

PATIENT COUNSELLING INFORMATION

Suspension of Calcium with Vitamin D₃

Miracal[®] Suspension

Read the entire leaflet carefully before you start taking this medicine:

- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.
- 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.

1. What is Miracal[®] Suspension and what is it used for?

Miracal[®] Suspension is a combination of Calcium (as Calcium carbonate) and Vitamin D₃.

It is recommended for the treatment of Calcium and Vitamin D deficiency states and during growth, pregnancy & lactation.

2. What you need to know before you take Miracal[®] Suspension?

Do not take Miracal[®] Suspension

- if you are allergic to active substances or any of the other ingredients of this medicine.
- if you have kidney stones.
- if you have kidney failure or severe renal impairment.
- if you have excessive amounts of Vitamin D in the blood.
- if you have chronically increased Calcium level in your urine or elevated blood-Calcium level.

Warnings and precautions

Talk to your doctor before taking Miracal[®] Suspension

- if you have kidney disease or impaired kidney function.
- if you have sarcoidosis (an inflammatory disease of unidentified origin characterised by formation of cell agglomerates [lumps] in different locations).
- if you are prone to development of kidney stones.
- if you are an immobilised patient with osteoporosis.

Your doctor should decide whether Calcium and/or Vitamin D₃ supply can be used in these conditions.

If you use Miracal[®] Suspension in osteoporosis, your doctor may determine your blood-calcium level (calcaemia) before starting the treatment with Miracal[®] Suspension.

If you are on long-term treatment your doctor may, from time to time wish to check the level of Calcium in your blood and take urine sample to monitor kidney function.

Depending upon the results, your doctor may reduce the dosage or decide to discontinue the treatment.

Other medicines and Miracal[®] Suspension

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Consult your doctor if you use:

- other medicines containing Vitamin D or Calcium, because concomitant [accompanying] use of such products with Miracal[®] Suspension may lead to a significant elevation of blood-calcium levels and cause adverse effects that may be harmful. During the treatment with Miracal[®] Suspension, do not use any other products containing Vitamin D or Calcium without medical advice.
- thiazide diuretics.
- systemic (per os [oral] or injection) corticosteroids (anti-inflammatory drugs).
- cardiac glycosides (used for the treatment of cardiac [heart] failure).

Take special care if you use:

- ion exchange resins such as cholestyramine or laxatives such as paraffin oil, as these medicines may reduce the gastrointestinal absorption of Vitamin D.
- tetracycline containing preparations (antibiotics), as Calcium carbonate may interfere with their absorption. Therefore, tetracycline preparations should be administered at least two hours before or four to six hours after using of Miracal[®] Suspension.
- bisphosphonate (used for the treatment of osteoporosis) or sodium fluoride is used concomitantly with Miracal[®] Suspension, these preparations should be administered at least three hours before using Miracal[®] Suspension.
- Rifampicin (a medicine for tuberculosis), phenytoin (a medicine for epilepsy) and barbiturates (medicines which are used for epilepsy or which help you sleep), as they may make the Vitamin D₃ less effective.
- Quinolone (antibiotics), as Calcium may interfere with its absorption. Quinolone antibiotics should be taken two hours before or six hours after intake of Calcium.
- Estramustine (a medicine used in chemotherapy), thyroid hormones or medicines containing iron, zinc or strontium, as the amount absorbed may be reduced. They should be taken at least 2 hours before or after Miracal[®] Suspension.

Miracal[®] Suspension with food and drink

Oxalic acid (found in e.g. spinach, sorrel and rhubarb) and phytic acid (found in whole cereals) may inhibit Calcium absorption. The patient should not take Miracal[®] Suspension within two hours after eating foods rich in oxalic acid and phytic acid.

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 for advice before taking this medicine.

During pregnancy, the daily intake should not exceed 1500 mg Calcium and 600 IU

(International Unit) Vitamin D. In pregnant women, overdoses of Calcium and Vitamin D should be avoided as permanent hypercalcaemia is related to adverse effects on the developing foetus. During pregnancy, Miracal[®] Suspension should be used in the recommended doses only in cases of Calcium and Vitamin D₃ deficiency.

Miracal[®] Suspension can be used during breast-feeding, but your doctor should be informed as Calcium and Vitamin D gets into the breast milk. This should be considered when giving additional Vitamin D to the child.

There are no data available on the effect of Miracal[®] Suspension on fertility.

Driving and using machines

There are no data on the effect of this product on the ability to drive or use machines.

Miracal[®] Suspension contain sucrose

If you have been told by your doctor that you have an intolerance to some sugar, contact your doctor before taking this medicinal product.

3. How to take Miracal[®] Suspension?

Always use this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose for adults and the elderly is 5 to 10 ml orally 1-2 times per day or as your doctor has told you.

The recommended dose for children and adolescents is 5 to 10 ml orally once a day or as your doctor has told you.

If you take more Miracal[®] Suspension than you should

Intake of higher dose than the proposed one may cause Calcium and Vitamin D overdose. Symptoms of Calcium overdosing: lack of appetite, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental disturbances, excess drinking and excess urination, bone pain, calcification of the kidneys and in severe cases cardiac arrhythmias (irregular heartbeat). In extreme cases, Calcium overdose can lead to coma and death. Long term increased Calcium level in the blood can lead to irreversible kidney impairment and calcification of soft tissues.

Treatment: intake of Miracal[®] Suspension must be discontinued and you must consult with a doctor.

If you forget to take Miracal[®] Suspension

Do not take a double dose to make up for a forgotten dose, as you would not substitute the missing amount, but you risk an overdosing. Continue the treatment according to the instructions.

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

4. What are the possible side effects of Miracal[®] Suspension?

Like all medicines, this medicine can cause side effects, although not everybody gets them. Adverse reactions are listed below by classes of organ systems and frequency of occurrence. Frequency is defined as:

- Uncommon (affects 1 to 10 users in 1,000)
- Rare (affects 1 to 10 users in 10,000)
- Very rare (affects less than 1 in 10,000)

Uncommon: significantly increased blood calcium level (hypercalcaemia) - the symptoms include nausea, vomiting, lack of appetite, constipation, stomach ache, bone pain, extreme thirst, needing to pass urine more often, muscle weakness, drowsiness and confusion; or markedly increased calcium content of the urine (hypercalciuria).

Rare: constipation, flatulence, nausea, abdominal pain, diarrhoea, itching, rash and urticaria (hives).

Very rare: dyspepsia, Milk alkali syndrome (usually only seen in overdose).

If you have impaired renal function, you may be at risk of increased amounts of phosphate in the blood, renal stone formation and increased amounts of calcium in the kidneys.

If you get any side-effects, talk to your doctor. This includes any possible side-effects not listed in this leaflet.

5. How to store Miracal[®] Suspension?

Store in a cool place. Protect from light.

Keep out of reach of children.

Do not take this medicine after the expiry date shown on the pack. The expiry date refers to the last day of that month.

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