**Does PRESCRIBING INFORMATION**
**INCLUDING PATIENT MEDICATION INFORMATION**

# [Pr] AG-Vitamine D

## Cholecalciferol Capsules, Mfr. Std.

## 10 000 IU

**Vitamin D Product**

**Prepared by:**

Revision Date: MAY 21, 2024

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**Submission Control Number: 281757**

## PRESCRIBING INFORMATION

**PrAG-Vitamine D**

Cholecalciferol Capsules, Mfr. Std.

10 000 IU

## THERAPEUTIC CLASSIFICATION

Vitamin D Product

## PHARMACOLOGY

Vitamin D is a fat-soluble vitamin that helps regulate serum calcium and phosphorous concentrations by enhancing the efficiency of the small intestine to absorb these minerals from the diet. Vitamin D has two main forms: cholecalciferol (Vitamin $D_3$), and ergocalciferol (Vitamin $D_2$).

In humans, cholecalciferol is synthesized in the skin from 7-dehydrocholesterol on exposure to ultraviolet radiation and obtained from the diet from fish liver oils and salt water fish. In the absence of adequate sunlight exposure, vitamin $D_3$ is an essential dietary nutrient.

Cholecalciferol is a prohormone with several active metabolites that act as hormones. Vitamin D is metabolised by the liver to form 25-hydroxycholecalciferol (calcifediol), which is then converted in the kidneys to the active Vitamin D hormone, 1,25-dihydroxyvitamin $D_3$ (calcitriol).

In its biologically active form vitamin $D_3$ 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 $D_3$. PTH secretion is inhibited further by the increased calcium uptake in the small intestine under the influence of biologically active vitamin $D_3$.

## PHARMACOKINETICS

Vitamin D from nutritional sources and its analogues are readily absorbed from the small intestine in the presence of dietary lipids and bile acids. Cholecalciferol is metabolised by microsomal enzyme vitamin D-25-hydroxylase to form 25-hydroxycolecalciferol ($25(OH)D_3$, calcidiol), the primary storage form of vitamin $D_3$. $25(OH)D_3$ undergoes a secondary hydroxylation within the kidney to form the predominant active metabolite 1,25-hydroxycolecalciferol ($1,25(OH)_2D_3$, calcitriol). The conversion to calcitriol is regulated by its own concentration, PTH, and serum concentrations of calcium and phosphate. The metabolites circulate in the blood bound to a specific α-globin. Vitamin D and its metabolites are excreted mainly in the bile and faeces.

## INDICATIONS

- Treatment and prevention of vitamin D deficiency;
- Management and prevention of primary and corticosteroid-induced osteoporosis, in conjunction with calcium;
- Treatment of refractory rickets (vitamin D resistant rickets);
- Treatment of familial hypophosphatemia;
- Treatment of hypoparathyroidism.

## CONTRAINDICATIONS

- Hypersensitivity to vitamin D, any of its analogues and derivatives or to any ingredient in the formulation component of the container (see Dosage Form, Composition, and Packaging).
- Hypercalcemia and/or hypercalciuria
- Nephrolithiasis (renal calculi)
- Severe renal impairment
- Malabsorption syndrome
- Abnormal sensitivity to the toxic effects of Vitamin D
- Sarcoidosis
- Hypervitaminosis D.

## WARNINGS AND PRECAUTIONS

### General

Chronic or acute administration of excessive doses of cholecalciferol may lead to hypervitaminosis D, manifested by hypercalcemia and its sequelae.

The therapeutic index of Vitamin D analogues is narrow and there is great interindividual variation in the dose that will lead to chronic toxicity. Daily doses of cholecalciferol ranging from 50 000 to 100 000 IU (1.25 to 2.5 mg) in adults and 1000 IU (25 mcg) in children may result in hypervitaminosis. Other Vitamin D analogues with shorter duration of action may have a lower propensity to accumulate and to cause hypercalcemia.

### Cardiovascular

Caution is required for patients receiving treatment for cardiovascular disease. (See DRUG INTERACTIONS)

### Immune

AG-Vitamine D should not be prescribed in patients with sarcoidosis, as there is increased conversion of vitamin D to its active metabolite. (See CONTRAINDICATIONS). High doses of Vitamin D can induce hypercalcemia and hypercalcuria. Serum and urinary calcium levels should be monitored.

**Renal**

AG-Vitamine D should not be used in patients with severe renal impairment and should be used with caution in patients with mild and moderate impairment of renal function. (See CONTRAINDICATIONS). The effect on calcium and phosphate levels should be monitored. The risk of soft tissue calcification should be taken into account.

