

PACKAGE LEAFLET: INFORMATION FOR THE USER

Cadelius 600 mg / 1,000 IU orodispersible tablets calcium/cholecalciferol

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 Cadelius is and what it is used for
2. What you need to know before you take Cadelius
3. How to take Cadelius
4. Possible side effects
5. How to store Cadelius
6. Contents of the pack and other information

1. What Cadelius is and what it is used for

Cadelius is used to prevent and treat calcium or vitamin D₃ deficiency in the elderly, and as an additional treatment in the management of osteoporosis for patients who are at risk of vitamin D or calcium deficiency, when a dietary supplement as large as 600 mg/day of calcium and 1000 IU/day of Vitamin D₃ is supposed to be adequate.

Cadelius contains calcium and vitamin D₃ which both are important components for the formation of bone. Vitamin D₃ regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.

Ask your doctor or pharmacist if you have further questions and always follow their instructions.

You must talk to a doctor if you do not feel better or if you feel worse after some days.

2. What you need to know before you take Cadelius

Do not take Cadelius

- if you are allergic to the calcium, vitamin D or any of the other ingredients of this medicine (listed in section 6)
- if you have hypercalcaemia (increased levels of calcium in the blood) or hypercalciuria (increased levels in the urine)
- if you have hypervitaminosis D (increased levels of vitamin D in the blood)
- if you have kidney stones
- if you have kidney failure
- if you are allergic to soya or peanuts.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cadelius:

- if you suffer from sarcoidosis (a special type of connective tissue disease that affects the lungs, skin and joints)
- if you are taking other drugs containing vitamin D or calcium
- if you have poor kidney function or high tendency of renal stone formation
- if you are immobilized with osteoporosis.

Other medicines and Cadelius

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

The effect of the treatment can be affected if this drug is taken simultaneously with certain other drugs against:

- high blood pressure (thiazide diuretic)
- heart problems (cardiac glycosides such as digoxin)
- high cholesterol (cholestyramine)
- constipation (laxatives such as liquid paraffin)
- epilepsy (phenytoin or barbiturates)
- inflammatory conditions/suppression of immunity (corticosteroids)
- obesity (orlistat).

Please make sure your doctor knows if you are taking any of the medicines listed above. Your dosage may need to be adjusted.

If you simultaneously use a certain drug for;

- osteoporosis (bisphosphonates)

you should take this at least one hour before you take Cadelius.

If you simultaneously use certain drugs for;

- infection (quinolones)

you should take these two hours before or six hours after taking Cadelius.

If you simultaneously use certain drugs for;

- infection (tetracyclines)

you should take these two hours before or four to six hours after taking Cadelius.

If you simultaneously take certain drugs for;

- dental caries (sodium fluoride)
- anaemia (iron)

you should take these drugs at least three hours before taking Cadelius.

If you simultaneously use a certain drug for;

- hypothyroidism (levothyroxine)

you should separate the intake with Cadelius by at least four hours.

Cadelius with food and drink and alcohol

The calcium absorption may be inhibited by food containing oxalic acid (found in spinach and rhubarb) and phytic acid (found in whole cereals). You should wait at least two hours before you take Cadelius if you have eaten food with high content of oxalic acid or phytic acid.

Pregnancy and breast-feeding and fertility

During pregnancy the daily intake should not exceed 1500 mg calcium and 600 IU vitamin D. Cadelius is therefore not recommended during pregnancy.

Cadelius can be used during breast-feeding. Calcium and vitamin D₃ pass over into breast milk. This

should be considered when giving additional vitamin D to the child.

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.

Driving and using machines

Cadelius has no known effects on ability to drive or use machines.

Cadelius contains aspartame

This medicine contains 8.67 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Cadelius contains lactose and sucrose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product. The content of sucrose may be harmful to the teeth.

Cadelius contains soya oil

If you are allergic to peanut or soya, do not use this medicinal product.

3. How to take Cadelius

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

The dosage is individually decided for you by your doctor. The recommended dose is 1 tablet daily.

The tablets may be sucked, they should not be swallowed whole. The tablets should be taken preferably after meals.

The amount of calcium in Cadelius is lower than the usually recommended daily intake. Cadelius is therefore meant for patients with need for additional vitamin D, but with a dietary intake of 500-1000 mg of calcium per day. Your dietary intake of calcium should be estimated by your doctor.

Use in children and adolescent

Cadelius are not intended for use in children and adolescents.

If you take more Cadelius than you should

If you may have taken more Cadelius than you should, talk to your doctor or pharmacist immediately.

Some symptoms of overdose of Cadelius are loss of appetite, thirst, abnormal increased urine secretion, nausea, vomiting and constipation.

If you forget to take Cadelius

Take it as soon as you remember. Then take your next dose at the usual time. However, if it is almost time for your next dose, skip the missed dose and continue as usual. Never take two doses at the same time.

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.

You should stop taking Cadelius and see your doctor immediately if you experience symptoms of serious allergic reactions, such as

- swollen face, lips, tongue or throat

- difficult to swallow
- hives and difficulty breathing

Uncommon (may affect up to 1 in 100 people): hypercalcaemia (increased levels of serum calcium) and/or hypercalciuria (increased levels of urine calcium).

Rare (may affect up to 1 in 1,000 people): constipation, flatulence, nausea, abdominal pain, diarrhoea, pruritus, rash and urticaria.

Not known (frequency cannot be estimated from the available data): serious allergic reactions.

Other special population:

Patients with renal impairment could have a potential risk of hyperphosphatemia, nephrolithiasis and nephrocalcinosis.

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via: HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Cadelius

- Keep this medicine out of the sight and reach of children.
- Keep container tightly closed. Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- Store in the original package in order to protect from light. Keep the container tightly closed in order to protect from moisture.
- After first opening, the shelf life is 60 days.
- Do not use this medicine if you notice any signs of deterioration.
- 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 to protect the environment.

6. Contents of the pack and other information

What Cadelius contains

- The active substances are calcium carbonate 1500 mg corresponding to calcium 600 mg and cholecalciferol (Vitamin D₃) 1000 IU corresponding to 0,025 mg.
- The other ingredients are maltodextrin, aspartame (E951), hydroxypropyl cellulose low- substituted (E463), lactose monohydrate, citric acid anhydrous (E330), orange flavour, stearic acid, all-rac- α -tocopherol (E307), partially hydrogenated soya bean oil, gelatine, sucrose, maize starch, silicon dioxide.

What Cadelius looks like and contents of the pack

Cadelius is an orodispersible tablet, white to almost white, with round, bevelled edge shape, 30 or 60 tablets in the bottle.

Multipacks contain 60 (2 packs of 30) orodispersible tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer responsible for batch release:

Marketing Authorisation Holder:

ITALFARMACO S.A.

C/ San Rafael, 3 - 28108 Alcobendas
(Madrid) - España

Manufacturer responsible for batch release:

Italfarmaco S.p.A
Viale F.Testi, 330 – 20126 Milano (Italy)

Distributor in Ireland:

Consilient Health Limited
Block 2A, Richview Office Park,
Clonskeagh, Dublin 14,
Ireland

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

Italy: Dincrel 600 mg / 1.000 UI compresse orodispersibili
France: Demilos 600 mg / 1.000 UI comprimés orodispersibles
Spain: Demilos 600 mg/1,000 IU comprimidos bucodispersables
Portugal: Demilos 600 mg + 1000 UI comprimidos orodispersíveis
Ireland: Cadelius 600 mg /1,000 IU orodispersible tablets

This leaflet was last revised in May 2023.