Package leaflet: Information for the patient

Domnisol 266 micrograms soft capsules

calcifediol monohydrate

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, pharmacist, or nurse.
- 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 possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

1. What Domnisol is and what it is used for

Domnisol is a soft capsule containing a form of vitamin D called calcifediol. Vitamin D is found in the diet and is also produced in the skin after exposure to the sun. Domnisol 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. Domnisol may also be prescribed with other medicines, as part of treatment for certain bone conditions, such as thinning of the bone (osteoporosis).

2. What you need to know before you take Domnisol

Do not take Domnisol:

- If you are allergic to calcifediol or any of the other ingredients of this medicine (listed in section 6).
- If you have hypercalcaemia (high levels of calcium in the blood) or hypercalciuria (high levels of calcium in the urine).
- If you have kidney stones.
- If you have high levels of vitamin D in your blood (hypervitaminosis D).

Warnings and precautions

Talk to your doctor or pharmacist before taking Domnisol:

- If you are taking other Vitamin D medicines, as it is important that you do not take more Vitamin D than recommended by your doctor. (see section 3, paragraph *If you take more Domnisol than you should).*
- Your doctor may ask you to take blood or urine tests (e.g. for calcium, phosphorus) while you are taking this medicine or before you start. This is to check that your medicine is working correctly.
- If you have kidney damage or disease. Your doctor may want to take blood tests (e.g. for calcium) to monitor your treatment.

- If you have heart disease. Your doctor may want to take blood tests (e.g. for calcium) to monitor your treatment, especially those receiving treatment with cardiac glycosides (see in this section paragraph 'taking Domnisol with other drugs').
- If you have hypoparathyroidism (a condition where your parathyroid glands in your neck produce too little parathyroid hormone.
- If you have a tendency to get calcium-containing kidney stones, your doctor should monitor your blood calcium levels.
- Patients with prolonged immobilization may need lower dose of Domnisol
- Patients with sarcoidosis (disease with nodules, usually on the skin), tuberculosis or other diseases with nodules should be especially careful with this medication, as they have more risk of side effects at lower doses than the recommended ones. Periodic analyses should be performed to control the levels of calcium in blood and urine.
- Your doctor must inform you and your family and/or caregivers of the importance of taking the drug at the doses indicated by him/her and of recommendations about your diet and calcium supplements intake to avoid overdosing.
- Interference with laboratory tests: If you are going to have any diagnostic test done (including blood, urine, skin tests using allergen, etc.) inform the doctor that you are taking this medication because it may influence the results. For example, in a cholesterol test.

Children and adolescents

Domnisol is not recommended for use in children.

Other medicines and Domnisol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can alter the way this medicine works. On the other hand, Domnisol, or its active ingredient calcifediol monohydrate can affect the effectiveness of other drugs taken simultaneously.

Therefore, they may interact with the following drugs:
- Medicines used to treat epilepsy (such as phenytoin, phenobarbital, and primidone) and other enzyme-inducing drugs (favouring the reduction of Domnisol effect).
- Heart medicines and/or hypertension and cardiac glycosides, thiazide diuretics or verapamil.
- Cholestyramine, colestipol (for cholesterol), orlistat (for obesity). Intake of these drugs and calcifediol monohydrate should be separated at least 2 hours
- Mineral oil or paraffin, (laxatives): Using another type of laxative or separating intake of both drugs is recommended.
- Some antibiotics (such as penicillin, neomycin, and chloramphenicol)
- Magnesium salts
- Other products with Vitamin D
- Calcium supplements
- Corticosteroids (anti-inflammatory drugs).

Domnisol with food and drinks

Some foods and drinks are supplemented with vitamin D. This should be considered since the effects could be added to the effects of this medicine and therefore be excessive.

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.

Domnisol is not recommended during pregnancy.
Calcifediol monohydrate is poorly excreted into breast milk. Nevertheless, in case you are a breast-feeding woman, this should be considered by your doctor or pharmacist when prescribing a vitamin D supplement.

Driving and using machines
Domnisol should not affect your ability to drive or operate machinery.

Domnisol contains ethanol, and sorbitol (E.420)
This medicine contains 5 mg of alcohol (ethanol) in each capsule. The amount in 1 capsule of this medicine is equivalent to less than 1 ml beer or wine.
The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains 22 mg of sorbitol in each capsule.

3. How to take Domnisol

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

Do not take more medicine or more often than what has been prescribed (weekly, biweekly, or monthly). If you do, the risk of overdose increases.