There is no clear evidence for causation between vitamin D supplementation and renal stones, but the risk is plausible, especially in the context of concomitant calcium supplementation. The need for additional calcium supplementation should be considered for individual patients. Calcium supplements should be given under close medical supervision.

During treatment, the serum and urinary calcium levels should be monitored and the kidney function checked by measurement of serum creatinine. These checks are particularly important in concomitant treatment with diuretics. In the case of hypercalcaemia or signs of impaired kidney function, the dose must be reduced or treatment interrupted. It is recommended to reduce the dose or to interrupt treatment if the urinary calcium level exceeds 7.5 mmol/24 hours (300 mg/24 hours).

Vitamin D must be used with particular caution in patients with disturbed urinary excretion of calcium and phosphate, in treatment with benzothiadiazine derivatives. Plasma and urinary calcium levels should be monitored in these patients.

**Endocrine and Metabolism**

***Hypercalcemia***

Early symptoms of hypercalcemia may include weakness, fatigue, somnolence, headache, anorexia, dry mouth, metallic taste, nausea, vomiting, vertigo, tinnitus, ataxia and hypotonia. Later and possibly more serious manifestation include nephrocalcinosis, renal dysfunction, osteoporosis in adults, impaired growth in children, anemia, metastatic calcification, pancreatitis, generalized vascular calcification and seizures. Extreme hypercalcaemia may result in coma and death.

**Special Populations**

***Pregnant Women***

The recommended daily dose of Vitamin D in pregnant women in Canada is 600 IU (15 mcg) daily. Studies have shown safe use of Vitamin D at doses up to 4000 IU (100 mcg) daily during pregnancy although studies in animals have shown reproductive toxicity. Avoid the use of vitamin D in excess of the recommended dietary allowance during pregnancy unless potential benefits outweigh the possible adverse effects. Hypercalcemia during pregnancy may also lead to suppression of parathyroid hormone release in the neonate, resulting in hypocalcemia, tetany and seizures.

Severe deficiency of vitamin D during pregnancy can result in maternal osteomalacia and lead to significant morbidity in both mother and fetus.

***Breast-feeding***

The recommended daily dose of Vitamin D in nursing women is 600 IU (15 mcg). Vitamin D and its metabolites are excreted in breast milk. However, Vitamin D may be deficient in maternal milk; therefore, breastfed infants may require supplementation. Use of excessive amounts of Vitamin D in nursing mothers may result in hypercalcemia in infants. A daily dose of 4,000 IU (100 mcg) should not be exceeded. When prescribing additional vitamin D to a breast-fed child the practitioner should consider the dose of any additional vitamin D given to the mother.

**Monitoring and Laboratory Tests:**

Periodic monitoring of serum calcium, phosphate, magnesium, and alkaline phosphatase is recommended for patients taking Vitamin D3. Serum calcium should be maintained in the range of 2.25-2.5 mmol/L and not allowed to exceed 2.75 mmol/L.

The best indicator of vitamin D status is 25-hydroxyvitamin D or 25(OH)D serum concentration, as this level reflects total vitamin D exposure (from skin synthesis, food and supplements). However, there is no clinical benefit in monitoring vitamin D levels unless a clinical condition, such as malabsorption syndromes, chronic renal or liver failure, unexplained bone pain, unusual fractures, and other evidence of metabolic bone disorders, predisposes the patient to vitamin D deficiency. Other clinical situations where vitamin D testing is indicated include hypo- or hypercalcemia/hyperphosphatemia, hypo-or hyperparathyroidism, unexplained increases in serum alkaline phosphatase or patients with symptoms suggesting hypervitaminosis D. Testing for vitamin D levels may also be indicated when a patient is on medications that affect vitamin D metabolism or absorption (see Table 1)

