light.

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 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 D₃). 1 soft capsule contains 625 microgram cholecalciferol, which corresponds to 25000 IU vitamin D₃.

The other ingredients are: Refined Olive Oil, DL- Alpha Tocopherol (Vitamin E), Gelatin, Glycerol, Water and Sorbitol.

What Detremin looks like and contents of the pack

Detremin, 25 000 IU, soft capsule is oblong, clear, slightly yellow. Capsule dimensions are 15 mm x 6 mm.

Detremin softgels 25 000 IU is packaged into blister film and laminated paper or blister film and aluminium foil. The blisters are packaged into a carton box serving 3 or 12 capsules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Renapharma AB

Riddargatan 16,

SE-114 51 Stockholm, Sweden

Tel: +46 18 7001140

e-mail: info@renapharma.se

Manufacturer:

Patheon Softgels B.V., De Posthoornstraat 7, Tilburg, 5048AS, The Netherlands

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

This leaflet was last approved in 2022-10-05