

# Package leaflet: Information for the user

## Solferol 800 IU Soft Capsules

## Solferol 1,000 IU Soft Capsules

## Solferol 10,000 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 Capsules are and what they are used for
2. What you need to know before you take Solferol Capsules
3. How to take Solferol Capsules
4. Possible side effects
5. How to store Solferol Capsules
6. Contents of the pack and other information

### 1. WHAT SOLFEROL CAPSULES ARE AND WHAT THEY ARE USED FOR

The active substance of Solferol Capsules is vitamin D<sub>3</sub>. Vitamin D helps the body to absorb calcium and enhances bone formation.

This medicine is recommended in the following cases:

- For certain bone conditions, such as thinning of the bone (osteoporosis), when it will be given to you with other medicines.
- To prevent or treat vitamin D deficiency. Vitamin D deficiency may occur when your diet or lifestyle does not provide you enough vitamin D or when your body requires more vitamin D.

Solferol Capsules are used in adults, the elderly and adolescents.

### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SOLFEROL CAPSULES

#### Do not take Solferol Capsules:

- if you are allergic to vitamin D 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 severe kidney problems (severe renal impairment)
- if you have high levels of vitamin D in your blood (hypervitaminosis D)
- if you have kidney stones or calcium deposits in your kidneys.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Solferol Capsules if:

- You have high tendency to kidney stone formation.
- You have cancer or any other condition that may have affected your bones.
- You have parathyroid hormone imbalance (pseudohypoparathyroidism).

If you have any of the following conditions, your doctor will monitor the levels of calcium or phosphate in your blood, or the level of calcium in your urine:

- if you are on long term treatment with this medicine
- if you have kidney problems
- if you suffer from ‘sarcoidosis’; an immune system disorder which may affect your liver, lungs, skin or lymph nodes.

#### Children

Solferol Capsules are not indicated for use in children under 12 years.

#### Other medicines and Solferol 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:

- diuretics (water tablets). As your doctor will need to monitor your blood calcium levels regularly
- corticosteroids (‘steroids’ e.g. prednisolone, dexamethasone). As your dose of vitamin D may need to be increased
- colestyramine (a cholesterol lowering medicine) or laxatives (e.g. paraffin oil). As they reduce vitamin D absorption
- heart medicines (cardiac glycosides). As you should be monitored by a physician and possibly an ECG and your calcium levels monitored
- anticonvulsants (for the treatment of epilepsy), sleeping medicines (e.g. hydantoin barbiturates) or primidone. As these reduce the effect of vitamin D
- calcitonin, etidronate, gallium nitrate, pamidronate or plicamycin. As these decrease blood calcium levels
- calcium containing products in high doses. As these increase the risk of high blood calcium levels
- magnesium containing products (e.g. antacids). As these should not be used during treatment with vitamin D because of the risk of high magnesium levels
- phosphorus containing products in large doses. As these in large doses increase the risk of high phosphate blood levels.

#### Solferol Capsules with food and drink

You can take Solferol Capsules with or without food.

#### 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. These formulations can be used during pregnancy but only if you have been diagnosed with vitamin D deficiency and following the advice of your doctor.

#### 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 Capsules contain:

**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.

**Sunset yellow (10,000 IU only):** Solferol 10,000 Capsules contain sunset yellow which may cause allergic reactions.

Continued overleaf...

### 3. HOW TO TAKE SOLFEROL 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

##### 800 IU and 1,000 IU Solferol Capsules:

Your doctor will usually prescribe 1 capsule daily. In severe vitamin D deficiency for the adult and the elderly, the amount will depend on your vitamin D levels and on the response given to the treatment.

##### 10,000 IU Solferol Capsules:

Your doctor will usually prescribe 1 capsule every week. In severe vitamin D deficiency for the adult and the elderly, the amount will depend on your vitamin D levels and on the response given to the treatment.

#### Adolescents

##### 800 IU Solferol Capsules:

Your doctor will usually prescribe 1 capsule daily. The amount will depend on your vitamin D levels and on the response given to the treatment.

#### Use in children

Solferol Capsules are not suitable for children under 12 years.

#### Method of administration

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

#### If you take more Solferol Capsules than you should

You may develop the following symptoms: loss of appetite, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, tiredness, confusion, having to pass urine more than usual, bone pain, kidney problems and in severe cases, irregular heartbeat, coma or even death.

If you take too many capsules, contact your doctor immediately or go to the emergency department of the nearest hospital. Take the packet and any remaining capsules with you.

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

#### If you forget to take Solferol Capsules

If you forgot to take a dose of Solferol 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.