## DRUG INTERACTIONS

**Table 1: Drug-Drug Interactions**

| Interacting Drug | Effect | Clinical Comment |
|---|---|---|
| Antacids (aluminum-containing) | Increased intestinal absorption of aluminum may lead to increased aluminum levels. | Avoid this combination if possible. |
| Antacids (magnesium-containing) | Hypermagnesemia may develop when these agents are used concurrently with vitamin D. | Monitor magnesium levels particularly in patients with chronic renal failure. |
| Anticonvulsants (e.g., phenytoin, phenobarbital, carbamazepine) | Strong CYP3A4 inducers can reduce vitamin D levels, potentially causing vitamin D deficiency. | Consider prophylactic vitamin D supplementation. Monitor serum 25(OH)D every 2 years; supplement with vitamin D if necessary |
| Cholestyramine, colestipol | Intestinal absorption of vitamin D may be impaired. | Patients should be advised to allow as much time as possible between the ingestion of these drugs and vitamin D. |
| Danazol | Danazol may increase the hypercalcemic response to vitamin D or its analogues.. | Monitor serum calcium levels. |
| Digoxin | Vitamin D or any analogues should be used with caution in patients taking digoxin. Hypercalcemia (which may result from concomitant use) may enhance the arrhythmogenic effects of digoxin. | Strict medical supervision is required.<br><br>Monitor serum calcium levels. |

| | | |
|---|---|---|
| Efavirenz | Increased metabolism of vitamin D via CYP24A induction leads to a deficiency state. | Consider prophylactic vitamin D supplementation. |
| Mineral oil | Intestinal absorption of vitamin D or its analogues may be impaired. | Patients should be advised to allow as much time as possible between the ingestion of these drugs. |
| Orlistat | Intestinal absorption of vitamin D or its analogues may be impaired. | Patients should be advised to allow as much time as possible between the ingestion of these drugs. |
| Sevelamer | Sevelamer may decrease the serum concentration of orally administered vitamin D or analogues. | Monitor serum 25(OH)D levels and adjust vitamin D or analogue dose if necessary. |
| Sucralfate | Increased intestinal absorption of aluminum from sucralfate may lead to increased aluminum levels. | Avoid this combination if possible. |
| Thiazide diuretics | Increased risk of hypercalcemia and associated calcium toxicity. Thiazides decrease renal excretion of calcium and increase calcium release from bone. Thiazides may also enhance the effect of parathyroid hormone and vitamin D on release of calcium from bone. | Monitor serum calcium levels with concomitant therapy. |

## DOSAGE AND ADMINISTRATION

**NOTE: AG-Vitamine D capsules is only available in 10 000 IU.**

**Dosing Consideration**

At the higher doses of Vitamin D used for active treatment, the range between therapeutic and toxic doses is narrow.

The dosage of vitamin $D_3$ must be individualized with careful monitoring of serum-calcium levels. Readjust therapeutic dosage as soon as there is clinical improvement. Careful titration is necessary to avoid overdose. Dietary and other sources of vitamin D must be considered. Calcium intake should be adequate.

Blood calcium, phosphorus and urea determinations must be made every two weeks or more frequently if necessary.

The bones should be x-rayed every month until the condition is corrected and stabilized.

**Recommended Dose and Dosage Adjustment**

***Treatment and prevention of vitamin D deficiency***

2000 IU (50 mcg) to 5000 IU (125 mcg) daily until a biochemical and radiographic response is achieved. Alternatively, a dose of 50 000 units may be given once weekly for 8 wk.

A specialist must be consulted prior to treatment.

***Treatment of refractory rickets (vitamin D resistant rickets)***

12 000 to 500 000 IU (0.3 mg to 12.5 mg) daily

***Treatment of hypoparathyroidism***

50 000 to 200 000 IU (1.25 mg to 5.0 mg) daily. Calcium supplementation is also required

A specialist must be consulted in the treatment of Hypophosphatemia, Hypocalcemia, and Corticosteroid induced Osteoporosis.

**Missed Dose**

If a dose of this medication has been missed, it should be taken as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not take a double dose to make up for the missed dose.

## OVERDOSE

**Symptoms:** Acute intoxication with Vitamin $D_3$ (cholecalciferol) may cause hypervitaminosis D, manifested by hypercalcemia and its sequelae. Hypercalcemia is usually reversible, however, if metastatic calcification has occurred, severe renal or cardiac failure or even death may result (see PRECAUTIONS).

**Treatment:** Treatment of acute or chronic intoxication includes withdrawal of the Vitamin $D_3$ and any calcium supplements, maintenance of low-calcium diet, administration of oral IV fluids and, if needed, corticosteroids or calciuric diuretics, such as furosemide and ethacrymic acid, to decrease serum calcium concentrations. Peritoneal or hemodialysis with calcium free dialysate will help remove calcium.

If acute ingestion is recent, gastric lavage or emesis may minimize further absorption. If the drug has already passed through the stomach, administration of mineral oil may promote faecal elimination.

Hypercalcemia is usually reversible, however, if metastatic calcification has occurred, severe renal or cardiac failure or even death may result.

For management of a suspected drug overdosage, contact your regional Poison Control Center immediately.

