

Package leaflet: Information for the user

Solferol 20,000 IU Soft Capsules

Colecalciferol

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 Solferol 20,000 IU Capsules are and what they are used for
2. What you need to know before you take Solferol 20,000 IU Capsules
3. How to take Solferol 20,000 IU Capsules
4. Possible side effects
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6. Contents of the pack and other information

1. WHAT SOLFEROL 20,000 IU CAPSULES ARE AND WHAT THEY ARE USED FOR

Solferol 20,000 IU Capsules contains colecalciferol (vitamin D). Vitamin D is found in some foods and is also produced in the body when skin is exposed to sunlight. Vitamin D helps the kidneys and intestine absorb calcium and it helps build bones.

Solferol 20,000 IU Capsules are used:

- To prevent vitamin D deficiency when there is a significant risk of deficiency or an increased demand for vitamin D.
- With other medicine to treat certain bone conditions, such as thinning of the bone (osteoporosis).
- To treat vitamin D deficiency that has been confirmed by laboratory tests.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SOLFEROL 20,000 IU CAPSULES

Do not take Solferol 20,000 IU Capsules:

- if you are allergic to colecalciferol or any of the other ingredients of this medicine (listed in section 6)
- if you have high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria)
- if you have a condition which means that your body is resistant to parathyroid hormone (pseudohypoparathyroidism)
- if you have high levels of vitamin D in your blood (hypervitaminosis D)
- if you have kidney stones or serious kidney problems.

Warnings and precautions

Talk to your doctor or pharmacist before taking Solferol 20,000 IU Capsules if you:

- are undergoing treatment with certain medicines used to treat heart disorders (e.g. diuretics, cardiac glycosides such as digoxin)
- have sarcoidosis (an immune system disorder which may cause increased levels of vitamin D in the body)
- are taking medicines containing vitamin D, or eating foods or milk enriched with vitamin D
- are likely to be exposed to a lot of sunlight whilst using Solferol 20,000 IU Capsules
- take additional supplements which contain calcium or you take medicines or have a condition that can alter your calcium or phosphate levels. Your doctor will monitor your blood levels of calcium to make sure they are not too high whilst you are using Solferol 20,000 IU Capsules
- have kidney damage or disease. Your doctor may want to measure the levels of calcium in your blood or urine.

Children

Solferol 20,000 IU Capsules are not indicated for use in children.

Other medicines and Solferol 20,000 IU Capsules

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

This is especially important if you are taking:

- medicines that act on the heart or kidneys, such as cardiac glycosides (e.g. digoxin) or diuretics (e.g. bendroflumethazide). When used at the same time as vitamin D these medicines may cause a large increase in the level of calcium in the blood and urine. Your doctor may monitor your heart with an electrocardiogram (ECG) and measure the levels of calcium in your blood
- medicines containing vitamin D or eating food rich in vitamin D, such as, some types of vitamin-enriched milk
- actinomycin (a medicine used to treat some forms of cancer) and imidazole antifungals (e.g. clotrimazole and ketoconazole, medicines used to treat fungal disease). These medicines may interfere with the way your body processes vitamin D
- the following medicines because they can interfere with the effect or the absorption of vitamin D:
 - antiepileptic medicines (anticonvulsants such as phenytoin)
 - medicines that alter your nervous system (sedatives such as barbiturates)
 - glucocorticoids (steroid hormones such as hydrocortisone or prednisolone). These can decrease the effect of vitamin D
 - medicines that lower the level of cholesterol in the blood (such as cholestyramine or colestipol)
 - certain medicines for weight loss that reduce the amount of fat your body absorbs (e.g. orlistat)
 - certain laxatives (such as liquid paraffin)
 - antibiotics used to treat the bacterial infection called tuberculosis (TB) (e.g. rifampicin and isoniazid) as they may reduce the effectiveness of vitamin D.

Solferol 20,000 IU Capsules with food and drink

You should take Solferol 20,000 IU Capsules with a large meal to help your body absorb the vitamin D.

