

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

One-Alpha® (alfacalcidol)
Capsules (0.25mcg and 1 mcg) and Oral Drops (2 mcg/mL)

Read this carefully before you start taking **One-Alpha®** 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 **One-Alpha®**.

What is One-Alpha® used for?

One-Alpha® is used in adult patients with chronic kidney failure to treat:

- Low calcium levels in the body
- Bone disease
- A condition in which the parathyroid gland is overactive (hyperparathyroidism)

How does One-Alpha® work?

One-Alpha® contains the medicinal ingredient alfacalcidol, which works similarly to vitamin D. Alfacalcidol is a medication that helps your body absorb calcium from your diet.

What are the ingredients in One-Alpha®?

Medicinal ingredients: alfacalcidol

Nonmedicinal ingredients:

- a) One-Alpha® Capsules: all-rac- α -tocopherol and sesame oil; shell composition: gelatin, glycerol, potassium sorbate, titanium dioxide, red iron oxide E172 and black iron oxide E172
- b) One-Alpha® Oral Drops: all-rac- α -tocopherol, citric acid monohydrate, ethanol, macrogolglycerol hydroxystearate, methylparahydroxybenzoate, purified water, sodium citrate and sorbitol
- c) One-Alpha® Injection; citric acid monohydrate, ethanol, propylene glycol, sodium citrate and water

ONE-ALPHA is available in the following dosage forms:

One-Alpha® Capsules:

- 0.25 mcg – cream-coloured, egg-shaped capsule
- 1 mcg – brown, egg-shaped capsule

One-Alpha® oral drops:

- clear or slightly opalescent colourless solution

One-Alpha® Injection:

- brown single-dose glass ampoules containing clear colourless solution for intravenous injection

Do not use One-Alpha® if:

- you are allergic to any of the ingredients in One-Alpha®
- you have high calcium levels in your blood (hypercalcemia)
- you know you have high phosphate levels in your blood (hyperphosphatemia)
- you took a very big dose of Vitamin D

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

- have been told that you have hardened arteries or cardiac valve sclerosis
- are taking heart medications called a cardiac glycoside, such as digoxin
- have any kidney problems, including kidney stones
- are pregnant or if you become pregnant during your treatment. Use of One-Alpha® during pregnancy may harm your baby.
- are breast feeding
- are suffering from alcoholism and have liver disease or epilepsy as One-Alpha® solution for injection and oral drops contain alcohol

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

The following may interact with One-Alpha®:

- medications to treat seizures (anticonvulsants)
- medications called barbiturates that help you sleep
- medications to treat heart problems (cardiac glycosides such as digoxin)
- medication called cholestyramine, used for lowering your cholesterol level, or to help stop some types of diarrhoea or itching
- medications that help your body get rid of water ("water pills" or diuretics)
- medications for heartburn and ulcers (antacids) that contain magnesium or aluminum hydroxide or sucralfate
- mineral oil used as a laxative

How to take One-Alpha®:

The amount of One-Alpha will be determined by your doctor. CAREFULLY FOLLOW YOUR DOCTOR'S INSTRUCTIONS ABOUT WHEN AND HOW TO USE THIS MEDICINE. Your doctor will send you for blood tests to determine if a dosage adjustment of ONE-ALPHA is needed.

One-Alpha® is usually taken once daily with or without food and/or drink.

Your doctor may also prescribe other medications and a special diet in order to help improve your medical condition.

Do not stop taking One-Alpha® without first checking with your doctor.

When using the One-Alpha® Oral Drops, remove the protective cap but not the plastic dropper which is inserted into the bottle. To use the dropper, hold the bottle upside down. The liquid should flow immediately, but if it does not, tap the bottle gently. Do not shake the bottle.

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One-Alpha® Injection is to be given only by a doctor or nurse during haemodialysis in patients with chronic renal failure.

Overdose:

If you think you have taken too much One-Alpha®, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

If a dose is forgotten, take it as soon as possible. If it is almost time for the next dose, do not double the dose.

What are possible side effects from using One-Alpha®?

These are not all the possible side effects you may feel when taking One-Alpha®. If you experience any side effects not listed here, contact your healthcare professional.

Gastrointestinal: Nausea, vomiting, constipation, diarrhoea, loss of appetite, weight loss, abdominal pain, dry mouth

Nervous system: Feeling weak, sleepy, dizzy

Skin: Itching, rash

General: Headache, sweating, runny nose, decreased sex drive, feeling hot

ONE-ALPHA can cause abnormal blood and / or urine tests. Your doctor will decide when to perform these tests and will interpret the results.

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	
Nausea/vomiting	✓		
Feeling weak, sleepy	✓		
Feeling dizzy	✓		
Feel fast heart pounding or an irregular heartbeat		✓	
High blood pressure: severe headache, feeling tired and confused, vision problems, chest pain, difficulty breathing, feeling a pounding in your chest, neck or ears		✓	
Severe, new and/or unusual bone, joint and/or muscle pain		✓	
Metallic taste		✓	
Excessive thirst and/or urination		✓	

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	
Eye inflammation associated with eye pain, eye redness, sensitivity to light, decreased vision		✓	
Pancreatitis (swelling of the pancreas): long periods of pain in the stomach and/or intestine area. You may feel pain going around to your back. You may also vomit		✓	
Calcification (hardening) of soft tissues, blood vessels or eyes		✓	
Unusual blood test results: high cholesterol, elevated BUN, high albumin and/or calcium in urine, high calcium and/or phosphatase and/or liver enzymes in the blood		✓	
Kidney stones: severe pain in side and back, pain during urination, unusual appearance of urine. You may also have nausea and vomiting.			✓
Mental health problems like loss of contact with reality (psychosis)			✓

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.

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Storing your One-Alpha®:

0.25 mcg Oral Capsules should be stored below 25°C. Protect from direct sunlight.

1 mcg Oral Capsules should be stored below 25°C. Protect from direct sunlight.

Oral Drops should be stored in its carton in your refrigerator (2-8°C). Protect from direct sunlight. Use within 4 months of first opening the bottle.

Intravenous Ampoules should be stored in their outer carton in the refrigerator (2-8°C). Protect from direct sunlight. Shake well before use. Ampoule is for single use only.

Keep away from children. One-Alpha® contains enough medication to seriously harm a child.

Do not use One-Alpha® after the expiry date indicated on the label.

If you want more information about One-Alpha®:

- 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>); the manufacturer's website www.leo-pharma.ca, or by calling 1-800-668-7234.

This leaflet was prepared by LEO Pharma Inc.

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