## DOSAGE FORMS, COMPOSITION AND PACKAGING

PrAG-Vitamine D softgel capsules are available in 1 strength and is supplied as clear transparent oval shaped gelatin softgel capsules.

**Table 2. PrAG-Vitamine D Softgel Capsules Characteristics**

| Strength (IUs) | Colour and non-medicinal Ingredients |
|---|---|
| **10 000:**<br>Contains 10 000 IUs of Cholecalciferol | Each clear transparent oval shaped red coloured gel caps contains 10 000 IU of Vitamin $D_3$. Non-medicinal ingredients: Ponceau 4R FCF, gelatin, glycerin, medium-chain triglycerides, sorbitol, vanillin, water |

All PrAG-Vitamine D strengths are available in bottles of 100 softgel capsules.

## STORAGE CONDITIONS

Store between 15°C and 30°C. Protect from light.

## SPECIAL HANDLING INSTRUCTIONS

Keep out of the reach and sight of children.

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**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

**PATIENT MEDICATION INFORMATION**

**[Pr]AG-Vitamine D**
Cholecalciferol Capsules
10 000 IU

Read this carefully before you start taking **AG-Vitamine D** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **AG-Vitamine D**.

**What is AG-Vitamine D used for?**

AG-Vitamine D is used to treat and prevent vitamin D deficiency:

- to manage and prevent osteoporosis or osteoporosis caused by corticosteroid. Osteoporosis is a bone disorder Osteoporosis is a bone disorder;
- to treat unmanageable rickets (vitamin D resistant rickets). Rickets is a bone disorder in children;
- to treat genetic hypophosphatemia. Hypophosphatemia is a condition that causes low levels of phosphate in the blood;
- to treat of hypoparathyroidism, a condition that occurs when the glands in the neck don't product enough hormones.

**How does AG-Vitamine D work?**

The Vitamin D (Cholecalciferol) component of AG-Vitamine D increases your body's absorption of calcium and phosphorus from your diet. It also prevents the release of calcium and phosphate from your kidneys.

**What are the ingredients in AG-Vitamine D?**

Medicinal ingredients: Vitamin $D_3$ (Cholecalciferol)

Non-medicinal ingredients: Poceau 4R FCF, gelatin, glycerin, medium-chain triglycerides, sorbitol, vanillin, water

**AG-Vitamine D comes in the following dosage forms:**

Softgel capsules; 10 000 IU (Red)

**Do not use AG-Vitamine D if:**

- you have known allergy:
  - to Vitamin D or any of its forms (analogues and derivatives)
  - to any of the other ingredients in AG-Vitamine D
- you have high levels of calcium in your body or urine
- you have kidney stones
- you have severe kidney disease
- you have a disorder in which your small intestine cannot absorb enough of certain nutrients and fluids from foods
- you have unusual sensitivity to the harmful effects of Vitamin D (for example high levels of calcium in your body)
- you currently have high levels of Vitamin D in your body

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take AG-Vitamine D. Talk about any health conditions or problems you may have, including if you are:**

- pregnant or planning on becoming pregnant
- breastfeeding or planning to breastfeed

**Other warnings you should know about:**

Treatment with AG-Vitamine D can increase your risk of certain side effects, including:

- Hypervitaminosis D. Hypervitaminosis D is a condition in which the Vitamin D levels in the body is high.
- Hypercalcemia. Hypercalcemia is a condition in which the calcium level in the body is above normal.

**Monitoring and Laboratory Tests:** Your doctor will monitor you for your calcium, phosphate, and magnesium levels while you are taking AG-Vitamine D.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with AG-Vitamine D:**

- Heartburn medicines (Antacids):
    - Magnesium-containing antacids. Your doctor may monitor you if you have kidney failure and you are taking these types of antacids with AG-Vitamine D.
    - Aluminum-containing antacids. You should avoid taking these types of antacids with AG-Vitamine D.
- Anti-seizure medicines (such as phenytoin, phenobarbital and carbamazepine)
- Medicines used to lower cholesterol (such as cholestyramine and colestipol). You should allow as much time as possible between taking cholesterol lowering medicines and AG-Vitamine D.
- Digoxin (used to treat heart failure)
- Efavirenz (used to treat HIV)
- Orlistat (used in medications for weight loss)
- Sevelamer (used to treat high phosphorous levels)
- Mineral oil. You should allow as much time as possible between taking mineral oils and AG-Vitamine D.
- Sucralfate (used to treat ulcers). You should avoid taking this with AG-Vitamine D.
- Thiazide diuretics, also known as "water pills" (such as hydrochlorothiazide, used to treat high blood pressure)
- Danazol

Do **not** take AG-Vitamine D along with any other products that may contain Vitamin D unless advised by your doctor.