Stop taking Solferol Capsules and seek immediate medical help if you experience symptoms of serious allergic reactions, such as:

- swollen face, lips, tongue or throat
- difficult to swallow
- hives and difficulty breathing.

Side effects with Solferol Capsules may include:

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

- too much calcium in your blood (hypercalcaemia). Symptoms include nausea, vomiting, lack of appetite, constipation, stomach ache, bone pain, extreme thirst, a need to pass more water than usual, muscle weakness, drowsiness and confusion
- too much calcium in your urine (hypercalciuria).

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

- skin rash (pruritus, urticaria)
- itching.

#### 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](http://www.hpra.ie).

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

### 5. HOW TO STORE SOLFEROL CAPSULES

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

Store below 30°C.

HDPE Containers and 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 Capsules contain

– The active substance is colecalciferol:

Each 800 IU capsule contains 800 IU of colecalciferol, equivalent to 20 micrograms Vitamin D<sub>3</sub>.

Each 1,000 IU capsule contains 1,000 IU of colecalciferol, equivalent to 25 micrograms Vitamin D<sub>3</sub>.

Each 10,000 IU capsule contains 10,000 IU of colecalciferol, equivalent to 250 micrograms Vitamin D<sub>3</sub>.

– The other ingredients are:

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

Capsule shell 800 IU: Gelatin, glycerol (E422), sorbitol liquid partially dehydrated (E420), brilliant blue (E133) and purified water.

Capsule shell 1,000 IU: Gelatin, glycerol (E422), sorbitol liquid partially dehydrated (E420), brilliant blue (E133), quinoline yellow (E104) and purified water.

Capsule shell 10,000 IU: Gelatin, glycerol (E422), sorbitol liquid partially dehydrated (E420), sunset yellow (E110) and purified water.

#### What Solferol Capsules looks like and contents of the pack

- Solferol 800 IU Capsules are blue coloured, clear transparent round shaped gelatin capsules with a clear, colourless liquid fill.
- Solferol 1,000 IU Capsules are green coloured, clear transparent round shaped gelatin capsules with a clear, colourless liquid fill.
- Solferol 10,000 IU Capsules are orange coloured, clear transparent round shaped gelatin capsules with a clear, colourless liquid fill.

Solferol 800 IU and 10,000 IU Capsules are available in glass amber bottles, HDPE bottles and blister strips containing 20, 30, 50, 60 or 90 capsules.

Solferol 1,000 IU Capsules are available in glass amber bottles and HDPE bottles containing 20, 30, 50, 60 or 90 capsules and blister strips containing 20, 28, 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:

Copea Pharma Europe Limited,  
Unit 2, Medici House,  
Ashbourne Manufacturing Park,  
Ashbourne, Co. Meath, A84 KH58,  
Ireland

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

United Kingdom: Vitamin D<sub>3</sub> 800 IU Capsules, soft  
United Kingdom: Vitamin D<sub>3</sub> 1,000 IU Capsules, soft  
United Kingdom: Vitamin D<sub>3</sub> 10,000 IU Capsules, soft  
Ireland: Solferol 800 IU Soft Capsules  
Ireland: Solferol 1,000 IU Soft Capsules  
Ireland: Solferol 10,000 IU Soft Capsules

This leaflet was last revised in 05/2021

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## Solferol 1,000 IU Soft Capsules

## Solferol 10,000 IU Soft Capsules

## Colecalciferol

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- 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

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5. How to store Solferol Capsules
6. Contents of the pack and other information

### 1. WHAT SOLFEROL CAPSULES ARE AND WHAT THEY ARE USED FOR

The active substance of Solferol Capsules is vitamin D<sub>3</sub>. Vitamin D helps the body to absorb calcium and enhances bone formation.

This medicine is recommended in the following cases:

- For certain bone conditions, such as thinning of the bone (osteoporosis), when it will be given to you with other medicines.
- To prevent or treat vitamin D deficiency. Vitamin D deficiency may occur when your diet or lifestyle does not provide you enough vitamin D or when your body requires more vitamin D.

Solferol Capsules are used in adults, the elderly and adolescents.

### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SOLFEROL CAPSULES

#### Do not take Solferol Capsules:

- if you are allergic to vitamin D 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 severe kidney problems (severe renal impairment)
- if you have high levels of vitamin D in your blood (hypervitaminosis D)
- if you have kidney stones or calcium deposits in your kidneys.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Solferol Capsules if:

- You have high tendency to kidney stone formation.
- You have cancer or any other condition that may have affected your bones.
- You have parathyroid hormone imbalance (pseudohypoparathyroidism).