Pregnancy and breast-feeding

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. This high strength formulation is not recommended for use in pregnant and breast-feeding women.

Driving and using machines

There is limited information on the possible effects of this medicine on your ability to drive. However, it is not expected that it would affect your ability to drive or operate machinery.

Solferol 20,000 IU Capsules contains Sorbitol

This medicine contains 16.5 mg sorbitol in each capsule. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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3. HOW TO TAKE SOLFEROL 20,000 IU CAPSULES

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

Adults

Prevention of vitamin D deficiency: 20 000 IU every 4 weeks (1 capsule), higher doses may be required in certain situations, as directed by your doctor.

Addition to specific therapy for osteoporosis: 20,000 IU (1 capsule) once a month.

Treatment of vitamin D deficiency: 40 000 IU/week (2 capsules) for 7 weeks, followed by maintenance therapy of 2-3 capsules (equivalent to 1400-2000 IU/day) every 4 weeks as directed by your doctor.

Use in pregnancy and breast-feeding

This high strength formulation is not recommended.

Use in children

Solferol 20,000 IU Capsules are not suitable for children.

Method of administration

You should swallow the capsules whole with water, do not chew the capsules.

If you take more Solferol 20,000 IU Capsules than you should

If you take more medicine than prescribed, stop taking this medicine and contact your doctor. If it is not possible to talk to your doctor go to the nearest hospital emergency department and take the medicine package with you. The most common symptoms of overdose are: feel or be sick (nausea & vomiting), excessive thirst, production of large amounts of urine over 24 hours, constipation and dehydration, high levels of calcium in the blood and urine (hypercalcaemia and hypercalciuria) shown by lab tests.

If you forget to take Solferol 20,000 IU Capsules

If you forgot to take a dose of Solferol 20,000 IU Capsules, take the forgotten dose as soon as possible. Then take the next dose at the correct time. However, if it is almost time to take the next dose, do not take the dose you have missed; just take the next dose as normal. Do not take a double dose to make up for a forgotten dose.

After that, take the next capsule in accordance with the instructions given to you by your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Side effects with Solferol 20,000 IU Capsules may include:

Uncommon (may affect up to 1 in 100 people):

- too much calcium in your blood (hypercalcaemia)
- too much calcium in your urine (hypercalciuria).

Rare (may affect up to 1 in 1,000 people):

- skin rash
- itching
- hives.

Not known (we do not know how often these happen):

- altered bowel movements
- wind
- feeling sick (nausea)
- stomach pain.

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 national reporting system.

HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SOLFEROL 20,000 IU CAPSULES

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

Store below 30°C.

HDPE Containers & Amber Glass Bottles: Once opened use within 105 days.

Do not use this medicine after the expiry date which is stated on the label 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 OTHER INFORMATION

What Solferol 20,000 IU Capsules contains

– The active substance is colecalciferol. Each capsule contains 20,000 IU of colecalciferol (equivalent to 500 micrograms Vitamin D).

– The other ingredients are:

Capsule: medium chain triglycerides and vitamin E acetate (α -tocopheryl acetate)

Capsule shell: gelatin, glycerol (E422), sorbitol liquid partially dehydrated (E420) and purified water.

What Solferol 20,000 IU Capsules looks like and contents of the pack

Solferol 20,000 IU Capsules are light yellow coloured, clear transparent round shaped gelatin capsules with a clear, colourless liquid fill.

It is available in glass amber bottles, HDPE bottles containing 20, 30, 50, 60 or 90 capsules and blister strips containing 4, 10, 20, 30, 50, 60 or 90 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Windzor Pharma Ireland Limited, The Office Suite, Unit 2 Holywell Commercial Centre, Swords, Co. Dublin, Ireland

Manufacturer: HC Clover Productos Y Servicios, S.L. C/ Alicante, 8-10, Arganda del Rey, Madrid, 28500, Spain

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland: Solferol 20,000 IU Soft Capsules

United Kingdom: Vitamin D₃ 20,000 IU Capsules, soft

This leaflet was last revised in 06/2021