Doses vary according to the person and indications. Your prescriber should monitor your calcium and vitamin D levels periodically, usually before starting the treatment and after 3-4 months.

Depending on the indication, doses will be generally reduced or spaced in time when symptoms improve, or vitamin D deficiency has been overcome.

Recommended doses are as follows:

Treatment of vitamin D deficiency and prevention of vitamin D deficiency in patients with identified risks: one capsule (266 micrograms of calcifediol monohydrate) once a month.

Addition to specific therapy for osteoporosis: one capsule (266 micrograms of calcifediol monohydrate) once a month.

There are populations at high risk of vitamin D deficiency which may need to take higher doses, after analytical verification of the extent of the deficiency, the prescriber may consider a dose of one capsule every two weeks or every week. This medicine should not be administered with a daily frequency.

Domnisol should be taken orally.

If you feel that the effect of this medicine is too strong or too weak, please contact your doctor or pharmacist.

If you take more Domnisol than you should

If you take more Domnisol than the dose prescribed by your doctor (overdose) and/or for a long time, hypercalcemia (high blood calcium levels) and phosphates in urine and blood may appear, possibly leading to kidney failure. Some symptoms of toxicity can appear early and others later. Initial symptoms include weakness, fatigue, headache, loss of appetite, dry mouth, digestive disorders such as vomiting, abdominal cramps, constipation or diarrhoea, increased thirst, increased urination, muscle pain. Some

symptoms that may occur later are itching, weight loss, stunted growth in children, kidney disorders, intolerance to sunlight, conjunctivitis, increased cholesterol, transaminases, inflammation of the pancreas, calcification (calcium salts deposits) in blood vessels and other tissues such as tendons and muscles, increased blood pressure, mental disorders, irregular heartbeat. The symptoms of overdose usually improve or disappear when treatment is stopped, but if intoxication is severe kidney or heart failure can occur.

If you forget to take Domnisol

Do not take a double dose to make up for a forgotten capsule.

If you stop taking Domnisol

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

4. Possible side effects

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

Side effects are in general uncommon (may affect up to 1 in 100 people) if the doses are adjusted to the recommendations. However, significant adverse effects can occur in case of excessive or more prolonged treatment than prescribed by your doctor, which may cause hypercalcemia (increased levels of calcium in blood).

The following side effects can occur:
Nausea, vomiting, dry mouth, constipation, taste alterations with a metallic taste, abdominal cramps (cramping sensation in the gut), anorexia (loss of appetite).

In case of moderate hypercalcemia (increased calcium levels) weakness, fatigue, drowsiness, headache (headache) and irritability may occur.

In cases of hypercalcemia, arrhythmia (heart rhythm disorders) may appear.

In case of hypercalcemia bone and muscle pain and appearance of calcifications (calcium deposits) in soft tissues may occur. Also, nephrocalcinosis (formation of calcium deposits in the kidney), impairment of renal function with polyuria (increased frequency of urination), polydipsia (increased thirst), nocturia (night urine) and proteinuria (proteins in urine).

In rare cases (may affect up to 1 in 1 000 people), at very high doses, photophobia (intolerance of the eyes to light) and conjunctivitis with calcifications (calcium deposits) on the cornea may occur.

Other adverse effects include: rhinorrhoea (runny nose), itching, hyperthermia (fever) and decreased libido (sexual desire). Pancreatitis (inflammation of the pancreas). Increase of urea nitrogen in blood, albuminuria (albumin in the urine), hypercholesterolaemia (increased cholesterol in the blood) and hypercalcemia (increased calcium in blood).

With high levels of blood calcium, increased transaminase (SGOT and SGPT) can occur.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Domnisol

Keep this medicine out of the sight and reach of children.

Do not refrigerate. Store in the original package to protect from moisture

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.

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 further information

What Domnisol contains

- The active substance is calcifediol monohydrate. Each capsule contains 266 micrograms of calcifediol monohydrate.
- The other ingredients are anhydrous ethanol, medium chain triglycerides and the components of the capsule include gelatin, glycerol, sorbitol (E-420), titanium dioxide (E-171) and iron oxide yellow (E-172).

What Domnisol looks like and content of the pack

Domnisol capsules are yellow coloured oval soft gelatin capsule containing a clear, low viscous liquid free from particles packed in PVC/PVDC-Al blisters containing 1, 3, 5 or 10 capsules.

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