Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Solferol 400 IU Soft Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:
400 IU Colecalciferol (equivalent to 10 micrograms Vitamin D_3)

Excipients with known effect:
Each capsule also contains 16.5 milligrams of sorbitol and 40.5 micrograms of allura red.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, soft (Capsule)

Purple coloured clear transparent round shaped gelatin capsule.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention of Vitamin D deficiency in pregnant and breastfeeding women with an identified risk.

Solferol Capsules is indicated in adults and adolescents.

4.2 Posology and method of administration

Posology
Adults and adolescents
Dose should be established on an individual basis depending on the extent of the necessary vitamin D supplementation.

Pregnancy and breast-feeding
- Prevention of deficiency: The usual dose is 400 IU/day (1 capsule)

Before starting the vitamin D therapy, the patient's dietary habits should be carefully evaluated by the doctor and artificially added vitamin D content of certain food types should be taken into consideration.

Certain populations are at high risk of vitamin D deficiency, and may require higher doses and monitoring of serum 25(OH)D:

- Breast-feeding women who choose not to give the infant a vitamin D3 supplement.
- Institutionalised or hospitalised individuals
- Dark skinned individuals
- Individuals with limited effective sun exposure due to protective clothing or consistent use of sun screens
- Obese individuals
- Patients being evaluated for osteoporosis
- Use of certain concomitant medications (e.g., anticonvulsant medications, glucocorticoids)
- Patients with malabsorption, including inflammatory bowel disease and coeliac disease
- Those recently treated for vitamin D deficiency, and requiring maintenance therapy.

Paediatric population

Solferol Capsules should not be used in children under 12 years.

Method of administration

Oral

The capsules should be swallowed whole (not chewed) with water.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Diseases/conditions associated hypercalcaemia and / or hypercalciuria.
- Calcium nephrolithiasis, nephrocalcinosis, D- hypervitaminosis
- Severe renal impairment.

4.4 Special warnings and precautions for use

During long-term use, serum calcium level, urinary calcium excretion and renal function should be monitored by measuring the serum creatinine level. Monitoring is especially important for patients who concomitantly take cardiac glycosides or diuretics (see section 4.5), and in the case of hyperphosphataemia, as well as for patients with an increased risk of lithiasis. In case of hypercalciuria (exceeding 300 mg (7.5 mmol)/24 hours) or signs of impaired renal function the dose should be reduced or the treatment discontinued.
Vitamin D should be used with caution in patients with impaired renal function. In this case monitoring of calcium and phosphate levels is necessary, and the risk of soft tissue calcification should be taken into consideration. In patients with severe renal insufficiency, vitamin D in the form of colecalciferol is not metabolised normally and other forms of vitamin D should be used. Similar monitoring is necessary for children whose mother receive treatment with vitamin D in pharmacological amounts. Some children may react with increased sensitivity to the effect of vitamin D.
Solferol Capsules should not be taken if pseudohypoparathyroidism is present (the need for vitamin D may be reduced by the sometimes normal sensitivity to vitamin D, with a risk of long-term overdose). In such cases, more manageable vitamin D derivatives are available.
Solferol Capsules should be used with caution in patients with sarcoidosis because of the risk of vitamin D's increased transformation to its active form. Blood and urine calcium levels should be regularly monitored in these patients.
In the case of concomitant use with other medicinal product containing vitamin D, its vitamin D content should be taken into consideration. The concomitant use of multivitamin products and dietary supplements containing vitamin D should be avoided.
Medicinal products having effect through the inhibition of bone resorption decrease the calcium amounts derived from bone. In order to avoid this, as well as concomitantly to treatment with medicines enhancing bone development, it is necessary to take vitamin D and ensure proper calcium levels.
Paediatric population
Solferol Capsules are not indicated for use in children under 12 years.
This product contains sorbitol liquid partially dehydrated. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account.
The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.
Patients with rare hereditary problems of fructose intolerance should not take this medicine**.**
This product contains allura red which may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use with calcium containing products administered in large doses may increase the risk of hypercalcaemia.
Thiazide diuretics reduce the excretion of calcium with urine. Regular monitoring of the serum calcium level is necessary in the case of concomitant use with thiazide diuretics or with calcium containing products taken in large doses because of the increased risk of hypercalcaemia.

The effects of digitalis and other cardiac glycosides may be accentuated with the oral administration of calcium combined with Vitamin D. Strict medical supervision is needed and, if necessary monitoring of ECG and calcium.

Systematic corticosteroids inhibit the absorption of calcium. Long-term use of corticosteroids may offset the effect of vitamin D.

Simultaneous treatment with ion exchange resins (e.g. colestyramine), or laxatives (like paraffin oil) may impair the absorption of vitamin D.

Products containing magnesium (like antacids) may not be taken during vitamin D treatment because of the risk of hypermagnesaemia.

Anticonvulsants, hydantoin, barbiturates or primidone may reduce the effect of vitamin D due to the activation of the microsomal enzyme system.

Concomitant use of calcitonin, etidronate, gallium nitrate, pamidronate or plicamycin with vitamin D may antagonise the effect of these products in hypercalcaemia treatment.

Products containing phosphor used in large doses, given concomitantly may increase the risk of hyperphosphataemia.