If you have any of the following conditions, your doctor will monitor the levels of calcium or phosphate in your blood, or the level of calcium in your urine:

- if you are on long term treatment with this medicine
- if you have kidney problems
- if you suffer from ‘sarcoidosis’; an immune system disorder which may affect your liver, lungs, skin or lymph nodes.

#### Children

Solferol Capsules are not indicated for use in children under 12 years.

#### Other medicines and Solferol 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:

- diuretics (water tablets). As your doctor will need to monitor your blood calcium levels regularly
- corticosteroids (‘steroids’ e.g. prednisolone, dexamethasone). As your dose of vitamin D may need to be increased
- colestyramine (a cholesterol lowering medicine) or laxatives (e.g. paraffin oil). As they reduce vitamin D absorption
- heart medicines (cardiac glycosides). As you should be monitored by a physician and possibly an ECG and your calcium levels monitored
- anticonvulsants (for the treatment of epilepsy), sleeping medicines (e.g. hydantoin barbiturates) or primidone. As these reduce the effect of vitamin D
- calcitonin, etidronate, gallium nitrate, pamidronate or plicamycin. As these decrease blood calcium levels
- calcium containing products in high doses. As these increase the risk of high blood calcium levels
- magnesium containing products (e.g. antacids). As these should not be used during treatment with vitamin D because of the risk of high magnesium levels
- phosphorus containing products in large doses. As these in large doses increase the risk of high phosphate blood levels.

#### Solferol Capsules with food and drink

You can take Solferol Capsules with or without food.

#### 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. These formulations can be used during pregnancy but only if you have been diagnosed with vitamin D deficiency and following the advice of your doctor.

#### 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 Capsules contain:

**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.

**Sunset yellow (10,000 IU only):** Solferol 10,000 Capsules contain sunset yellow which may cause allergic reactions.

Continued overleaf...

### 3. HOW TO TAKE SOLFEROL 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

##### 800 IU and 1,000 IU Solferol Capsules:

Your doctor will usually prescribe 1 capsule daily. In severe vitamin D deficiency for the adult and the elderly, the amount will depend on your vitamin D levels and on the response given to the treatment.

##### 10,000 IU Solferol Capsules:

Your doctor will usually prescribe 1 capsule every week. In severe vitamin D deficiency for the adult and the elderly, the amount will depend on your vitamin D levels and on the response given to the treatment.

#### Adolescents

##### 800 IU Solferol Capsules:

Your doctor will usually prescribe 1 capsule daily. The amount will depend on your vitamin D levels and on the response given to the treatment.

#### Use in children

Solferol Capsules are not suitable for children under 12 years.

#### Method of administration

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

#### If you take more Solferol Capsules than you should

You may develop the following symptoms: loss of appetite, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, tiredness, confusion, having to pass urine more than usual, bone pain, kidney problems and in severe cases, irregular heartbeat, coma or even death.

If you take too many capsules, contact your doctor immediately or go to the emergency department of the nearest hospital. Take the packet and any remaining capsules with you.

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

#### If you forget to take Solferol Capsules

If you forgot to take a dose of Solferol 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

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Stop taking Solferol Capsules and seek immediate medical help if you experience symptoms of serious allergic reactions, such as:

- swollen face, lips, tongue or throat
- difficult to swallow
- hives and difficulty breathing.

Side effects with Solferol Capsules may include:

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

- too much calcium in your blood (hypercalcaemia). Symptoms include nausea, vomiting, lack of appetite, constipation, stomach ache, bone pain, extreme thirst, a need to pass more water than usual, muscle weakness, drowsiness and confusion
- too much calcium in your urine (hypercalciuria).

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

- skin rash (pruritus, urticaria)
- itching.

#### 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](http://www.hpra.ie).

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### 5. HOW TO STORE SOLFEROL CAPSULES

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### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

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Each 10,000 IU capsule contains 10,000 IU of colecalciferol, equivalent to 250 micrograms Vitamin D<sub>3</sub>.

– The other ingredients are:

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

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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:

United Kingdom: Vitamin D<sub>3</sub> 800 IU Capsules, soft  
United Kingdom: Vitamin D<sub>3</sub> 1,000 IU Capsules, soft  
United Kingdom: Vitamin D<sub>3</sub> 10,000 IU Capsules, soft  
Ireland: Solferol 800 IU Soft Capsules  
Ireland: Solferol 1,000 IU Soft Capsules  
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**This leaflet was last revised in 05/2021**