**How to take AG-Vitamine D:**

While taking AG-Vitamine D, your doctor:

- will monitor you closely
- may do additional tests to check your blood calcium, magnesium, phosphorus and urea level every two weeks or more often if needed
- send you for an x-ray every month to check the conditions of your bones
- Your doctor may also prescribe a calcium supplement depending on the type of treatment you are receiving.

**Usual dose:**

**NOTE: AG-Vitamine D capsules is only available in 10 000 IU.**

Take exactly as prescribed by your doctor. Do not change your dose on your own. Your doctor will decide when to end your treatment.

**Treatment to maintain Vitamin D levels**:

Take 2000 IU to 4000 IU daily until your doctor ends your treatment.

**Treatment for Vitamin D resistant rickets:**

Take 12 000 IU to 500 000 IU daily

**Treatment for Vitamin D deficiency:**

Take 5000 IU daily until your doctor ends your treatment or 50 000 IU once a week for 8 weeks.

**Treatment of hypoparathyroidism:**

Take 50 000 IU to 200 000 IU daily. Treatment should also include a calcium supplement.

**Overdose:**

If you think you have taken too much AG-Vitamine D contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Taking too much AG-Vitamine D can cause high levels of calcium in your body (hypercalcemia). See **What are possible side effects from using AG-Vitamine D?**

**Missed Dose:**

If you miss a dose of this medication, take the next dose as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not take a double dose to make up for the missed dose.

**What are possible side effects from using AG-Vitamine D?**

These are not all the possible side effects you may feel when taking **AG-Vitamine D**. If you experience any side effects not listed here, contact your healthcare professional.

Side effects include:

- hypercalcaemia (high levels of calcium in blood):
    - weakness
    - feeling tired and sleepy
    - headache
    - loss of appetite
    - dry mouth
    - a metallic taste
    - nausea and vomiting
    - dizziness
    - ringing in the ears
    - unusual muscle movements
    - decreased muscle tone
- itching
- rash
- skin with red spots which burn, itch or sting

| **Serious side effects and what to do about them** | | | |
|---|---|---|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| **COMMON** | | | |
| **Anemia** (decreased number of red blood cells): feeling tired, lack of energy, irregular heartbeats, pale complexion, shortness of breath, weakness | | √ | |
| **Impaired growth in children** (stunted, abnormal growth): abnormal size of arms or legs, lack of energy, dry skin, dry hair, feeling cold, blood in the stool, diarrhea, constipation, vomiting, nausea. | | √ | |
| **Generalized vascular calcification** (hardening of the blood vessels): peripheral artery disease, stroke, high blood pressure, pain or cramping in leg muscles. | | √ | |
| **Metastatic calcification** (deposition of calcium salts in normal tissue): hardening of body tissues that otherwise should be soft and malleable. | | √ | |
| **Nephrocalcinosis** (calcification of the tubules of the kidney): blood in the urine, fever, chills, nausea and vomiting, sever pain in the belly area, sides of the back, groin or testicles. | | √ | |
| **Osteoporosis in adults** (decrease of bone mass and density): backache, gradual loss of height, stooped posture, fractures of the spine, wrist or hip. | | √ | |
| **Pancreatitis** (inflammation of the pancreas): pain in your belly that spreads to your back, or feels worse after eating, fever, rapid heartbeat, nausea, vomiting, tenderness when touching the abdomen. | | | √ |
| **Renal dysfunction** (abnormal functioning of the kidney): less than normal urination, fluid retention, swelling of the legs, ankles or feet, shortness of breath, fatigue, confusion, nausea, weakness, irregular heartbeat. | | | √ |
| **Seizures** (sudden convulsions or loss of consciousness): temporary confusion, a staring spell, uncontrollable jerking movements of the arms and legs, loss of consciousness or awareness, fear, anxiety or dejà vu (a disquieting feeling of having been somewhere or done something before, even though one has not.) | | | √ |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**Storage:**

Store at room temperature between 15°C and 30°C. Protect from light.

Keep out of reach and sight of children.

**If you want more information about AG-Vitamine D:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); or the manufacturer's website: www.angitapharma.ca.

This document, prepared for health professionals, can be obtained by contacting the sponsor, Angita Pharma Inc. at 450-449-9272.

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Last Revised: MAY 21, 2024