4.6 Fertility, pregnancy and lactation

Pregnancy
The recommended daily intake for pregnant women is 400 IU, however, in women who are considered to be vitamin D deficient a higher dose may be required. During pregnancy women should follow the advice of their medical practitioner as their requirements may vary depending on the severity of their disease and their response to treatment. In patients without a vitamin D deficiency, the daily vitamin D intake during pregnancy may not exceed 600 IU. Overdoses of vitamin D have been shown to have teratogenic effects in animal experiments (See section 5.3). In pregnant women, overdosage of vitamin D3 should be avoided, since prolonged hypercalcaemia has been sometimes associated with retardation of physical and mental development, supravalvular aortic stenosis and retinopathy in the child.

Breastfeeding
Solferol Capsules can be used during breastfeeding. Vitamin D and its metabolites pass into breast-milk. This should be considered when giving additional vitamin D to the child.

4.7 Effects on ability to drive and use machines

Solferol Capsules has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The frequency of possible side effects listed below are defined as:

Very common (≥ 1/10)
Common (≥ 1/100 to <1/10)
Uncommon (≥ 1/1,000 to <1/100)
Rare (≥ 1/10,000 to <1/1,000)
Very rare (<1/10,000)
Not known (cannot be estimated from the available data)

Immune system disorders:
Not known (cannot be estimated from the available data): Hypersensitivity reactions such as angio-oedema or laryngeal oedema.

Metabolism and nutrition disorders:
Uncommon: hypercalcaemia and hypercalciuria.

Skin and subcutaneous disorders:
Rare: Pruritus, rash and urticaria.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

HPRA Pharmacovigilance
Website: www.hpra.ie.

4.9 Overdose

Overdose of the product may cause hypervitaminosis, hypercalcaemia and hyperphosphatemia. Symptoms of hypercalcaemia: anorexia, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, confusion, polydipsia, polyuria, bone pain, calcification in the kidneys, kidney stones, vertigo, and cardiac arrhythmia in severe cases. Hypercalcaemia in extreme cases may lead to coma or even death. Persistently high levels of calcium may cause irreversible renal impairment and soft tissue calcification.

Treatment of hypercalcaemia: treatment with vitamin D (and calcium) should be discontinued. At the same time, the use of thiazide diuretics, lithium, vitamin D and A as well as cardiac glycosides should also be discontinued. In the case of patients with impaired consciousness gastric emptying is also necessary. Rehydration and mono- or combined therapy with loop diuretics, bisphosphonates, calcitonin and corticosteroids may be used depending on the severity of the overdose. Serum electrolyte levels, renal function and diuresis should be monitored. In severe cases ECG and central venous pressure monitoring may be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vitamin D and analogues, ATC code: A11CC05

Mechanism of action
In its biologically active form Vitamin D3 stimulates intestinal calcium absorption, incorporation of calcium into the osteoid, and release of calcium from bone tissue. In the small intestine it promotes rapid and delayed calcium uptake.
The passive and active transport of phosphate is also stimulated. In the kidney, it inhibits the excretion of calcium and phosphate by promoting tubular resorption. The production of parathyroid hormone (PTH) in the parathyroids is inhibited directly by the biologically active form of Vitamin D, PTH secretion is inhibited 3 additionally by the increased calcium uptake in the small intestine under the influence of biologically active Vitamin D3.

5.2 Pharmacokinetic properties

Absorption
Fat-soluble vitamin D3 is absorbed through the small intestine in the presence of bile acids with the help of micellum and gets into the blood through lymphatic circulation.

Distribution
Following absorption, vitamin D3 enters the blood as part of chylomicrons. Vitamin D3 is rapidly distributed mostly to the liver where it undergoes metabolism to 25-hydroxyvitamin D3, the major storage form. Lesser amounts are distributed to adipose and muscle tissue and stored as vitamin D3 at these sites for later release into the circulation. Circulating vitamin D3 is bound to vitamin D-binding protein.

Biotransformation
Vitamin D3 is rapidly metabolized by hydroxylation in the liver to 25-hydroxyvitamin D3, and subsequently metabolized in the kidney to 1,25-dihydroxyvitamin D3, which represents the biologically active form. Further hydroxylation occurs prior to elimination. A small percentage of vitamin D3 undergoes glucuronidation prior to elimination.

Elimination
Vitamin D and its metabolites are excreted in faeces and urine.

5.3 Preclinical safety data

At doses far higher than the human therapeutic range teratogenicity has been observed in animal studies. There is no further information of relevance to the safety assessment in addition to what is stated in other parts of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule content:
Medium chain triglycerides
Vitamin E Acetate (α-Tocopheryl Acetate)

Capsule Shell:
Gelatin
Glycerol (E422)
Sorbitol liquid partially dehydrated (E420)
Brilliant Blue (E133)
Allura Red (E129)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Aluminium PVCPVDC Blisters:
36 months

HDPE Containers and Amber Glass Bottles:
30 months

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

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

HDPE Containers
Amber Glass Bottles
Aluminium PVCPVDC Blisters
Pack sizes: 20 capsules/30 capsules/50 capsules/60 capsules/90 capsules

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Windzor Pharma Ireland Limited
The Office Suite
Unit 2 Holywell Commercial Centre
Swords
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23126/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th October 2017
Date of last renewal: 21st June 2022

10 DATE OF REVISION OF THE TEXT

May 2022